

**SUMMARY MONTHLY SAFETY REPORT 2**  
**for**  
**ACTIVE SUBSTANCE: PF-07302048 (BNT162b2)**

**ATC CODE: J07BX03<sup>1</sup>**

**AUTHORISATION PROCEDURE in the EU: Centralised**

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**01 JANUARY 2021 through 31 JANUARY 2021**

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**Report Prepared by: Worldwide Medical & Safety**

**Pfizer - BioNTech**

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<sup>1</sup> Temporary ATC code.

<sup>2</sup> It corresponds to the earliest conditional approval date.

## EXECUTIVE SUMMARY

This is the 2<sup>nd</sup> Summary Monthly Safety Report (SMSR) for PF-07302048 (COVID-19 mRNA Vaccine, hereafter referred to as BNT162b2), covering the reporting interval 01 January 2021 through 31 January 2021.

BNT162b2 is a white to off-white frozen dispersion (pH: 6.9 - 7.9), provided as concentrate for dispersion for injection (sterile concentrate) as multidose vial to be diluted before use. The multidose vial contains 6 doses of 0.3 mL after dilution; low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Each dose contains 30 micrograms of BNT162b2 embedded in lipid nanoparticles (LNPs). The vaccine also contains (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium phosphate dihydrate, sucrose and water for injections as excipients.

BNT162b2 is single-stranded, 5'-capped mRNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2. The nucleoside-modified mRNA is formulated in LNPs, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older. No dosage adjustment is required in elderly individuals  $\geq 65$  years of age. It is administered intramuscularly, preferably in the deltoid muscle of the upper arm, after dilution as a course of 2 doses (0.3 mL each) at least 21 days apart.

It is estimated that approximately 66,416,610 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 31 January 2021 and that approximately 42,122,535 doses of BNT162b2 were shipped worldwide during the current reporting interval from 01 January 2021 through 31 January 2021.

BNT162b2 has received temporary authorisation for emergency supply in 25 countries and conditional marketing authorisation approval in 34 countries globally.

The Core Data Sheet (CDS), currently in development, will be designated as the unique reference safety information (RSI) for all the countries, once it is finalized and effective.

For the European Union and other countries that use it as reference, the RSI for this SMSR is the BNT162b2 EU Summary of Product Characteristics (EU SmPC), dated 28 January 2021, in effect at the end of the reporting period. Previous versions of the combined EU SmPC,

dated 21 December 2020 and 08 January 2021, were in effect during the reporting period, and they were updated respectively on 08 January 2021 and 28 January 2021 without safety-related changes.

For the United States and other countries that use it as reference, the RSI for this SMSR is the BNT162b2 combined Emergency Use Authorisation (EUA) Fact Sheet for the Healthcare Professional (HCP) and Full EUA Prescribing Information (PI), dated 25 January 2021, in effect at the end of the reporting period. Previous versions of the combined EUA Fact Sheet for the HCP and Full EUA PI, dated 23 December 2020 and 05 January 2021, were also in effect during the reporting period, and they were respectively updated on 05 January 2021 without safety-related changes and on 25 January 2021 to add 'anaphylaxis' as an adverse reaction.

During the reporting period, the following safety signals were addressed:

1. Hypersensitivity reactions (other than anaphylaxis)\*\* were evaluated and Hypersensitivity (e.g. rash, pruritus, urticaria, angioedema) was added to labelling as an adverse reaction;\*
2. Pain in extremity\*\* was evaluated and will be added to labelling as an adverse reaction;
3. Diarrhoea was evaluated and will be added to labelling as an adverse reaction;\*
4. Vomiting was evaluated and will be added to labelling as an adverse reaction;\*
5. Injection site pruritus\*\* was evaluated and determined not to be a risk;
6. Insomnia\*\* was evaluated and determined not to be a risk;
7. Deaths including in elderly or frail individuals was evaluated and determined not to be a risk;
8. Immune thrombocytopenia was evaluated and determined not to be a risk;
9. Overdose was evaluated and it was determined that no update to the Overdose section of labelling was warranted;
10. Eye pain and Eye swelling were evaluated and determined not to be risks;\*
11. Dizziness evaluation is ongoing;
12. Facial paralysis evaluation is ongoing;
13. Paraesthesia evaluation is ongoing.

The events added to labeling as adverse reactions are considered to be identified risks (not important for the purpose of inclusion in the Risk Management Plans and Pharmacovigilance Plans).

\*After the data-lock point of this SMSR.

\*\*These events were included in the EU SmPC as adverse reactions at the request of the EMA at the time of conditional approval of the vaccine.

Based on the new safety and efficacy/effectiveness data from the reporting interval for BNT162b2, the benefit-risk profile of BNT162b2 remains favorable.

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**LIST OF ABBREVIATIONS**

<b>Acronym</b>	<b>Term</b>
AE	adverse event
AESI	adverse event of special interest
BMI	body mass index
CDS	core data sheet
CI	confidence interval
COPD	chronic obstructive pulmonary disease
COVID-19	coronavirus disease 2019
DLP	data lock point
DME	designed medically event
DNA	deoxyribonucleic acid
DSPC	Distearoyl-sn-glycero-3-phosphocholine
EMA	European Medicines Agency
EU	European Union
EUA	emergency use authorisation
EURD	European Union Reference Date
HCP	healthcare professional
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
IBD	international birth date
ICH	International Conference on Harmonisation
LNP	lipid nanoparticle
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
mRNA	messenger ribonucleic acid
NAAT	nucleic acid amplification tests
PI	prescribing information
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RMP	risk management plan
ROW	rest of world
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SAE	serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SmPC	Summary of Product Characteristics
SMQ	standardised MedDRA query
SMSR	summary monthly safety report
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease

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<b>Acronym</b>	<b>Term</b>
VAERD	vaccine-associated enhanced respiratory disease

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## 1. INTRODUCTION

This is the 2<sup>nd</sup> SMSR for PF-07302048 (COVID-19 mRNA Vaccine, hereafter referred to as BNT162b2), covering the reporting interval 01 January 2021 through 31 January 2021. The format and content of this SMSR is in accordance with the EMA coreRMP19 Guidance (EMA/544966/2020) and, as applicable, with ICH Guideline E2C (R2) Periodic Benefit-Risk Evaluation Report [Step 5, January 2013] considering the information for the evidence from post-EUA/conditional marketing authorisation approval data sources.

BNT162b2 is a white to off-white frozen dispersion (pH: 6.9 - 7.9), provided as concentrate for dispersion for injection (sterile concentrate) as multidose vial to be diluted before use. The multidose vial contains 6 doses of 0.3 mL after dilution; low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial (see [Section 4](#)). Each dose contains 30 micrograms of BNT162b2 (embedded in LNPs). The vaccine also contains ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium phosphate dihydrate, sucrose and water for injections as excipients.

BNT162b2 is single-stranded, 5'-capped mRNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2. The nucleoside-modified mRNA is formulated in LNPs, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older. No dosage adjustment is required in elderly individuals  $\geq 65$  years of age. It is administered intramuscularly, preferably in the deltoid muscle of the upper arm, after dilution as a course of 2 doses (0.3 mL each); it is recommended to administer the second dose 3 weeks after the first dose.

Pfizer is responsible for the preparation of the SMSR on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech will be included in the report when applicable.

A complete list of the finalized SMSRs is provided in Table 1 below.

**Table 1. List of SMSRs**

SMSR Number	Reporting Period
1	01 December 2020 Through 31 December 2020

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## 2. WORLDWIDE APPROVAL OR AUTHORISATION STATUS

BNT162b2 received first temporary authorisation for emergency supply under regulation 174 in the UK on 01 December 2020 and is currently authorised for emergency use in 25 countries.

BNT162b2 received first regulatory conditional marketing authorisation approval in Switzerland on 19 December 2020 and is currently conditionally approved in 34 countries.

Details of the current authorisation/approval status are presented in [Appendix 4](#).

## 3. ACTIONS TAKEN IN THE REPORTING INTERVAL FOR SAFETY REASONS

On 15 January 2021, following fatal events involving elderly patients vaccinated with BNT162b2 in Norway, the Norwegian Agency updated their guidance for vaccination, advising that caution and case-by-case judgement should be used when vaccinating frail, elderly subjects.

There were no withdrawals for safety reasons during the reporting interval.

## 4. CHANGES TO REFERENCE SAFETY INFORMATION

The CDS, currently in development, will be designated as the RSI for all countries, once it is finalized and effective.

For the EU and other countries that use it as reference, the RSI for this SMSR is the BNT162b2 EU SmPC, dated 28 January 2021, in effect at the end of the reporting period which is located in [Appendix 1](#). Previous versions of the EU SmPC, respectively dated 21 December 2020 and 08 January 2021, were also in effect during the reporting period. The EU SmPC dated 21 December 2020 was updated without safety-related changes, to indicate that the use of 6 doses/vial in place of 5 doses/vial was approved, on 08 January 2021. It was specified that low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. The EU SmPC dated 08 January 2021 was updated without safety-related changes made on 28 January 2021.

For the US and other countries that use it as reference, the RSI for this SMSR is the BNT162b2 combined EUA Fact Sheet for the HCP and Full EUA PI, dated 25 January 2021, in effect at the end of the reporting period which is located in [Appendix 1.1](#). Previous versions of the combined EUA Fact Sheet for the HCP and Full EUA PI, respectively dated 23 December 2020 and 05 January 2021, were also in effect during the reporting period. The combined EUA Fact Sheet for the HCP and Full EUA PI dated 23 December 2020 was updated on 05 January 2021 without safety-related changes to indicate that the use of 6 doses/vial was approved, while the combined EUA Fact Sheet for the HCP and Full EUA PI dated 05 January 2021 was updated on 25 January 2021 to add ‘anaphylaxis’ as an adverse reaction. The summary of the safety-related changes made is presented in [Appendix 1.2](#).



After the data-lock point of this SMSR, on 04 February 2021, an update to include Hypersensitivity specific reactions (e.g. rash, pruritus, urticaria, angioedema) to the EUA Fact Sheets and EUA PI was submitted to the FDA.

**5. ESTIMATED EXPOSURE AND USE PATTERNS**

**5.1. Cumulative and Interval Exposure Data**

It is not possible to determine with certainty the number of individuals who received BNT162b2 during the period of this review. Estimated worldwide shipped doses may serve as a reasonable indicator of patient exposure.

With these caveats in mind, it is estimated that approximately

- 66,416,610 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 31 January 2021 and that
- approximately 42,122,535 doses of BNT162b2 were shipped worldwide during the current reporting interval from 01 January 2021 through 31 January 2021.

The estimated cumulative number of shipped doses of BNT162b2 by region<sup>3</sup> based on data provided in the shipment tracker (b) (4)<sup>4</sup> from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 31 January 2021, are summarized in Table 2.

**Table 2. Cumulative Estimated Shipped Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses
<b>Europe</b>	(b) (4)	(4)
European Union <sup>a</sup> (27)		
European Free Trade Association <sup>a</sup> (3)		
Switzerland <sup>a</sup>		
UK <sup>b</sup>		
Other Countries		
<b>Commonwealth of Independent States<sup>c</sup></b>		
<b>North America<sup>b</sup></b>		
US		
Canada		
<b>Central and South America</b>		
<b>Asia</b>		
Japan		
Other Countries		

<sup>3</sup> Currently there are no available data that allow to estimate exposure by gender and age group.

<sup>4</sup> The (b) (4) is the most accurate tracker of shipment used as data source for all the Regions and Countries; US shipment data not available in the (b) (4) were taken from the (b) (4) (b) (4).

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**Table 2. Cumulative Estimated Shipped Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses
<b>Oceania</b>	(b) (4)	(4)
Australia/New Zealand		
Other Countries		
<b>Africa</b>		
<b>Total</b>	<b>100.0%</b>	<b>66416610</b>

- a. In this Region BNT162b2 was conditionally approved;
- b. In this Region BNT162b2 received authorisation for emergency supply;
- c. Includes: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan.

The estimated interval number of shipped doses of BNT162b2 by region<sup>5</sup> based on data provided in the shipment tracker (b) (4)<sup>6</sup> from 01 January 2021 through 31 January 2021, are summarized in Table 3.

**Table 3. Interval Estimated Shipped Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses
<b>Europe</b>	(b) (4)	(4)
European Union <sup>a</sup> (27)		
European Free Trade Association <sup>a</sup> (3)		
Switzerland <sup>a</sup>		
UK <sup>b</sup>		
Other Countries		
<b>Commonwealth of Independent States<sup>c</sup></b>		
<b>North America<sup>b</sup></b>		
US		
Canada		
<b>Central and South America</b>		
<b>Asia</b>		
Japan		
Other Countries		
<b>Oceania</b>		
Australia/New Zealand		
Other Countries		
<b>Africa</b>		
<b>Total</b>	<b>100.0%</b>	<b>42122535</b>

<sup>5</sup> Currently there were no available data that allow to estimate exposure by gender and age group.

<sup>6</sup> The (b) (4) is the most accurate tracker of shipment used as data source for all the Regions and Countries; US shipment data not available in the (b) (4) were taken from the (b) (4) (b) (4).

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**Table 3. Interval Estimated Shipped Doses of BNT162b2 by Region Worldwide**

Region/Country/Other	% of Doses	Total Number of Shipped Doses
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- a. In this Region BNT162b2 was conditionally approved;
- b. In this Region BNT162b2 received authorisation for emergency supply;
- c. Includes: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan.

Table 4 provides the estimated interval/cumulative number of shipped doses of BNT162b2 from the receipt of the first conditional marketing authorisation approval through 31 January 2021 for the 27 European Countries and for the 3 of the European Free Trade Association.

**Table 4. Interval/Cumulative Estimated Shipped Doses of BNT162b2 by EU Countries (30)**

EU Country	Total Number of Interval Shipped Doses	Total Number of Cumulative Shipped Doses
<b>European Union (27)</b>	<b>(b)</b>	<b>(4)</b>
Austria		
Belgium		
Bulgaria		
Croatia		
Cyprus		
Czech Republic		
Denmark		
Estonia		
Finland		
France		
Germany		
Greece		
Hungary		
Ireland		
Italy		
Latvia		
Lithuania		
Luxembourg		
Malta		
Netherlands		
Poland		
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Sweden		
<b>European Free Trade Association</b>		
Iceland		
Liechtenstein		

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**Table 4. Interval/Cumulative Estimated Shipped Doses of BNT162b2 by EU Countries (30)**

EU Country	Total Number of Interval Shipped Doses	Total Number of Cumulative Shipped Doses
Norway	(b) (4)	
<b>Total</b>		

## 6. DATA IN SUMMARY TABULATIONS

### 6.1. Reference Information

The MedDRA version 23.1 was used to code adverse events/reactions in summary tabulations.

### 6.2 Cumulative and Interval Summary Tabulations from Post-Marketing Data Sources

- [Appendix 2](#) and [Appendix 2.1](#) respectively provide interval and cumulative number of case reports (serious and non-serious, medically confirmed and non-medically confirmed) received from post-marketing authorization data sources<sup>7</sup>, overall, by sex, country, age groups and in special populations, and summary tabulations of events by PT and SOC respectively for the interval and cumulative periods.

The cumulative data include all data up to 31 January 2021 while the interval data are for the period from 01 January 2021 to 31 January 2021.

- [Appendix 2.2](#) provides an interval summary tabulation of case reports with DMEs from post-marketing data sources.<sup>7</sup>
- [Appendices 2.3](#) and [2.4](#) are referred to data stratified by country. In these appendices, spontaneous cases (including regulatory authority and literature cases) are presented separately from non-interventional cases:

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<sup>7</sup> This refers to post-EUA/conditional marketing authorisation approval data sources. Please note that in the first SMSR, all cases received in the reporting period and uploaded in the safety database (as of date, 01 January 2021) were included, regardless of their position in the workflow process. However, for this and subsequent monthly reports, only cases having a complete workflow cycle in the safety database (meaning that they went to Distribution or Closed workflow status) have been included. This approach will prevent the inclusion of cases initially received and not fully processed since cases in early steps of the workflow process may still undergo changes and not accurately reflect final data. Each month, Pfizer applies a Late condition process that retrieves cases received in the reporting period but not included due to lack of completeness; this ensures no cases will be missed for inclusion in monthly reports.

- [Appendix 2.3](#) provides a cumulative and interval summary tabulation of cases organized as medically confirmed and non-medically confirmed (fatal, serious and non-serious).
- [Appendix 2.4](#) provides a cumulative and interval summary tabulation of fatal cases.
- [Appendix 2.5](#) and [Appendix 2.6](#)<sup>8</sup> provide a cumulative and interval summary tabulation of adverse reactions from post-marketing authorization data sources<sup>7</sup> respectively by PT and by HLT organized according to SOC. Please refer to [Appendix 2.5.1](#) and [Appendix 2.6.1](#) for data per country.

Adverse events totals presented in [Appendix 2](#), [Appendix 2.1](#) and for safety topic evaluations in [Section 9.5](#) may differ from those presented in [Appendix 2.5](#) and [Appendix 2.6](#), due to the fact that [Appendix 2.5](#) and [Appendix 2.6](#) only display the number of serious and non-serious reactions from spontaneous sources, serious reactions from non-interventional studies and from solicited sources as described above, whereas [Appendix 2](#), [Appendix 2.1](#) and the safety topic evaluation includes all the reported events.

*As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002) received on the first SMSR:*

- [Appendix 2.5.2](#),<sup>9</sup> [Appendix 2.5.3](#) and [Appendix 2.5.4](#)<sup>10</sup> were added to include a cumulative and interval summary tabulation of adverse events from post-authorization data sources<sup>7</sup> by PT per country, stratified respectively for age, gender and relevant co-morbidities.
- Available relevant information with regard to the differences in vaccination prioritization in EU countries,<sup>11</sup> US<sup>12</sup>, UK and ROW<sup>13</sup> was taken into account in the evaluation of adverse events trends, clusters or signals.

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<sup>8</sup> Due to a technical formatting issue, 1 blank page (5) appears in this Appendix; the total data are however correctly displayed.

<sup>9</sup> Due to a technical formatting issue, 7 blank pages (66, 100, 135, 306, 366, 408, 446) appear in this Appendix; the total data are however correctly displayed.

<sup>10</sup> Due to a technical formatting issue, 1 blank page (102) appears in this Appendix; the total data are however correctly displayed.

<sup>11</sup> Overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA. ECDC, February 2021.

<sup>12</sup> <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table-phase-1b-1c.html>

<sup>13</sup> WHO Roadmap for Prioritizing Population Groups for Vaccines against COVID-19; ACIP COVID-19 Vaccines Working Group, Phased Allocation of COVID-19 Vaccines (Dec 01, 2020); JCVI updated interim advice on priority groups for COVID-19 vaccination (Sept 25, 2020)

## 7. MEDICATION ERRORS

Cases potentially indicative of medication errors<sup>14</sup> that occurred in the reporting period are summarized below.

- Number of cases: 872 (6% of 14,525 cases, the total PM dataset) of which 650 (74.5%) are medically confirmed, compared to 323 (8.9% in the first monthly report of which 87% medically confirmed). Out of the 872 cases, 33 cases<sup>15</sup> were determined to be off label use, reporting PTs including: Inappropriate schedule of product administration (28), Incomplete course of vaccination (4), Incorrect route of product administration (3), Product administration error and Wrong product administered (1 each); thus these are excluded from discussion in this Section. Upon review, 3<sup>16</sup> additional cases determined to be non-contributory are not included in the discussion.
- Number of relevant medication error cases: 836  
Number of relevant events: 1067.
- Number of medication errors by country:
  - There were 176 cases describing medication errors, which occurred in the EU/EEA countries [Sweden (39), Germany (30), France (28), Romania (24), Italy (16), Norway (10), Spain (5), Poland and Denmark (4 each), Greece and Netherlands (3 each), Austria and Portugal (2 each) and Belgium, Estonia, Hungary, Lithuania, Slovakia and Slovenia (1 each)].

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<sup>14</sup> MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

<sup>15</sup> In one case, the PT Product administration error was determined to be off-label and was excluded; the second medication error PT (Circumstance or information capable of leading to medication error) included in the same case, is evaluated as a medication error.

<sup>16</sup> One case was made invalid and in 2 cases the PTs Underdose and Incorrect dose administered, respectively were removed.

- There were 660 cases with medication errors from other countries [US (580), UK (48), Canada (15), Israel (12), Andorra, Chile, Mexico, United States minor outlying Islands and Qatar (1 each)].

In some instances, clusters of medication errors were reported, generally by HCPs, suggesting that rather than a systematic issue worldwide, these errors were repeated mistakes at certain vaccination locales:

- Sweden (2 clusters of 7 and 29 cases, respectively),
- France (1 cluster of 3 and 2 clusters of 5 cases),
- Norway (1 cluster of 6 cases)
- United Kingdom and Canada (2 clusters of 2 and 3 cases, respectively)
- US (21 clusters, the largest one with 26 cases),
- Romania - administration of the vaccine using syringes and needles for insulin administration through incorrect route (subcutaneous) to 180 individuals was described in a case.
- Medication error PTs in the EU and ex-EU<sup>17</sup>
  - EU/EEA countries: There were 246 PTs indicative of medication errors Poor quality product administered (49), Circumstance or information capable of leading to medication error and Underdose (35 each), Product preparation issue (24), Incorrect route of product administration (22), Wrong technique in product usage process (21), Product preparation error (14), Inappropriate schedule of product administration, Product temperature excursion issue and Product administered at inappropriate site (7 each), Accidental overdose and Incorrect dose administered (6 each), Product label confusion and Medication error (3 each), Product administration error (2), Drug administered in wrong device, Exposure via skin contact, Intercepted medication error, Intercepted product preparation error and Product administered to patient of inappropriate age (1 each).
  - In other countries, a total of 821 medication errors were reported; those reported at least thrice included: Inappropriate schedule of product administration (263), Poor quality product administered (96), Underdose (77), Product preparation error (67), Product preparation issue (61), Incorrect route of product administration (60),

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<sup>17</sup> As per EMA assessment received on the first SMSR, the MAH was requested to should keep medication errors under close scrutiny especially within the EU context and discuss whether the current product information is sufficiently clear or whether there is room for improvement. The Rapporteurs should be notified immediately in case of unexpected findings or trends.

Circumstance or information capable of leading to medication error (40), Product administered at inappropriate site and Wrong technique in product usage process (25 each), Product temperature excursion issue (18), Product administered to patient of inappropriate age (12), Incorrect dose administered (11), Accidental exposure to product, Exposure via skin contact and Product administration error (10 each), Accidental overdose (9), Incomplete course of vaccination (7), Wrong product administered (5) and Contraindicated product administered (3).

- Medication error by seriousness
  - Serious (13), out of these, 2 serious medication errors (PTs Product administered at inappropriate site and Accidental overdose, 1 each) were reported in 1 EU/EEA country (Germany). Seriousness criteria<sup>18</sup> were life-threatening (1 event), hospitalization and disability or permanent damage (3 events each) and important medical events (7 events); all serious events, but 3, were medically confirmed.
  - Non-serious (1054).
- Medication error outcomes:
  - Fatal (3),
  - Resolved/resolving (139, of which 29 serious),
  - Not resolved (77, of which 23 serious),
  - Unknown (612, of which 9 serious).
- Medication errors of special interest were:
  - a. The preparation and administration of undiluted vaccine (27 individuals, 31 events), see Medication Error Harm Analysis – Medication errors with no harm.

Country	No. of Cases	Medication Error Analysis (Number of Events)	
Italy	1	Without harm – full undiluted vial (0.45 mL)	(1, Administration)
US	4	Without harm – full undiluted vial (0.45 mL)	(4, Preparation)
France	1	Without harm - undiluted dose (0.3 mL)	(1, Preparation)
Israel	2	Without harm - undiluted dose (0.3 mL)	(2, Preparation)
Qatar	1	Without harm - undiluted dose (0.3 mL)	(1, Preparation)
US	6	Without harm - undiluted dose (0.3 mL)	(7; Preparation 6, Administration 1)
UK	2	Without harm (volume unknown)	(2, Preparation)
US	10	Without harm (volume unknown)	(13; Preparation 9, Administration 4)

<sup>18</sup> One not medically confirmed serious case reported 2 different seriousness criteria.



- b. The administration of a “full diluted vial” (3 individuals, 3 events), see Medication Error Harm Analysis – Medication errors associated with harm.
- c. The administration of an erroneous third dose (1 individual) see Medication Error Harm Analysis – Medication errors associated with harm.

The events above are further detailed in [Table 5](#), [Table 6](#) and [Table 7](#).

### Medication Errors Harm Analysis

Among the medication error cases, the following scenarios, categorized according to the EMA guidance “Good practice guide on recording, coding, reporting and assessment of medication errors” (EMA/762563/2014) were encountered:

- Medication errors associated with harm [i.e., resulting in adverse reaction(s)] were reported in 15 cases (17 in the first SMSR);
- Medication errors without harm [i.e. not resulting in adverse reaction(s)]<sup>19</sup> were reported in 713 cases (in 288 of them there were co-reported AEs) compared to 282 cases of which 59 included co-reported AEs in the first SMSR;
- Intercepted medication errors were reported in 2 cases, compared to no cases in the first SMSR;
- Potential medication errors were reported in 106 cases, compared to 24 cases in the first SMSR.

#### *Medication errors associated with harm (16 medication errors in 15 cases)*

There were 6 cases from the EU/EEA area (Germany), and 9 from non-EU/EEA countries [US (8) and the UK (1)].

#### Medication errors of special interest (associated with harm) including

- the administration of a full diluted vial of vaccine (3 events) and
- the administration of an erroneous third dose of vaccine (1 event)

are detailed in the table below.

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<sup>19</sup> AEs may be co-reported in a case, but they are not considered as a result of the medication error.

**Table 5. Medication Errors of Special Interest Associated with Harm**

Country/ Case Seriousness	Number of Doses Administered	Volume of vaccine administered	Medication Error PTs	Associated Reaction(s)
Germany / Serious	1	2.25 mL diluted vaccine	Accidental overdose	Pain in extremity, Headache, Asthenia, Pain, Weight bearing difficulty, Dizziness
Germany / Non-serious	1	2.25 mL diluted vaccine	Accidental overdose	Body temperature increased, Headache, Dizziness, Pain in extremity, Fatigue, Local reaction
Germany / Non-serious	1	2.25 mL diluted vaccine	Accidental overdose	Headache, Pain, Swelling, Asthenia, Limb discomfort, Palpitations, Sense of oppression, Dizziness
US / Serious	3	Unknown	Incorrect dose administered	Somnolence

Other medication errors associated with harm

Medication error of unspecified overdose: this occurred in 1 individual in Germany; the associated non-serious reactions included Headache, Fatigue, Palpitations, Asthenia.

Medication error of vaccination at the wrong anatomical site: This occurred in 8 cases (2 from Germany and 6 from the US), the vaccination was not administered in the deltoid (PT Product administered at inappropriate site). Associated serious reactions (in 2 cases) included: Pain (2), Musculoskeletal disorder, Joint range of motion decreased, Hypoaesthesia, Paraesthesia, Asthenia, Periarthritis (1 each). Associated non-serious reactions (in 6 cases) included: Vaccination site pain and Vaccination site vesicles (2 each), Arthropathy, Constipation, Nerve compression, Vaccination site swelling (1 each).

In 2 US cases, the vaccine was not administered intramuscularly; in the first one, serious, the vaccine was also not administered in the deltoid (see above), in the second case, non-serious, local vaccination site reactions (erythema and pruritus) were reported.

In the last case from UK, Anaphylactic reaction ([Section 9.5.1, Anaphylactic reaction](#)) and Pulmonary oedema occurred, on the same day of the vaccination, to an individual with multiple allergies (PT Contraindicated product administered).

**Medication errors without harm<sup>19</sup> (941 medication errors in 713 cases)**

These medication error PTs describe errors occurring during 1 or more steps of the vaccination process: preparation, administration, or scheduling of second dose.

Overall, there were

- 165 cases from the EU/EEA area [Sweden (39), France (27), Germany (24), Romania (23), Italy (16), Norway (10), Spain (5), Denmark (4), Greece (3), Austria, Netherlands, Poland and Portugal (2 each), and Belgium, Estonia, Hungary, Lithuania, Slovakia, Slovenia (1 each)] and

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- 548 from non-EU/EEA countries [those with more than 1 medication error included the US (473), the UK (46), Canada (13) and Israel (11)].

Vaccine preparation errors (259 events, all non-serious): events mainly described errors in storage conditions, during dilution before use.

- *Incorrect thawing procedure (34 events):* 14 events described an inadvertent refreezing of the vials after these were thawed; a “slushy” appearance of the content of the vial after diluent was added was reported in 5 of them. There were 20 events describing the vaccine was left at room temperature for a longer time than the one specified in the RSI; no events were reported upon vaccine administration.
- *Incorrect dilution (107 events):*  
 Dilution was not performed (25 events); medication errors of special interest in the dilution step included:
  - dilution not performed and preparation of a 0.3 mL dose of undiluted vaccine (10 events),
  - dilution not performed and preparation of a 0.45 mL dose of undiluted vaccine (4 events) and
  - dilution not performed and preparation of an unknown volume of undiluted vaccine (11 events).

These events are detailed in the table below.

**Table 6. Preparation Errors of Special Interest with No Harm**

Country/ Case Seriousness	Number of Cases	Volume of vaccine administered	Co-Reported AEs (Relevant <u>Medication Error</u> <u>PTs</u> )
France / Non-serious	1	0.3 mL undiluted vaccine	<u>Product preparation error</u> , Overdose, Injection site erythema
Israel / Non-serious	2	0.3 mL undiluted vaccine	<u>Product preparation error</u> , Overdose
Qatar / Non-serious	1	0.3 mL undiluted vaccine	Overdose, <u>Product preparation error</u>
US / Non-serious	1	0.3 mL undiluted vaccine	Overdose, <u>Product preparation error</u>
US / Non-serious	3	0.3 mL undiluted vaccine	Overdose, <u>Product preparation issue</u>
US / Non-serious	1	0.3 mL undiluted vaccine	<u>Product preparation error</u> , Accidental overdose
US / Serious	1	0.3 mL undiluted vaccine	Nausea, <sup>a</sup> Feeling abnormal, Pain, Pyrexia, Blood pressure increased, Chest discomfort, Migraine, Peripheral swelling, Vaccination site pain, Movement disorder, Overdose, <u>Product preparation error</u>
US / Non-serious	4 <sup>c</sup>	0.45 mL undiluted vaccine	Overdose, <u>Product preparation error</u>
UK / Non-serious	2 <sup>b</sup>	Unknown volume of undiluted vaccine	<u>Product preparation issue</u> , Overdose
US / Non-serious	1	Unknown volume of undiluted vaccine	Overdose, <u>Product preparation error</u>
US / Non-serious	4	Unknown volume of undiluted vaccine	<u>Product preparation error</u> , Overdose

**Table 6. Preparation Errors of Special Interest with No Harm**

Country/ Case Seriousness	Number of Cases	Volume of vaccine administered	Co-Reported AEs (Relevant Medication Error PTs)
US / Non-serious	3	Unknown volume of undiluted vaccine	<u>Product preparation error</u> , Accidental overdose
US / Non-serious	1	Unknown volume of undiluted vaccine	<u>Product preparation error</u> , Overdose, Pyrexia, Myalgia, Headache, Pain in extremity

- a. Only the PTs Nausea, Feeling abnormal and Pain, were reported as serious occurrences.
- b. Cluster of 2 cases from the same reporter who suspected the vaccine might have been given undiluted, or an incorrect amount of solution to dilute was used.
- c. Cluster of 4 cases from the same reporter.

Other incorrect dilution errors

Dilution was performed either with a smaller volume of normal saline (10 events), or with a larger volume of normal saline (19 events) than instructed and dilution with improper volume was reported with a variable total number of available doses after dilution from a single vial (16 events). There were 37 events indicative of dilution performed with sterile water rather than normal saline; no adverse events were reported upon vaccine administration.

- *Vaccine appearance after dilution (57 events)*: there were 29 cases, all from Sweden, in which the color of the vaccine after dilution was transparent instead of off-white; no events were reported after the vaccine was administered.
- *Lack of vial inversion (31 events)*: inversion of the vial after dilution was not performed in accordance to instructions.
- *Other preparation errors (30 events)*.

Vaccine administration errors (679 events, 7 of which were serious): events mainly described errors in administration of vaccine dose not adequately prepared (see Preparation subset), errors in the volume or dosage of the vaccine administered, errors in administering the second dose in less than 21 days or after more than 21 days, and errors in route of administration.

- *Incorrect interval between doses (188 events, all non-serious)*: the second dose of the vaccine was administered at less than 21 days of interval (166 events); interval between the first and the second dose ranged between 1 day and 20 days, with the majority of the second doses administered between the 17<sup>th</sup> and the 20<sup>th</sup> day after the first dose (114 events); the second dose was administered after more than 21 days (22 events).
- *Administration after inadequate preparation (116 events, all non-serious)*: these events referred to vaccine administered after inadequate preparation: dilution performed with sterile water instead of normal saline (42 events); vaccine administered incorrect thawing procedure (left at room temperature for a longer time than the one specified in the RSI), or thawed and inadvertently refrozen (40 events); inversion after dilution not performed

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(27 events); and other errors including reconstitution before vaccine was fully thawed (7 events).

- *Errors in the volume administered (116 events, all non-serious):* partial doses were administered due to leakage, syringe or needle malfunction (100 events); larger volume of vaccine was administered (15 events), and accidental overdose (1 event).
- *Errors in the route of administration (79 events, of which 2 serious<sup>20</sup>):* the vaccine was administered subcutaneously (65 events)<sup>21</sup>; parenterally without any further detail (11 events); and through other routes (3 events).
- *Vaccination site other than deltoid muscle (30 events, of which 2 were serious<sup>22</sup>):* the vaccine was administered in the vaccinee’s arm but not in the deltoid muscle (24 events); the administration site was in the leg or in the gluteus (5 events) and not specified (1 event).
- *Errors in vaccine dosage (24 events, all non-serious):*  
 Wrong dosage of vaccine was administered (6 events); medication errors of special interest in dosing the vaccine included:
  - administration of a 0.3 mL dose of undiluted vaccine (1 event),
  - administration of a 0.45 mL dose of undiluted vaccine (1 event) and
  - administration of an unknown volume of undiluted vaccine (4 events).

These events are detailed in the table below.

**Table 7. Administration Errors of Special Interest with No Harm**

Country/ Case Seriousness	Number of Cases	Volume of vaccine administered	Co-Reported AEs (Relevant <u>Medication Error PTs</u> )
Italy / Non-serious	1	0.45 mL undiluted vaccine	Hypotension, Pruritus, Anaphylactic shock, Bradycardia, <u>Incorrect dose administered</u>
US / Non-serious	1	0.3 mL undiluted vaccine	Product preparation error, <u>Accidental overdose</u>
US / Non-serious	1	Unknown volume of undiluted vaccine	<u>Product preparation error</u> , Overdose, Vaccination site reaction
US / Non-serious	3	Unknown volume of undiluted vaccine	Product preparation error, <u>Accidental overdose</u>

<sup>20</sup> PT Incorrect route of product administration (2).

<sup>21</sup> One of these cases with a fatal case outcome is referenced in Death subsection in [Table 14](#).

<sup>22</sup> PTs Wrong technique in product usage process and Product administered at inappropriate site (1 each).

Other wrong dosage errors

Dilution performed with a larger volume of normal saline than recommended leading to lower concentration (15 events), 2 doses at the same date (3 events).

- *Accidental exposure to vaccine (22 events, of which 2 serious<sup>23</sup>):* all but 2 (eye) involved skin exposure.
- *Dose of vaccine not administered (21 events, all non-serious):* the second dose was not administered (12 events); presence of air or empty syringe (8 events); or diluent was administered (1 event).
- *Paediatric Individuals <16 Years of Age (13 events, of which 1 serious<sup>24</sup>):* the vaccine was inadvertently administered to paediatric individuals below 16 years ([Section 9.5.3 Table 15, Use in Paediatric Individuals <16 Years of Age](#)).<sup>25</sup>
- *Wrong vaccine administered (12 events, all non-serious):* the Moderna vaccine was administered to individuals who received the first dose of BioNTech-Pfizer vaccine (8 events); it was unknown if the BioNTech-Pfizer or Moderna vaccine were administered (3 events) and a dose of BioNTech -Pfizer vaccine was administered as first dose instead of a dose of Moderna (1 event).
- *Vaccination card errors (3 events, all non-serious):* there were 2 errors in the date planned for the second dose (wrong date or not filled in) and in 1 case the card was not given to the vaccinee.
- *Other vaccine administration errors (55 events, all non-serious):* the majority of the events were indicative of administration of the vaccine using syringes and needles for insulin administration or in order to avoid repeated puncture of the diluted vial a needle was left in the vial to which all the syringes were subsequently attached (31 events); some doses were administered after collection of residual vaccine from different vials (5 events); the presence of “an object” or “1-2 black objects” were noted in the vial after the first dose of the vial was administered<sup>26</sup> and was notified through product complaint reports (3 events for lot EJ6795), and expired vaccine (2 events).

Scheduling (3 events, all non-serious): the second dose of the vaccine was not scheduled according to the 21 days interval (3 events).

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<sup>23</sup> One case reported Accidental exposure to product and Exposure via skin contact (1 each).

<sup>24</sup> PT Product administered to patient of inappropriate age (1). Co-reported AES included Rash pruritic, Renal failure, Blood urine present, Pyrexia, Hyperhidrosis.

<sup>25</sup> Out of these 13 cases, 11 are cross-referenced in [Section 9.5.4](#); for the remaining 2 cases, follow-up information has been requested after data-lock point.

<sup>26</sup> Only one dose was administered (with no events) and the vaccine in the vial was discarded.

***Intercepted medication errors (2 medication errors in 2 cases)***

There were 2 cases from the EU/EEA area [France and Romania (1 each)] and none from non-EU/EEA countries.

A vial, reconstituted with a larger volume of diluent, was not used (1 event); an insulin needle was removed from the syringe and another needle suitable for intramuscular injection was used (1 event).

***Potential medication errors (108 medication errors in 106 cases)***

There were 3 cases from the EU/EEA area [Poland (2), and Netherlands (1)] and 103 from non-EU/EEA countries [US (99), Canada (2) and 1 case each from the UK and Israel].

- Potential vaccine preparation error (5 events, all non-serious): events mainly described product label confusion (5 events).
- Potential dosing interval error (103 events, all non-serious): events mainly described potential errors in the scheduling for the second dose not according to the 21 days interval.

Some medication errors are expected to occur despite written instructions and educational activities for HCPs administering the vaccine. The number and seriousness of the reported medication errors do not indicate a need for additional mitigation activity.

**8. OVERALL SAFETY EVALUATION**

*As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002) received on the first SMSR, the MAH was requested to add a summary overview of the presented adverse events which highlights the main (safety) findings from the case reports in the section.*

**8.1. General Overview**

A total of 14,525 adverse event reports (9193 medically confirmed and 5332 non-medically confirmed) containing 51,765 events fulfilled criteria for inclusion in this SMSR. Refer to [Appendix 2](#) for the summary tabulations of all cases received during the current reporting period.

**PRESENTATION OF CASE CHARACTERISTICS**

**Table 8. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval**

	Characteristics	Relevant cases (N=14525)
Gender:	Female	10011
	Male	3093
	No Data	1421

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**Table 8. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval**

Characteristics	Relevant cases (N=14525)	
Age range (years):	70 <sup>a</sup>	
0.01-104 years	1764	
Mean = 49.1 years	4809	
n = 11294	2552	
	686	
	1473	
	3171 <sup>b</sup>	
Case outcome:	Resolved/Resolving	6134
	Resolved with sequelae	141
	Not resolved at the time of report	3907
	Fatal	410
	Unknown	3933
Presence of relevant comorbidities <sup>a</sup>	Yes	2535
	No	11990

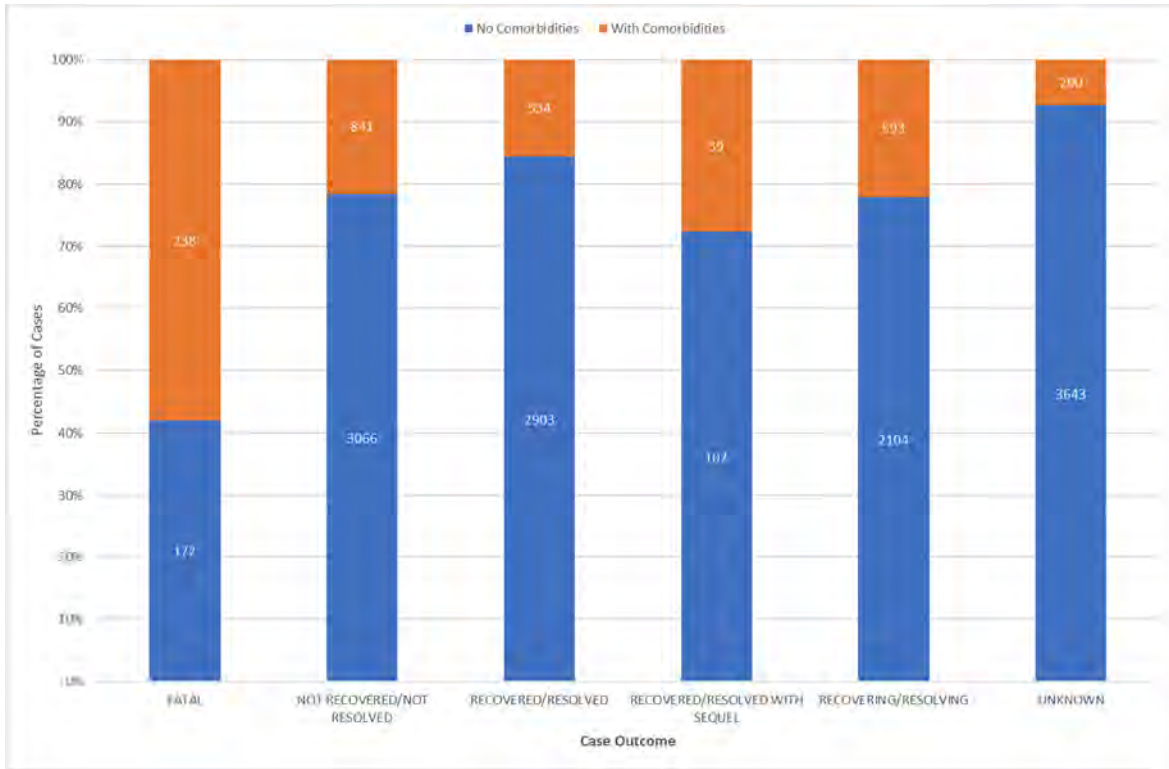
- a. Including 13 cases for which a paediatric age was initially reported but that they re-evaluated as not consistent with this age upon review (see [Table 15](#), *Use in Paediatric Individuals <16 Years of Age*); and 33 breastfed babies for which paediatric age was reported;
- b. Including 37 breastfed babies for which age was not reported;
- c. Cases retrieved applying the criteria in place to identify the reports involving the special populations of Immunocompromised patients, Patients with autoimmune or inflammatory disorders, Frail patients with comorbidities (e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders) described as Missing Information in [Table 15](#).

Case outcome by age group, gender and presence of relevant comorbidities is presented in [Figure 1](#), [Figure 2](#) and [Figure 3](#). The fatal cases reported more comorbidities, but this is expected considering that the majority of fatal outcomes occurred in patients 75 years and older as shown in [Figure 2](#) (please also see *Death* in [Table 14](#) and *Frail patients with co-morbidities e.g. COPD, diabetes, chronic neurological disease, cardiovascular disorders*, described as Missing Information in [Table 15](#)).

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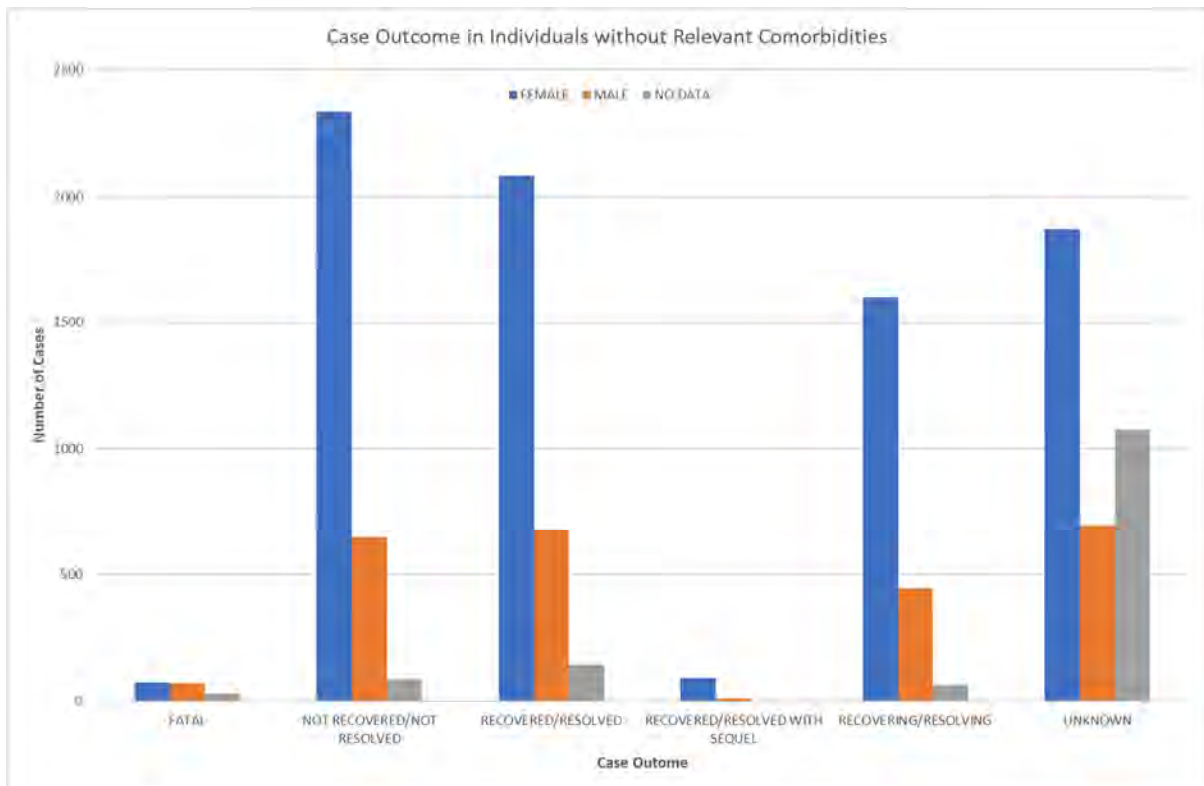
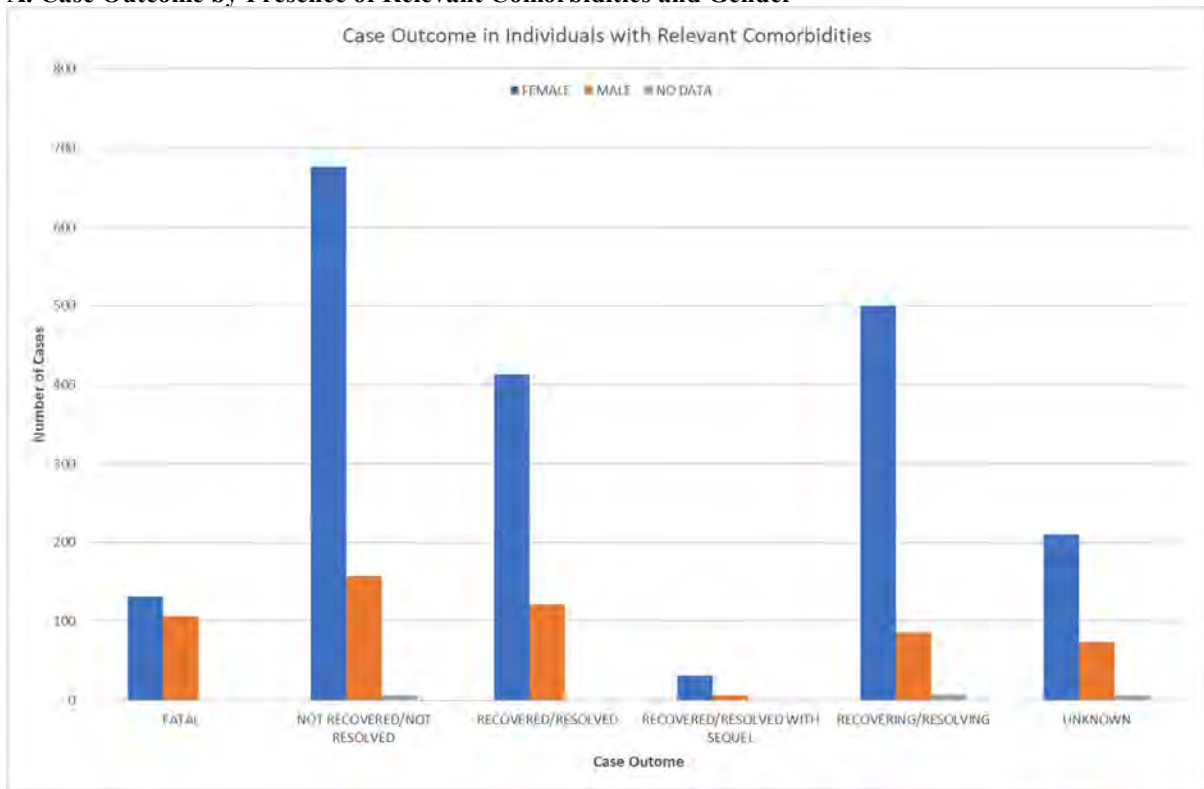
**Figure 1. Case Outcome by Presence of Relevant Comorbidities**



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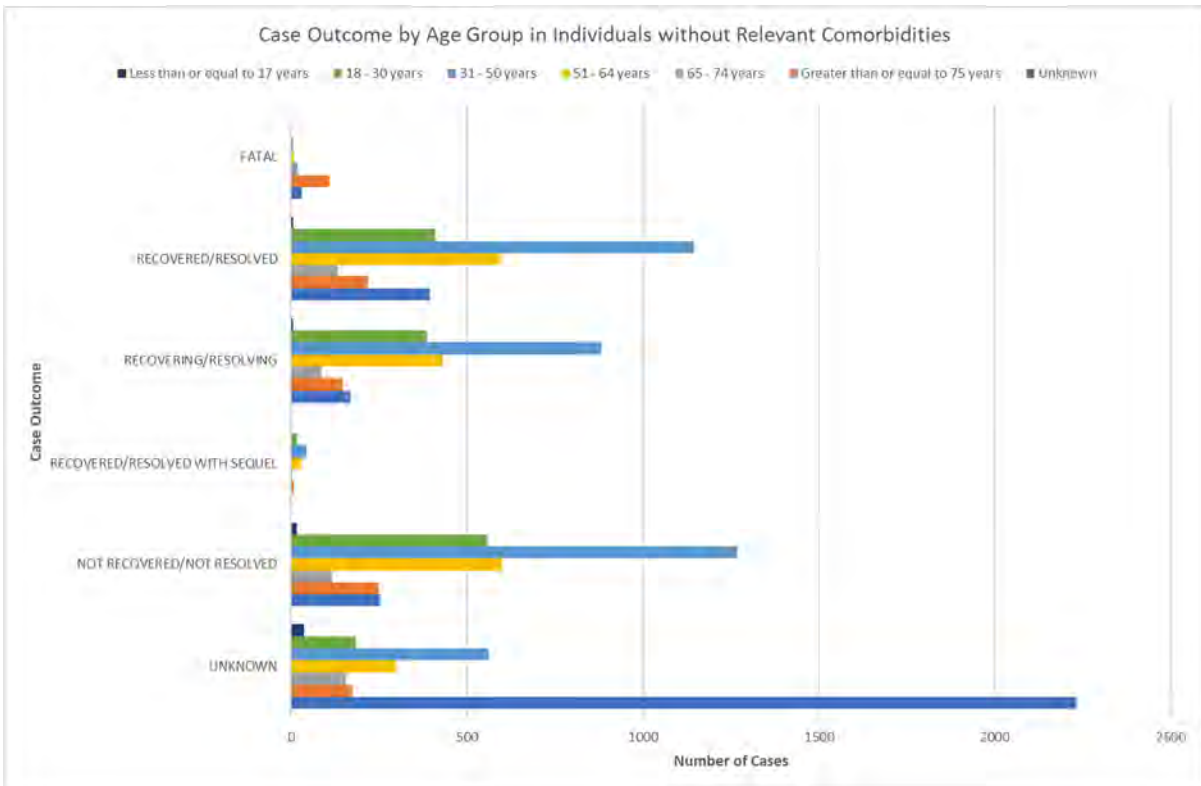
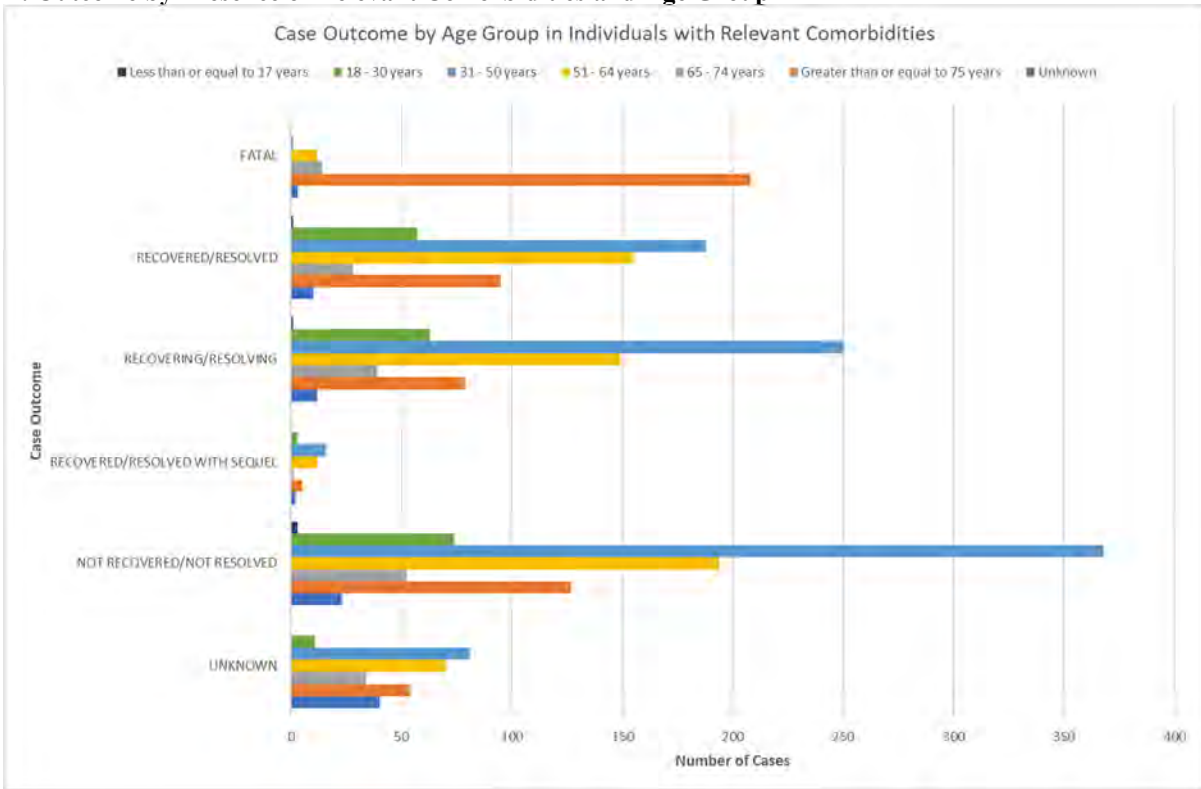
**Figure 2. Case Outcome by Presence of Relevant Comorbidities, Gender and Age Group**

**A. Case Outcome by Presence of Relevant Comorbidities and Gender**



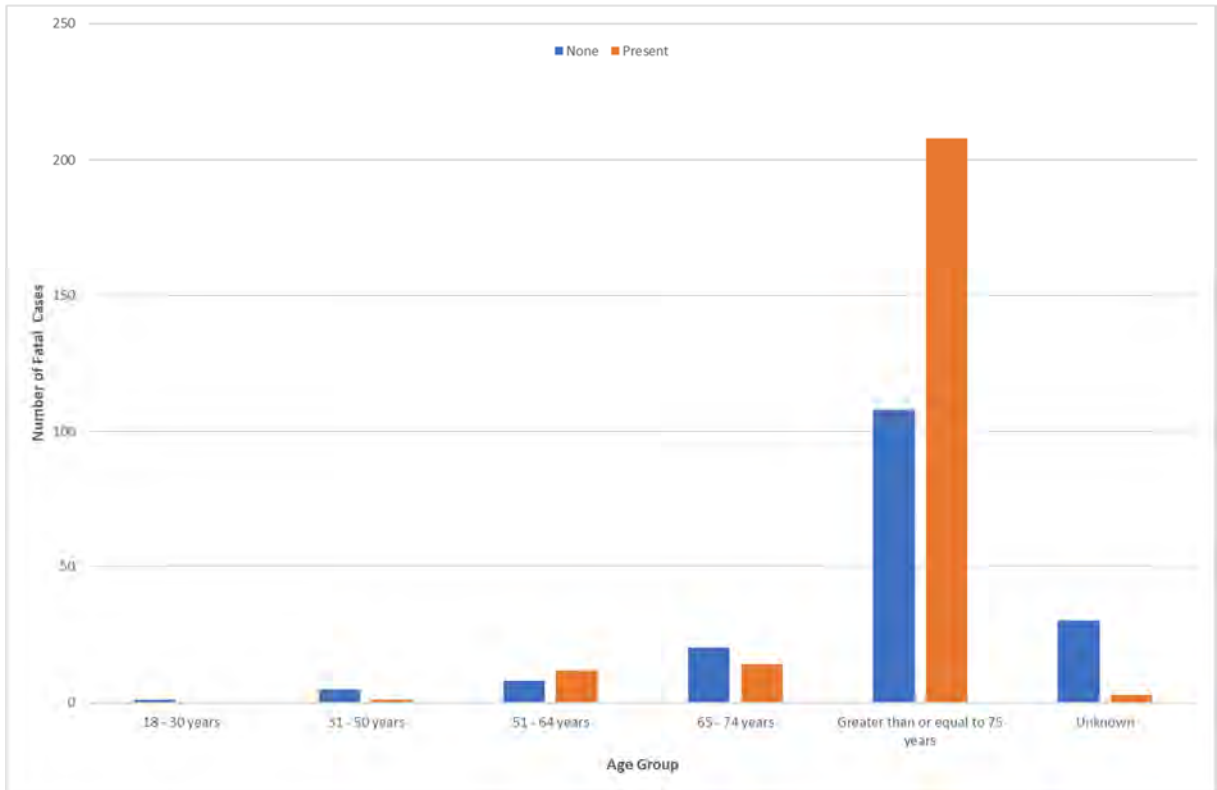
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**B. Outcome by Presence of Relevant Comorbidities and Age Group**



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**Figure 3. Fatal Case Outcome by Presence of Relevant Comorbidities and Age Group**

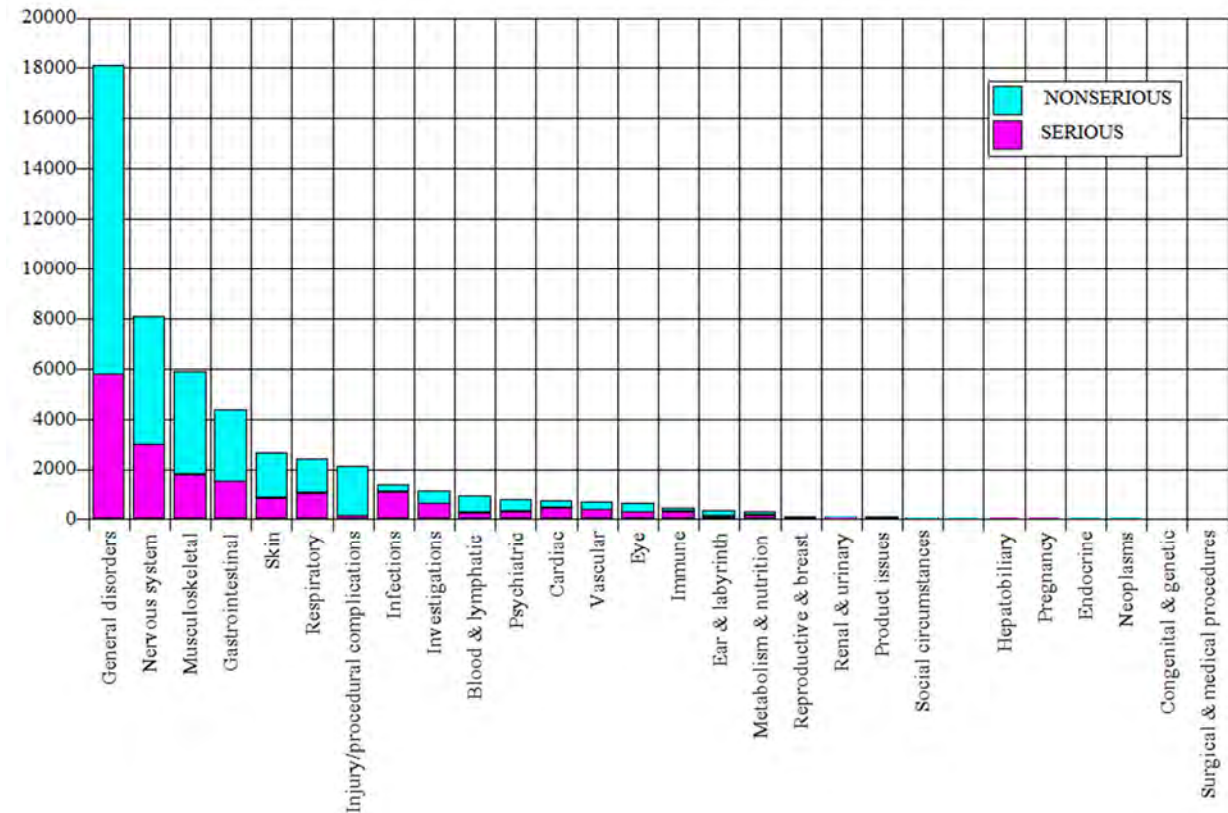


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**ADVERSE EVENT DATA**

As shown in Figure 4, the MedDRA SOC containing the greatest number of events ( $\geq 2\%$ ) were General disorders and administration site conditions (18,136), Nervous system disorders (8114), Musculoskeletal and connective tissue disorders (5896), Gastrointestinal disorders (4389), Skin and subcutaneous tissue disorders (2672), Respiratory, thoracic and mediastinal disorders (2408), Injury, poisoning and procedural complications (2125), Infections and infestations (1390) and Investigations (1173). Of note, multiple adverse events may be reported in a single case.

**Figure 4. General Overview: Total Number of Events by MedDRA SOC and Event Seriousness**



The overall safety evaluation includes a review of the most frequently reported events by SOC and by the PT for events reported in ( $\geq 2\%$ ) of all cases during the reporting interval as compared to the cumulative period since the first temporary authorisation for emergency supply on 01 December 2020.

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**Table 9. Events Reported in more than ≥2%\* Cases**

	<b>01 January 2021 Through 31 January 2021</b>	<b>Cumulatively Through 31 January 2021</b>
<b>MedDRA SOC MedDRA PT</b>	<b>AEs (AERP%) N = 14525</b>	<b>AEs (AERP%) N = 18061</b>
<b>Blood and lymphatic system disorders</b>		
Lymphadenopathy <sup>a</sup>	711 (4.90%)	832 (4.61%)
<b>General disorders and administration site conditions</b>		
Pyrexia <sup>a</sup>	2773 (19.09%)	3281 (18.17%)
Fatigue <sup>a</sup>	2401 (16.53%)	2984 (16.52%)
Chills <sup>a</sup>	2087 (14.37%)	2529 (14.00%)
Vaccination site pain <sup>a</sup>	2018 (13.89%)	2532 (14.02%)
Pain <sup>a</sup>	1454 (10.01%)	1797 (9.95%)
Drug ineffective <sup>b</sup>	1046 (7.20%)	1233 (6.83%)
Malaise <sup>a</sup>	924 (6.36%)	1141 (6.32%)
Asthenia <sup>a</sup>	597 (4.11%)	704 (3.90%)
Vaccination site erythema <sup>a</sup>	364 (2.51%)	448 (2.48%)
Vaccination site swelling <sup>a</sup>	350 (2.41%)	430 (2.38%)
Influenza like illness <sup>a</sup>	344 (2.37%)	398 (2.20%)
Feeling abnormal <sup>a</sup>	295 (2.03%)	376 (2.08%)
<b>Gastrointestinal disorders</b>		
Nausea <sup>a</sup>	1722 (11.86%)	2140 (11.85%)
Diarrhoea	574 (3.95%)	711 (3.94%)
Vomiting	509 (3.50%)	633 (3.50%)
<b>Infections and infestations</b>		
COVID-19 <sup>b</sup>	688 (4.74%)	789 (4.37%)
<b>Injury, poisoning and procedural complications</b>		
Inappropriate schedule of product administration <sup>b</sup>	297 (2.04%)	304 (1.68%)
<b>Musculoskeletal and connective tissue disorders</b>		
Myalgia <sup>a</sup>	1628 (11.21%)	1949 (10.79%)
Pain in extremity <sup>a</sup>	1472 (10.13%)	1817 (10.06%)
Arthralgia <sup>a</sup>	1173 (8.08%)	1382 (7.65%)
<b>Nervous system disorders</b>		
Headache <sup>a</sup>	3512 (24.18%)	4269 (23.64%)
Dizziness	1107 (7.62%)	1461 (8.09%)
Paraesthesia	445 (3.06%)	590 (3.27%)
Hypoesthesia	332 (2.29%)	440 (2.44%)
<b>Respiratory, thoracic and mediastinal disorders</b>		
Dyspnoea <sup>c</sup>	497 (3.42%)	612 (3.39%)
Cough <sup>c</sup>	350 (2.41%)	444 (2.46%)
<b>Skin and subcutaneous tissue disorders</b>		
Rash <sup>d</sup>	471 (3.24%)	596 (3.30%)
Pruritus <sup>d</sup>	460 (3.17%)	607 (3.36%)
Urticaria <sup>d</sup>	311 (2.14%)	403 (2.23%)
Erythema <sup>d</sup>	296 (2.04%)	371 (2.05%)
<b>Total number of events</b>	<b>31208</b>	<b>38203</b>

- a. Listed or consistent with listed AEs in current RSIs;
  - b. Listed per case processing conventions;
  - c. Consistent with anaphylactic reactions listed in the current RSIs;
  - d. Consistent with hypersensitivity reactions listed in the current RSIs; an update to include Hypersensitivity specific reactions (e.g. rash, pruritus, urticaria, angioedema) to the EUA Fact Sheets and EUA PI was submitted to the FDA after the data-lock point of this SMSR;
- \* Reporting proportion (% of total cases) in the current reporting period.

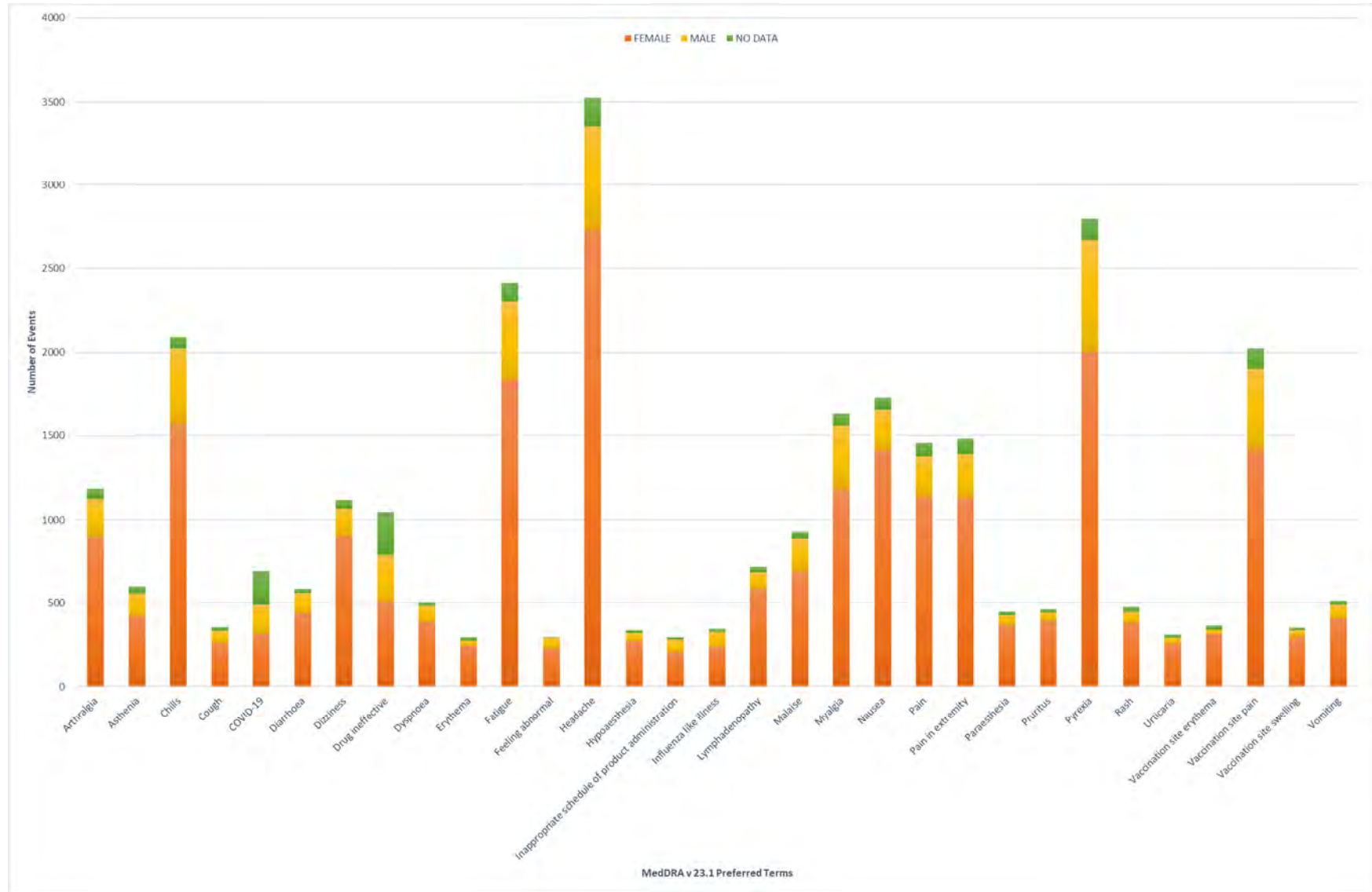
Most of the frequently reported events are listed or consistent with listed AEs as per the current RSIs. Of note, the most frequently reported events Diarrhoea, Vomiting, Dizziness and Paraesthesia, not listed as per the current RSIs, were signals under evaluation (see [Section 9.2](#)). After the data-lock point of this SMSR, the signals Diarrhoea and Vomiting were evaluated as adverse reactions that will be added to labelling and closed as identified risks (not important). Dizziness and Paraesthesia are still under evaluation.

During the reporting interval, the distribution of the AEs reported in more than 2% of the cases by gender is presented in [Figure 5](#). The observed imbalance in the female gender distribution reflects the imbalance in the gender distribution of the cases received in the reporting period.

The distribution of the AEs reported in more than 2% of the cases by age group and by SOC is showed in [Figure 6](#) and [Figure 7](#). The largest number of events is reported overall in the 31-50 years age group and within this group, there were more females than males. This difference may reflect the vaccination campaigns worldwide which mainly prioritizes healthcare professionals.<sup>11,12,13</sup>



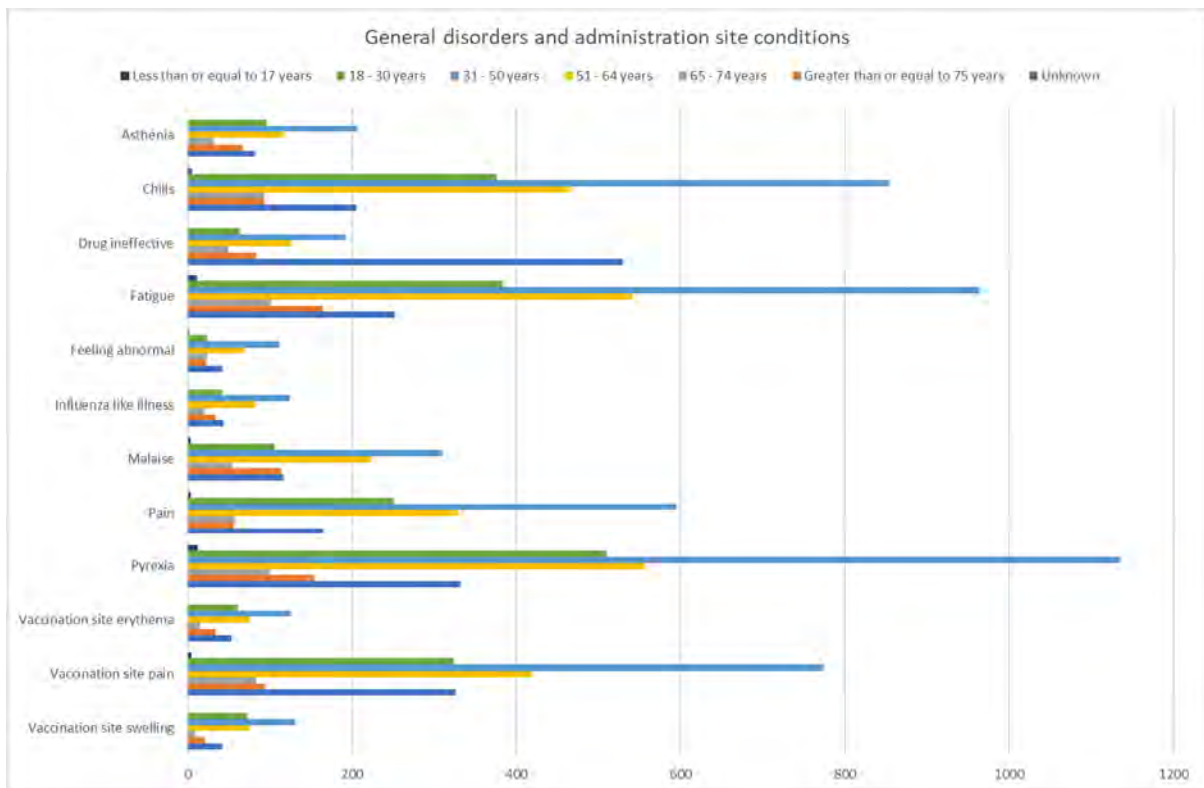
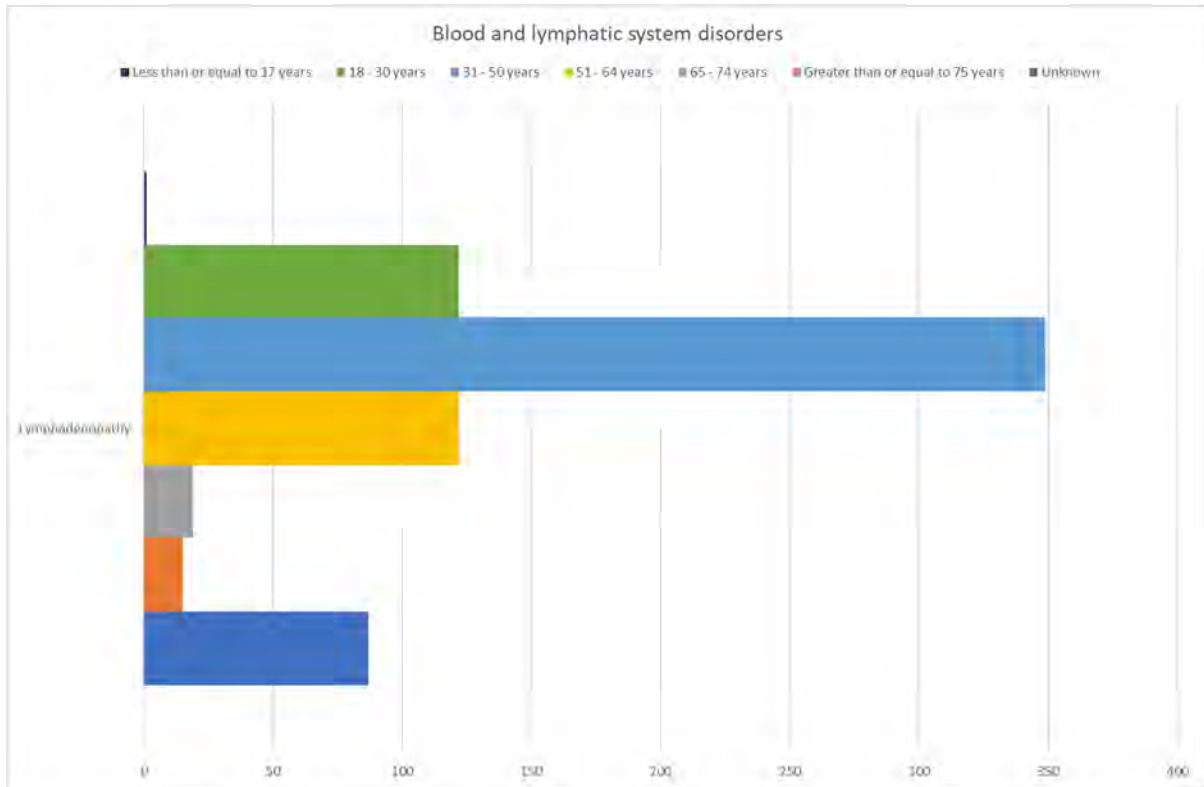
**Figure 5. Events Reported in more than ≥2% Cases in the Interval Period by Gender**



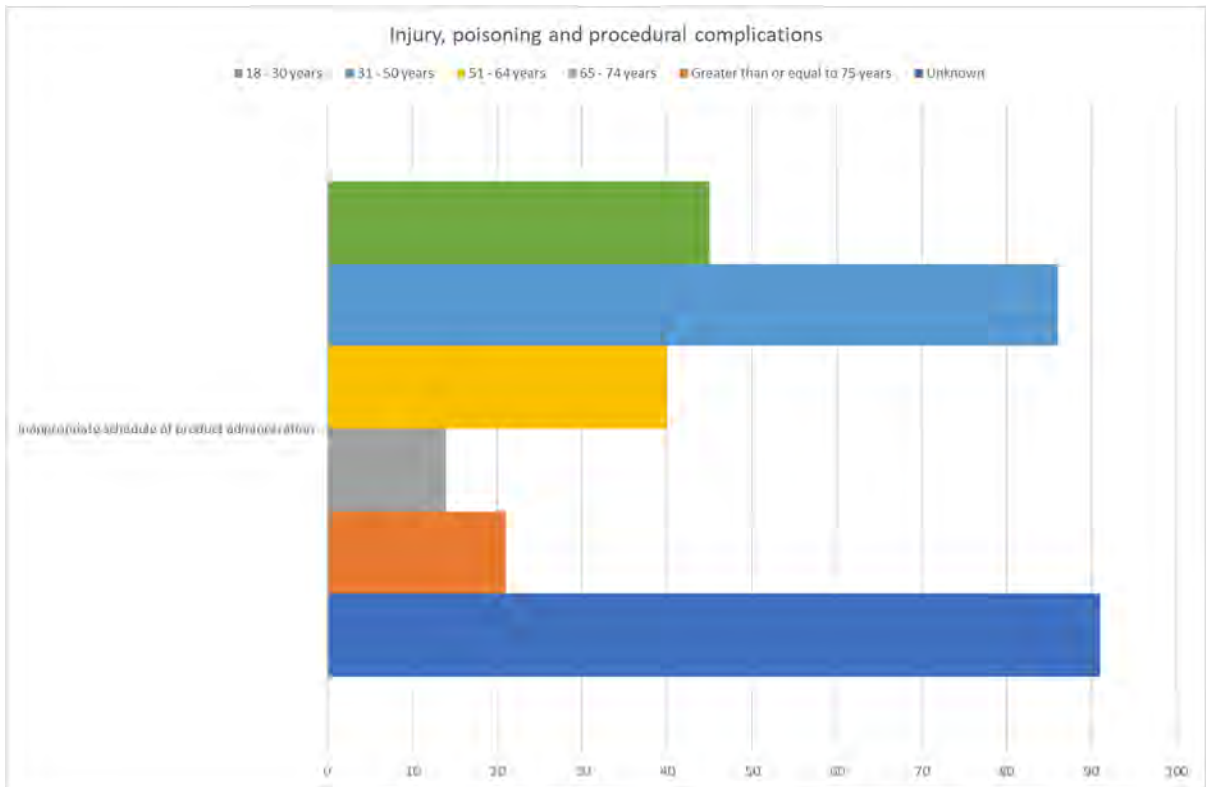
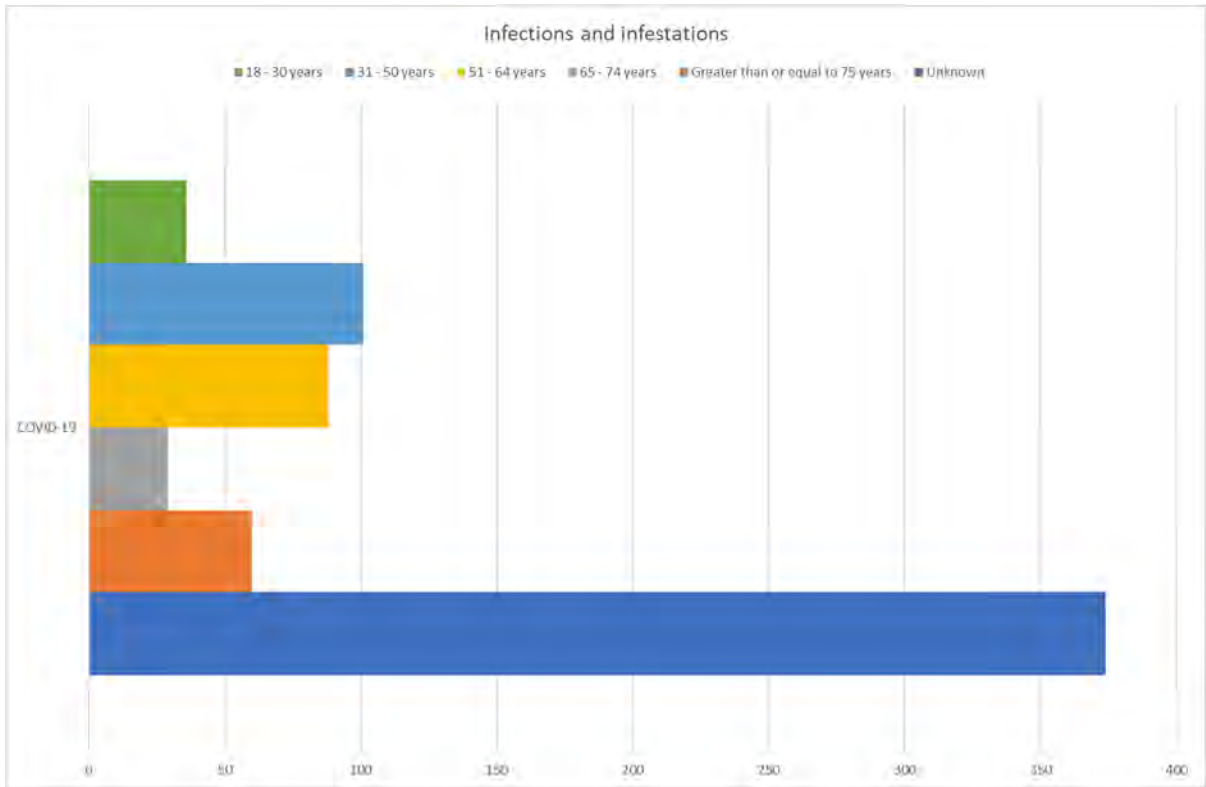
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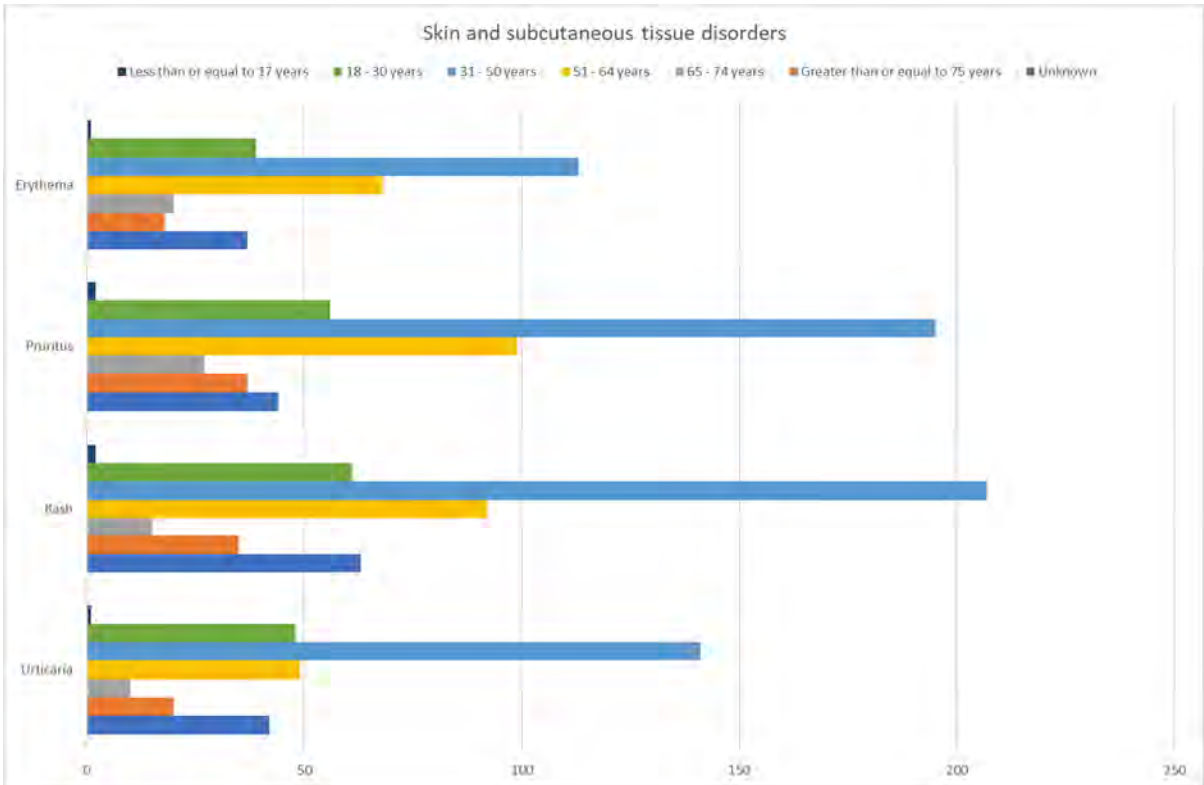
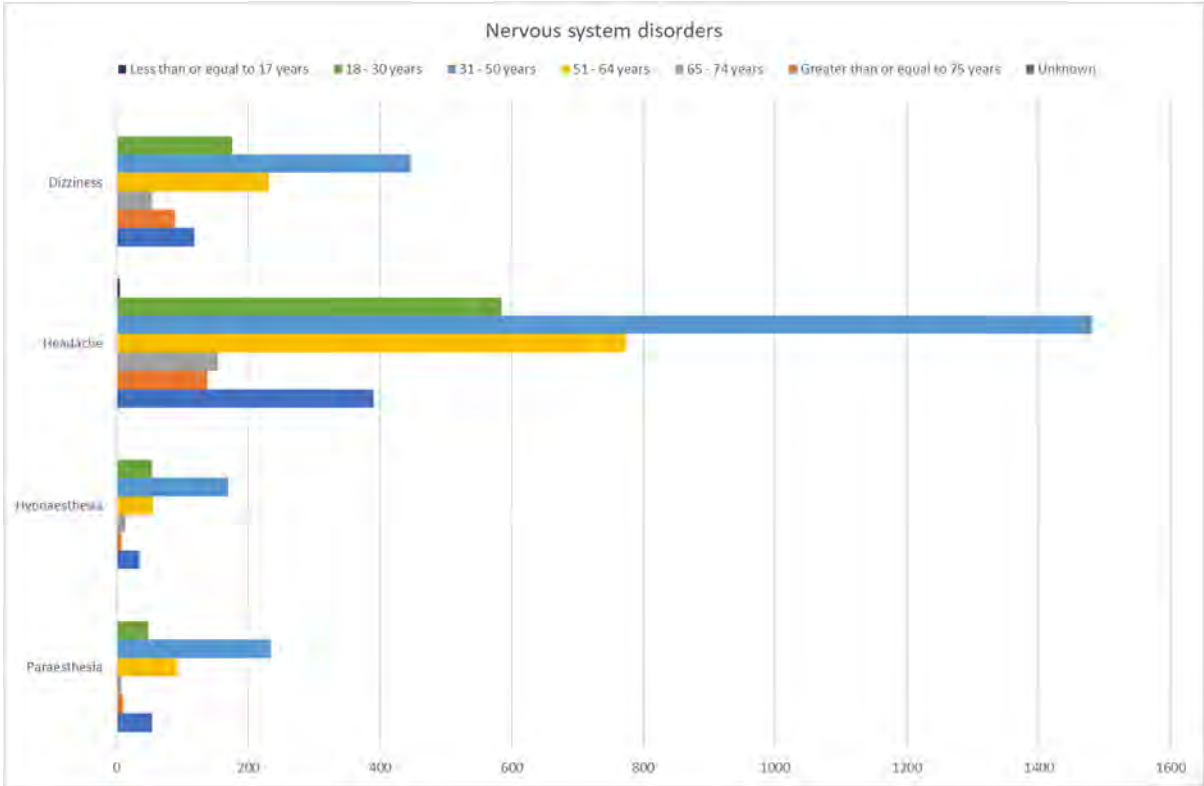
**Figure 6. PT Reported in more than  $\geq 2\%$  in the Interval Period - by SOC and Age Group**



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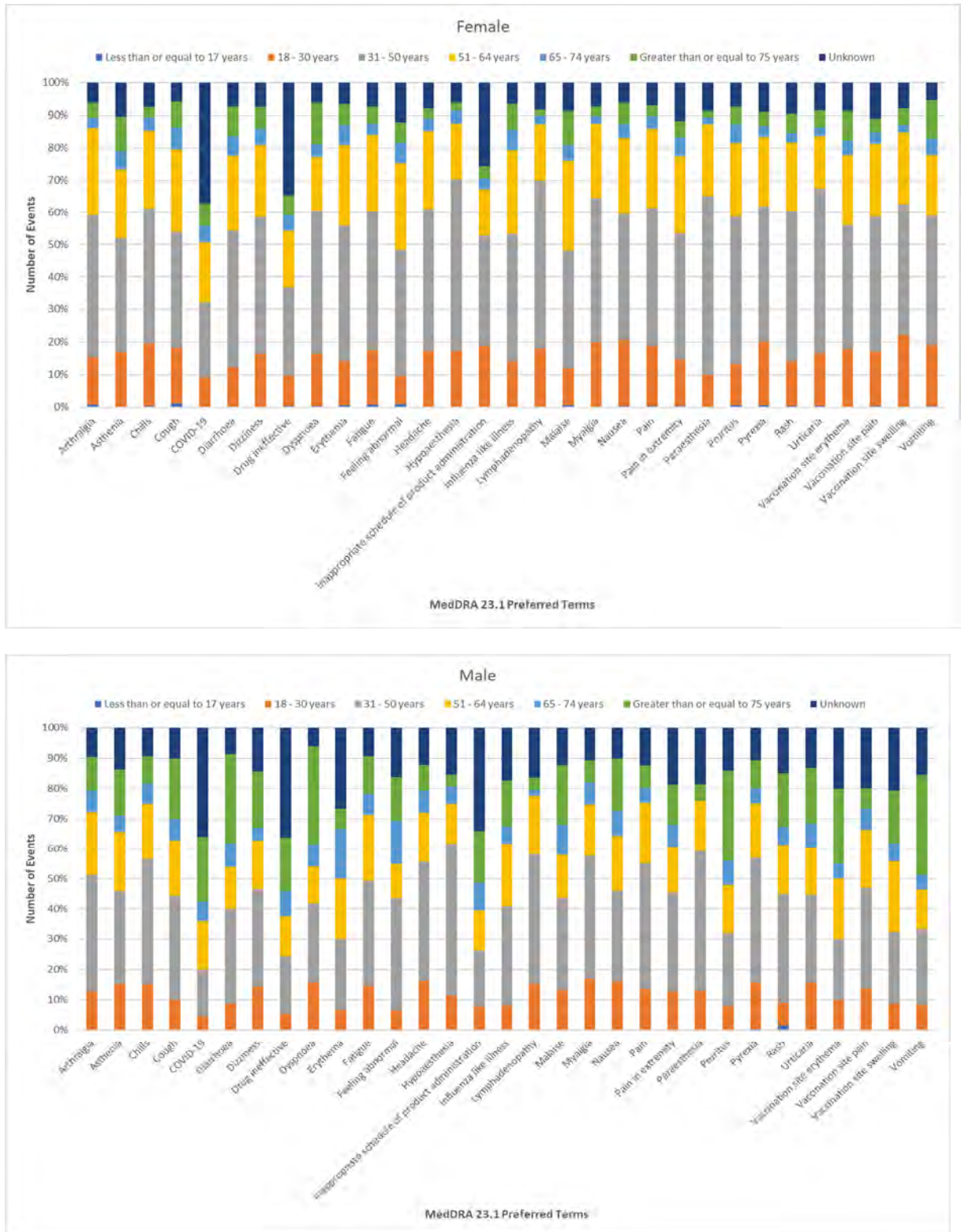


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**Figure 7. Events Reported in more than  $\geq 2\%$  in the Interval Period by Age Group within Gender**



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## 9. SIGNAL AND RISK EVALUATION

### 9.1. Literature Review

Please refer to [Appendix 6](#) for a summary description of the interval literature review that is performed for the purpose of signal detection. There were no literature articles identifying new safety topics that would represent signals for BNT162b2 during the reporting interval.

### 9.2. Overview of Signals During the Reporting Interval

Signals addressed during the reporting interval are presented below in Table 10.

**Table 10. Overview of Signals**

Signal	Status	Category
Hypersensitivity reactions (other than anaphylaxis)	Closed	Identified Risk (Not Important)
Insomnia	Closed	No Risk <sup>a</sup>
Injection site pruritus	Closed	No Risk <sup>a</sup>
Pain in extremity	Closed	Identified Risk (Not Important)
Facial paralysis	Ongoing	Under evaluation
Vomiting	Closed <sup>b</sup>	Identified Risk (Not Important)
Diarrhoea	Closed <sup>b</sup>	Identified Risk (Not Important)
Overdose	Closed	No Risk
Paraesthesia and Dysaesthesia	Ongoing	Under evaluation
Dizziness	Ongoing	Under evaluation
Immune thrombocytopenia	Closed	No Risk
Eye pain and Eye swelling	Closed <sup>b</sup>	No risk
Deaths including in elderly or frail individuals	Closed	No Risk

a. Insomnia and Injection site pruritus were included in the EU SmPC as adverse reactions at the request of the EMA at the time of conditional approval of the vaccine, however based on evaluation of available clinical and post-authorization data, they were determined not to be risks for inclusion in the company CDS or, therefore, in the US EUA Fact Sheet for the HCP and Full EUA PI;

b. After the data-lock of this SMSR.

[Appendix 3](#) provides a summary of the safety signals during the reporting interval. Please refer to [Appendix 3.1](#) for evaluation of signals during the reporting interval, to [Appendix 3.2](#) for specific evaluation of Facial paralysis and to [Appendix 3.3](#) for specific evaluation of Immune thrombocytopenia.



As per EMA PRAC assessment report received on the first SMSR, the following cumulative overviews were performed on:

Case reports of Diarrhoea and Vomiting ([Appendix 3.4](#));

Case reports of Eye pain and Eye swelling ([Appendix 3.5](#));

Case reports of Paraesthesia and Dysaesthesia ([Appendix 3.6](#)).

### 9.3. Summary of Safety Concerns

Table 11 summarises the comprehensive list of important risks and missing information reflected in risk management and pharmacovigilance plans globally for BNT162b2 at the beginning of the reporting period. The pharmacovigilance and risk management activities implemented for the safety concerns by Pfizer on behalf of BioNTech are global.

**Table 11. Safety Concerns**

Important Identified Risk	Anaphylaxis <sup>a,d</sup>
Important Potential Risk	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-Associated Enhanced Respiratory Disease (VAERD) <sup>b</sup>
Missing Information	Use in Pregnancy and While Breast Feeding <sup>b</sup>
	Use in Immunocompromised Patients <sup>a</sup>
	Use in Frail Patients With Co-Morbidities (e.g. COPD, Diabetes, Chronic Neurological Disease, Cardiovascular disorders) <sup>a</sup>
	Use in Patients With Autoimmune or Inflammatory Disorders <sup>a</sup>
	Interaction With Other Vaccines <sup>a</sup>
	Long-Term Safety Data <sup>a</sup>
	Use in Paediatric Individuals <16 Years of Age <sup>c</sup>
	Vaccine Effectiveness <sup>c</sup>

a. As per the EU RMP Version 1.0, dated 21 December 2020;

b. As per both the EU RMP Version 1.0, dated 21 December 2020 and the US PVP, Version 0.2, dated 05 December 2020;

c. As per the US PVP, Version 0.2, dated 05 December 2020;

d. The US PVP was updated during the reporting period with the finalization of the US PVP, Version 0.3, dated 20 January 2021, to include Anaphylaxis as an Important identified risk.

### 9.4. Summary of Adverse Events of Special Interest (AESIs)

Please refer to [Appendix 5](#) for the list of the company’s AESIs for BNT162b2. Please refer to [Appendix 5.1](#) for the observed versus expected analysis for AESIs.

The company’s AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list includes MedDRA PTs, HLTs, HLTGs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

**9.5. Evaluation of Safety Concerns**

Evaluation of new information collected from post-marketing data sources<sup>7</sup> for BNT162b2 during the interval reporting period for important identified and important potential risks, AESIs, special situations and missing information is provided below in Section 9.5.1, Section 9.5.2, Section 9.5.3 and Section 9.5.4.

**9.5.1. Evaluation of Important Identified and Important Potential Risks**

Table 12 below presents the evaluation of new information received during the interval reporting period from post-marketing data sources<sup>7</sup> for the important identified and important potential risks of BNT162b2.

**Table 12. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
<p><b>Important Identified Risk</b></p> <p>Anaphylaxis<sup>f</sup></p> <p><i>Note: 2 database search strategies were applied. First a broad and narrow search of PTs in the Anaphylactic reaction SMQ (Narrow and Broad), with the algorithm applied, then a focused search of narrow PTs in the Anaphylactic SMQ with the algorithm applied</i></p>	<p>Search strategy #1</p> <ul style="list-style-type: none"> <li>• Number of cases from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, applying the MedDRA algorithm based on all terms in the SMQ: 497 (3.4% of the total PM dataset), of which 397 were medically confirmed and 100 were non-medically confirmed;</li> <li>• Number of events: 1183;</li> <li>• Country of incidence: US (185), UK (159), Germany (26), Italy (25), Denmark and Israel (11 each), Greece (10), Mexico (9), Spain (8), Portugal and Sweden (6 each), Singapore (5), Canada, Czech Republic, Finland, France and Romania (4 each), Netherlands (3), Croatia and Switzerland (2 each) and Austria, Belgium, Bulgaria, Chile, Hungary, Iceland, Malta, Norway and Serbia (1 each);</li> <li>• Patients' gender: female (400), male (63) and unknown (34);</li> <li>• Patients' age (n = 450): ranged from 18 to 98 years (mean = 49.3 years, median = 46 years);</li> <li>• Most frequently reported individual PTs (≥2%): Anaphylactic reaction (162), Dyspnoea (123), Pruritus (72), Urticaria (64), Cough and Rash (55 each), Erythema (45), Chest discomfort and Swollen tongue (43 each), Throat tightness (42), Flushing (40), Lip swelling (33), Hypotension (31), Anaphylactic shock and Pharyngeal swelling (30 each), Circulatory collapse (28), Swelling face (27), Swelling (23), Wheezing (22), Angioedema (20), Rash erythematous (16), Blood pressure decreased (13) and Eye swelling (10);</li> <li>• Relevant event seriousness: serious (820), non-serious (363);</li> <li>• Relevant event outcome:<sup>c</sup> fatal (28), resolved/resolving (700), resolved with sequelae (18), not resolved (151), unknown (288).</li> </ul>

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**Table 12. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>Search strategy #2</p> <ul style="list-style-type: none"> <li>• Number of cases retrieved using the Anaphylaxis SMQ (Narrow) search strategy, applying the MedDRA algorithm based on all terms in the SMQ: 226 cases (1.6% of the total PM dataset), of which 198 are medically confirmed and 28 non-medically confirmed;</li> <li>• Patients' gender: female (182), male (27) and unknown (17);</li> <li>• Patients' age (n = 196): ranged from 18 to 98 years (mean = 49.3 years, median = 46 years);</li> <li>• Patient's age group (n = 198): Adults<sup>g</sup> (168), Elderly<sup>h</sup> (30), no cases involving Paediatric patients;</li> <li>• Events: 229 events, all serious, except 1 non-serious;</li> <li>• Relevant reported PTs: Anaphylactic reaction (162), Anaphylactic shock (30), Circulatory collapse (28), Anaphylactoid reaction (7), and Shock symptom and Type I hypersensitivity (1 each);</li> <li>• Relevant event onset latency (n = 176): Most of the events (153) occurred the same day of the vaccination, for the remaining 23 events for which a latency was reported, it ranged from 1 to 24 days;</li> <li>• Relevant event outcome: fatal (5), resolved/resolving (154), not resolved (16), resolved with sequelae (2) and unknown (52);</li> <li>• Of note in 143 out of these 226 cases, the patients had a medical history of allergies; the most frequently reported relevant medical histories (≥20) included Drug hypersensitivity (174), Asthma (161), Hypersensitivity (89), Season allergy (55), Anaphylactic reaction (54), Respiratory distress (31), Contrast media allergy (27), Iodine allergy (23) and Rhinitis allergic (20).</li> </ul> <p>Anaphylaxis is an adverse reaction in Section 4.8 of the EU SmPC, in the US combined EUA Fact Sheet for the HCP and Full EUA PI and it was added to the CDS. It is also included as an Important identified risk in the EU RMP and in the US PVP. <sup>f</sup> Based upon review of the available information, no additional change to the RSIs is warranted at this time.</p> <p>After the data-lock point of this report, on 08 February 2021, a cumulative review of all cases reporting serious hypersensitivity reactions suggestive of anaphylaxis using the Brighton Collaboration criteria and inclusive of Observed versus Expected analysis was submitted to EMA in a LEG procedure as per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002) received on the first SMSR.</p> <p>Conclusion: Anaphylaxis is appropriately specified in the product labeling. No new significant safety information was identified based on a review of these cases. Surveillance will continue.</p>
<p><b>Important Potential Risk</b></p> <p>Vaccine-Associated Enhanced Disease (VAED) Including Vaccine-Associated Enhanced Respiratory Disease (VAERD)<sup>b,c</sup></p>	<p>As noted by the Brighton Collaboration, there is currently no uniformly accepted definition of VAED (or VAERD) and the working group considers that a definitive case of VAED (Level 1 diagnostic</p>

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**Table 12. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>certainty) cannot be ascertained with current knowledge of the mechanisms of pathogenesis of the condition.<sup>27</sup></p> <p>Given this, identifying an individual case as a case of VAED/VAERD is currently not possible and, therefore, observed data is not available at this time. An expected rate of VAED is also difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue.</p> <p>The search criteria utilised to identify potential cases of VAED for this SMSR include PTs indicating a lack of effect of the vaccine and medical disorders chosen because they are PTs potentially indicative of severe or atypical COVID-19.</p> <p><b>Overview</b></p> <ul style="list-style-type: none"> <li>• Number of cases<sup>d</sup> based on search strategy: 63 (0.4% of the total PM dataset, compared to 0.1% of the previous reporting period), all serious (of which 45 medically confirmed);</li> <li>• Country of incidence: UK (33), US (16), Germany (9), Mexico (2), Israel, Bulgaria and Denmark (1 each);</li> <li>• Gender: female (37), males (26);</li> <li>• Age: 21 to 97 years (n = 60), mean = 57.5, median = 58.5;</li> <li>• Respiratory system PTs: Dyspnoea (28), COVID-19 pneumonia (8), Hypoxia, Respiratory failure, and Tachypnoea (2 each);</li> <li>• Gastrointestinal system PTs: Diarrhoea (18), Vomiting (9), Abdominal pain (1);</li> <li>• Cardiovascular system PTs: Cardiac failure (3), Acute myocardial infarction and Myocarditis (1 each);</li> <li>• Other systems, relevant PTs: Multiple organ dysfunction syndrome, Cerebrovascular accident, Deep vein thrombosis (1 each).</li> <li>• Case outcome: fatal (17), not resolved (28), resolved/resolving (13), unknown at the time of the reporting (5).</li> </ul> <p><b>COVID-19 positivity and severity of events</b></p> <ul style="list-style-type: none"> <li>• Suspected COVID-19 infection (test not performed or negative or inconclusive): 22.</li> <li>• COVID-19 positive test: 41.</li> <li>• Seriousness criteria for the 63 cases:                         <ul style="list-style-type: none"> <li>○ Medically significant: 37 (of which 3 serious also for disability and 1 for life threatening);</li> <li>○ Hospitalization required: 9 (of which 3 serious also for life threatening);</li> <li>○ Death: 17.</li> </ul> </li> </ul>

<sup>27</sup> Flor M Munoz, et al. Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data. Brighton Collaboration. September 2020, Vaccine Journal Draft Manuscript.

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**Table 12. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p><b>Seriousness criteria: medically significant</b></p> <ul style="list-style-type: none"> <li>• In 18 cases, out of 37 reporting “medically significant” as seriousness criteria, it was reported that the patients had a COVID-19 positive test after vaccination, while 19 patients had unconfirmed suspected COVID-19. These 37 patients did not require hospitalization.</li> </ul> <p>Among the 18 COVID-19 positive patients:</p> <ul style="list-style-type: none"> <li>○ 11 received the 1<sup>st</sup> vaccine dose. Latency to COVID 19 was reported for 10/11 and ranged from 0 to 14 days.</li> <li>○ 7 patients did not indicate if they had taken the first or second dose. Latency to COVID 19 was reported for all patients and ranged from 0 to 11 days.</li> </ul> <p>One of these 18 cases refers to a 60-year-old paramedic (medical history not provided) who developed life-threatening COVID-19 on the same day of vaccination. He had fever, myalgia, cough and shortness of breath, gradually worsened to hypoxia. He had not recovered at the time of the reporting.</p> <p><b>Seriousness criteria: hospitalization</b></p> <ul style="list-style-type: none"> <li>• Hospitalization occurred in 9 patients:                     <ul style="list-style-type: none"> <li>○ 27-year-old woman with an anaphylactic reaction following vaccine;</li> <li>○ 81-year-old woman and a 90-year-old man with unconfirmed COVID-19;</li> <li>○ 21-year-old female, with a history of COVID-19 infection prior to vaccination, was hospitalized for 1 day after having a COVID-19 test the day following her vaccination;</li> <li>○ The remaining patients had a positive test for COVID-19 with a latency (n=4) between 0 and 9 days after vaccine administration:                             <ul style="list-style-type: none"> <li>▪ a 43-year-old woman, with a history of hypertension, had mild dyspnea and COVID-19 related symptoms 1 day after the 1<sup>st</sup> vaccine dose and was hospitalized 10 days later due to increased systolic blood pressure;</li> <li>▪ 67-year-old man with CABG x 4 was admitted to the hospital with fever and diarrhoea 9 days after vaccination;</li> <li>▪ Male patient of unspecified age with tachypnoea was hospitalized;</li> <li>▪ 84-year-old man who tested positive for COVID-19 1 week after vaccination and was hospitalized 5 days later with pneumonia and acute myocardial infarction. At the time of the reporting he was not recovered from COVID-19 and the outcome of the cardiac event was not provided.</li> <li>▪ 34-year-old man who tested positive for COVID-19 the day after his 2<sup>nd</sup> vaccination and developed myocarditis 3 days after the vaccination. He was hospitalized for an ST segment elevated myocardial infarction and was improving at the time of the reporting.</li> </ul> </li> </ul> </li> </ul>

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**Table 12. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p><b>Seriousness criteria: death</b></p> <ul style="list-style-type: none"> <li>• Seventeen (17) patients died:                             <ul style="list-style-type: none"> <li>○ Age: 65 to 97 years (n = 17), mean = 83.9, median = 85.</li> <li>○ Countries of incidence: UK (8), Germany (7), Denmark and US (1 each).</li> <li>○ Gender: female (5), male (12).</li> <li>○ Medical history was provided for 11 patients:                                     <ul style="list-style-type: none"> <li>▪ Cardiac conditions: 6 (54.5%) [atrial fibrillation (4), hypertension (4), Cardiac failure (3), Coronary artery disease (3), Cardiovascular disorder (1), myocardial infarction (1)];</li> <li>▪ Other significant medical histories: 5 (45.5%) [diabetes mellitus (2), COVID-19 (2), chronic kidney disease, dementia, duodenal ulcer, haemochromatosis, obesity (1 each)].</li> <li>▪ Sixteen (16) patients had a COVID-19 positive test after vaccination, while 1 patient had unconfirmed suspected COVID-19.</li> </ul> </li> </ul> </li> <li>• Latency of COVID-19 occurrence was reported for 12 of the 16 COVID-19 positive fatal cases and ranged from the date of the vaccination to 15 days after vaccination:                             <ul style="list-style-type: none"> <li>○ 0 to 4 days after dose 1 (5);</li> <li>○ 15 days after dose 1 (1);</li> <li>○ 10 days after dose 2 (1);</li> <li>○ 1 to 7 days after vaccination (dose number not reported) (5).</li> </ul> </li> <li>• Cause of death was reported for all the 16 fatal COVID-19 positive cases:                             <ul style="list-style-type: none"> <li>○ 3 patients died from COVID-19 associated cardiac events and/or respiratory events;</li> <li>○ 10 cases reported the following cause of death: COVID-19, COVID-19 pneumonia (2 each), Death, Cardiac failure, Hypoxia, Pneumonia aspiration, Respiratory failure, Severe acute respiratory syndrome and Sudden death (1 each); and in 3 cases there were different causes of death:</li> <li>○ 87-year-old man died due to COVID-19 and cerebrovascular accident that occurred 3 days after the vaccination; the patient’s medical history was not provided;</li> <li>○ 89-year-old male, with a medical history of hypertension, atrial fibrillation, heart failure, and bladder cancer, who had a positive to COVID-19 1 day after vaccination, was admitted to the hospital the following day with low oxygen saturation (87%); he died on the same date due to cardiac failure, chronic kidney disease, COVID-19 pneumonia, and tachyarrhythmia.</li> </ul> </li> </ul>

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**Table 12. Risks Evaluation for BNT162b2**

Safety Risk	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>○ 74-year-old male patient (medical history not provided), developed COVID-19 pneumonia (revealed by autopsy) on the same day of vaccination, with pulmonary sepsis and multiorgan failure; he died 6 days later.</li> </ul> <p>Because VAED may present as severe or unusual clinical manifestations of COVID-19, cases resulting from the search strategy are reviewed for severity. Symptoms of COVID-19, not necessitating hospitalization, were reported for 37 patients and 9 patients were hospitalized however they did not present with signs that appeared to be atypical COVID-19 or more severe COVID-19 than anticipated.</p> <p>Conclusion: No new significant safety information was identified based on a review of these cases. VAED/VAERD continues to be a theoretical risk for the vaccine, rather than an identified safety concern. Surveillance will continue.</p>

- a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- b. As per both the EU RMP Version 1.0, dated 21 December 2020 and the US PVP, Version 0.2, dated 05 December 2020;
- c. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children;
- d. One additional case retrieved in the reporting period has been invalidated in the safety database after data-lock point.
- e. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events.
- f. As per the EU RMP Version 1.0, dated 21 December 2020; the US PVP was updated during the reporting period with the finalization of the US PVP, Version 0.3, dated 20 January 2021, to include Anaphylaxis as an Important identified risk.
- g. Patients with age ranged between 18 and 64 years;
- h. Patients with age equal to or above 65 years.

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### 9.5.2. Evaluation of AESIs

Table 13 below presents the evaluation of new information received during the interval reporting period from post-marketing data sources<sup>7</sup> with regard to the AESIs for BNT162b2. Where applicable, observed versus expected analysis is provided in [Appendix 5.1](#).

**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
<b>Anaphylactic Reactions</b> <i>Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied,</i>	please refer to the Risk 'Anaphylaxis' in <a href="#">Table 12</a> .
<b>Cardiovascular AESIs</b> <i>Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia</i>	<ul style="list-style-type: none"> <li>• Number of cases: 344 (2.4 % of the total PM dataset, as in the previous reporting period), of which 274 are medically confirmed and 70 non-medically confirmed;</li> <li>• Country of incidence: UK (102), US (101), Germany (34), Italy (30), Mexico (11), Greece (10), Israel (9), France (6), Canada, Portugal and Romania (5 each), Denmark, Iceland, Poland and Sweden (3 each) and Norway and Spain (2 each); the remaining 10 cases were distributed among 10 other countries;</li> <li>• Patients' gender: female (254), male (72) and unknown (18);</li> <li>• Patients' age (n = 314): ranged from 18 to 104 years (mean = 49.4 years, median = 45 years);</li> <li>• Patients' age group (=320): Adult<sup>f</sup> (264), Elderly<sup>g</sup> (56);</li> <li>• Number of relevant events: 349, of which 202 serious, 147 non-serious; in the cases reporting relevant serious events, patient's age ranges from 18 to 104 years (mean = 55.9 years, median = 49.5 years);</li> <li>• Reported relevant PTs: Tachycardia (272), Myocardial infarction* (25), Acute myocardial infarction* (18), Cardiac failure (16), Arrhythmia (14), Coronary artery disease (2) and Cardiogenic shock and Postural orthostatic tachycardia syndrome (1 each);</li> <li>• Relevant event onset latency (n = 278): Range from &lt;24 hours to 18 days, median 1 day;</li> <li>• Relevant event outcome:<sup>e</sup> fatal (38), resolved/resolving (178), resolved with sequelae (7), not resolved (39) and unknown (88);</li> <li>• Of note, in 29 cases out of 344 cases (involving 13 female and 16 male patients with age ranged from 23 to 100 years, median 73.4 years, median 83 years), 19 of which had fatal outcome, the patient's medical history was significant for the specific events Myocardial infarction (10), Cardiac failure (8), Coronary artery disease (7), Acute myocardial infarction, Postural orthostatic tachycardia syndrome and Tachycardia (2 each) and Arrhythmia (1). There were 3 cases reporting 2 relevant medical history terms each;</li> <li>• In additional 29 cases out of 344 cases, the patient's medical history was significant for other cardiac disorders, with the following conditions reported more than once: Myocardial ischaemia (6), Atrial fibrillation (5), Mitral valve prolapse, Extrasystoles, Pericarditis, Cardiac disorder and Supraventricular tachycardia (2 each);</li> </ul>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>In 40 out of 344 cases, the patients' medical history was significant for COVID-19 or suspected COVID-19.</li> </ul> <p>* Observed/Expected analysis performed for Acute myocardial infarction and Myocardial infarction.                      Conclusion: No cardiovascular signals have emerged from the review of post-authorization data. The review of cases and O/E analysis do not raise new concerns. Surveillance will continue (see <a href="#">Appendix 5.1</a>).</p>
<p><b>Covid-19 AESIs</b>                      Search criteria: Covid-19 SMQ                      (Narrow and Broad)</p>	<ul style="list-style-type: none"> <li>Number of cases: 1111 (7.6% of the total PM dataset, compared to 5.4% of the previous reporting period), of which 751 medically confirmed and 360 non-medically confirmed;</li> <li>Country of incidence: US (604), UK (235), Germany (125), Romania (19), Portugal (18), Israel (16), Italy and Poland (13 each), Mexico (11), France (10), Spain (8), Canada (7), Slovakia (6), Belgium and Latvia (5 each), Bulgaria, Czech Republic and Hungary (3 each) and the remaining 7 cases were distributed among 7 other different countries;</li> <li>Patients' gender: female (539), male (295) and unknown (277);</li> <li>Patients' age group (n= 582): Adults<sup>f</sup> (450), Elderly<sup>g</sup> (131), Adolescent (1);</li> <li>Number of relevant events: 1150, of which 1074 serious, 76 non-serious;</li> <li>Most frequently reported relevant PTs (&gt;1 occurrence): COVID-19 (688), SARS-CoV-2 test positive (252), Suspected COVID-19 (115), Exposure to SARS-CoV-2 (38), COVID-19 pneumonia and SARS-CoV-2 antibody test negative (12 each), SARS-CoV-2 antibody test positive (10), Occupational exposure to SARS-CoV-2 (6), Asymptomatic COVID-19 and SARS-CoV-2 test false positive (5 each), Coronavirus infection and Coronavirus test positive (3 each);</li> <li>Relevant event onset latency (n = 635): Range from &lt;24 hours to 40 days, median 6 days;</li> <li>Relevant event outcome: fatal (29), not resolved (123), resolved/resolving (130), resolved with sequelae (1) and unknown (867).</li> </ul> <p>Conclusion: No safety signals have emerged based on a review of these cases. Surveillance will continue.</p>
<p><b>Dermatological AESIs</b>                      Search criteria: PT Chillblains</p>	<ul style="list-style-type: none"> <li>Number of cases: 2 cases (0.01% of the total PM dataset, in the previous reporting period there were no relevant cases), 1 of which was medically confirmed and 1 non-medically confirmed;</li> <li>Country of incidence: UK and US (1 each);</li> <li>Patients' gender: female and unknown (1 each);</li> <li>Patients' age group (n=1): Adult<sup>f</sup> (1);</li> <li>Number of relevant events: 2 events, 1 serious, 1 non-serious (relevant PT: Chillblains);</li> <li>Relevant event onset latency (n = 1): 3 days;</li> <li>Relevant event outcome: not resolved and unknown (1 each).</li> </ul>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
	Conclusion: No safety signals have emerged based on a review of these cases. Surveillance will continue.
<b>Haematological AESIs</b> <i>Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Haemorrhage; Haemorrhagic disorder; Thrombocytopenia</i>	<ul style="list-style-type: none"> <li>• Number of cases: 19 (0.1% of the total PM dataset, compared to 0.08% of the previous reporting period), of which 14 medically confirmed and 5 non-medically confirmed;</li> <li>• Country of incidence: US (7), UK (6), France (2), Belgium, Hungary, Israel and Mexico (1 each);</li> <li>• Patients' gender (n=17): female (7) and male (10);</li> <li>• Patients' age group (n=15): Adult<sup>f</sup> (7), Elderly<sup>g</sup> (8);</li> <li>• Number of relevant events: 20, of which 19 serious, 1 non-serious;</li> <li>• Reported relevant PTs: Thrombocytopenia (10), Haemorrhage (5), Lymphopenia (3) and Febrile neutropenia and Neutropenia (1 each);</li> <li>• Relevant event onset latency (n = 11): Range from &lt;24 hours to 12 days, median = 5 days;</li> <li>• Relevant event outcome: fatal and resolved/resolving (4 each), resolved with sequelae (1), not resolved (3) and unknown (8).</li> </ul> <p>A cumulative review of all cases reporting thrombocytopenia was submitted to FDA and SwissMedic (see <a href="#">Appendix 3.3</a>), respectively during this reporting period and just after the data-lock point.                      Conclusion: Thrombocytopenia was determined to not be a risk for the vaccine. No other signals for the hematological AESIs have emerged based on a review of these cases.</p>
<b>Hepatic AESIs</b> <i>Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver Injury</i>	<ul style="list-style-type: none"> <li>• Number of cases: 14 cases (0.1% of the total PM dataset, compared to 0.03% of the previous reporting period), of which 12 medically confirmed and 2 non-medically confirmed;</li> <li>• Country of incidence: UK (8), US (3) and Belgium, Costa Rica and Romania (1 each);</li> <li>• Patients' gender: female (6), male (8);</li> <li>• Patients' age group (n=13): Adult<sup>f</sup> (7), Elderly<sup>g</sup> (6);</li> <li>• Number of relevant events: 20, of which 12 serious, 8 non-serious;</li> <li>• Reported relevant PTs: Alanine aminotransferase increased (5), Hepatic enzyme increased (3), Aspartate aminotransferase increased, Blood alkaline phosphatase increased, Liver function test abnormal and Liver function test increased (2 each) and Bilirubin urine present, Gamma-glutamyltransferase increased, Hepatic pain and Transaminases increased (1 each);</li> <li>• Relevant event onset latency (n = 9): Range from &lt;24 hours to 14 days, median 5 days;</li> <li>• Relevant event outcome: fatal (1), resolved/resolving (10), not resolved (3) and unknown (6).</li> </ul> <p>Conclusion: No safety signals have emerged based on a review of these cases. Surveillance will continue.</p>
<b>Facial Paralysis</b> <i>Search criteria: PTs Facial paralysis, Facial paresis</i>	<ul style="list-style-type: none"> <li>• Number of cases: 98<sup>c</sup> (0.7% of the total PM dataset, compared to 0.6% of previous reporting period), of which 71 medically confirmed and 27 non-medically confirmed;</li> </ul>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>• Country of incidence: US (44), UK (31), Israel (9), Romania (3), Cyprus (2); the remaining 9 cases originated from 9 different countries;</li> <li>• Patients' gender: female (65), male (25) and unknown (8);</li> <li>• Patients' age group (n=82): Adult<sup>f</sup> (71), Elderly<sup>g</sup> (11);</li> <li>• Number of relevant events: 102, of which 98 serious, 4 non-serious.</li> <li>• Relevant event onset latency (n = 71): Range from &lt;24 hours to 16 days, median 2 days;</li> <li>• Relevant event outcome: resolved/resolving (31), resolved with sequelae (1), not resolved (45) and unknown (25).</li> </ul> <p>The evaluation of facial paralysis* cases was made using the Brighton Collaboration criteria for individual case assessment:                      4 cases were assessed as Brighton Collaboration criteria Level 1 and they involved respectively:</p> <ul style="list-style-type: none"> <li>• A 35-year-old female patient who developed Facial paralysis (left sided facial palsy), Hypoaesthesia oral, Paraesthesia oral, Pain in extremity, Tachycardia, Blood pressure increased on the same day as vaccination; she was treated with steroids and valacyclovir (outcome of not resolved at the time of the report);</li> <li>• A 61-year-old male patient who experienced Facial paralysis (left side of face), Lacrimation increased, Vision blurred 5 days following the vaccination; he was treated with steroids, acyclovir and tetracycline (outcome of not resolved at the time of the report);</li> <li>• A 23-year-old female patient who experienced Facial paralysis (right side), Pain in extremity on the same day of her first vaccination; she was treated with steroids and eye ointment (outcome of unknown);</li> <li>• A 26-year-old female patient who experienced Facial paralysis (right side), Facial paresis, Ear pain, Disease recurrence, Headache, Hypoaesthesia 8 days following the first dose of vaccine; she was treated with steroids, acyclovir and eye drops and had full resolution after 11-12 days.</li> </ul> <p>1 case was assessed as Brighton Collaboration criteria Level 2 and it involved:</p> <ul style="list-style-type: none"> <li>• a 43-year-old female patient who experienced Fatigue, Nausea, Facial paralysis (mild facial palsy), Vaccination site pain, Vaccination site swelling, Headache, Pyrexia, Palpitations, Myalgia, Vaccination site erythema, Spinal pain, Sensory disturbance, Pyrexia on the same day of vaccination with influenza vaccine and BNT162b2; the facial palsy resolved within 2 days;</li> </ul> <p>The remaining 93 cases were assessed as Category 4 because they report facial nerve palsy without provision of enough detail to exclude known causes by clinical history, physical exam, labs or imaging.</p>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>Relevant events: 96, of which 92 serious, 4 non-serious;                      Relevant reported PTs: Facial paralysis (87), Facial paresis (9);                      Relevant event onset latency (n = 67): Range from &lt;24 hours to 16 days, median = 1 day;                      Relevant event outcome: not resolved (43), resolved/resolving (28), resolved with sequelae (1) and unknown (24).</p> <p>* Please see <a href="#">Appendix 5.1</a> for Observed versus Expected analysis of Facial paralysis/Facial paresis (Bell's palsy). No new significant safety information was identified based on a review of these cases, of the Observed versus Expected analysis (see <a href="#">Appendix 5.1</a>) and of the cumulative review of Facial paralysis case (see <a href="#">Appendix 3.2</a>).</p>
<p><b>Immune-Mediated/Autoimmune AESIs<sup>d</sup></b>  <i>Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 364 (2.5% of the total PM dataset, as well as in the previous reporting period), of which 251 medically confirmed and 113 non-medically confirmed;</li> <li>• Country of incidence: US (166), UK (101), Germany (17), Israel (11), Greece (10), Italy (8), Portugal (7), Poland (6), Canada, Denmark, Mexico and Romania (5 each), Chile and Serbia (3 each), Czech Republic and France (2 each); the remaining 8 cases were from 8 different countries;</li> <li>• Patients' gender (n=333): female (260), male (73);</li> <li>• Patients' age group (n=300): Adult<sup>f</sup> (246), Elderly<sup>g</sup> (54);</li> <li>• Number of relevant events: 371, of which 186 serious, 185 non-serious;</li> <li>• Most frequently reported relevant PTs (&gt;2 occurrences): Hypersensitivity (161), Anosmia (70), Arthritis (26), Dermatitis, Neuropathy peripheral (13 each), Pericarditis* (7), Myocarditis*, Neuritis and Rheumatoid arthritis* (5 each), Diabetes mellitus* (4) and Hypothyroidism, Immune thrombocytopenia, Neuralgic amyotrophy, Pancreatitis (3 each).</li> <li>• Relevant event onset latency (n = 236): Range from &lt;24 hours to 21 days, median 1 day;</li> <li>• Relevant event outcome:<sup>c</sup> resolved/resolving (136), not resolved (83), fatal (6), resolved with sequelae (5) and unknown (142).</li> </ul> <p>* Please see <a href="#">Appendix 5.1</a> for Observed/Expected analysis performed for Diabetes mellitus, Pericarditis, Myocarditis, Rheumatoid arthritis. Conclusion: No new safety signals have emerged based on a review of these cases and of the Observed versus Expected analysis (see <a href="#">Appendix 5.1</a>). Surveillance will continue.</p>
<p><b>Musculoskeletal AESIs</b>  <i>Search criteria: PTs Arthralgia; Arthritis; Chronic fatigue syndrome; Polyarthrititis; Polyneuropathy; Post viral fatigue syndrome</i></p>	<p>Number of cases: 1191 (8.2% of the total PM dataset, compared to 5.7% of the previous reporting period), of which 743 medically confirmed and 448 non-medically confirmed;                      Country of incidence (&gt;2%): US (498), UK (496), Italy (40) and Mexico (36);                      Patients' gender (n=1130): female (905), male (225);                      Patients' age group (n=1096): Adult<sup>f</sup> (977), Elderly<sup>g</sup> (117) and Adolescent (2).                      Number of relevant events: 1204, of which 392 serious, 812 non-serious;</p>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>Reported relevant PTs: Arthralgia (1173), Arthritis (26), Post viral fatigue syndrome (3) and Polyneuropathy (2);                      Relevant event onset latency (n = 962): Range from &lt;24 hours to 22 days, median 1 day;                      Relevant event outcome:<sup>c</sup> resolved/resolving (582), resolved with sequelae (16), not resolved (353) and unknown (265).</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases. Surveillance will continue.</p>
<p><b>Neurological AESIs (including demyelination)</b>  <i>Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Cerebrovascular accident; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 130 (0.9% of the total PM dataset, compared to 0.5% of the previous reporting period), of which 79 medically confirmed and 51 non-medically confirmed;</li> <li>• Country of incidence: UK (61), US (28), Germany (9), Mexico (8), Israel (7), Italy (4), France (3), Norway and Sweden (2 each); the remaining 6 cases originated from 6 different countries;</li> <li>• Patients' gender (n=123): female (85), male (38);</li> <li>• Patients' age group (n=121): Adult<sup>f</sup> (68), Elderly<sup>g</sup> (53);</li> <li>• Number of relevant events: 136, of which 127 serious, 9 non-serious;</li> <li>• Most frequently reported relevant PTs (&gt;1 occurrence) included: Cerebrovascular accident* (41), Seizure* (38), Epilepsy (8), Aura (7), Fibromyalgia*, Generalised tonic-clonic seizure* and Multiple sclerosis relapse* (5 each), Guillain-Barre syndrome*, Multiple sclerosis*, Petit mal epilepsy* and Trigeminal neuralgia (3 each) and Acute disseminated encephalomyelitis*, Demyelination and Optic neuritis* (2 each);</li> <li>• Relevant event onset latency (n = 102): Range from &lt;24 hours to 16 days, median 1 day;</li> <li>• Relevant events outcome: fatal (7), resolved/resolving (57), resolved with sequelae (3), not resolved (34) and unknown (35);</li> <li>• In 30 cases, the patient's medical history was relevant for Epilepsy (9), Multiple sclerosis (6), Fibromyalgia and Cerebrovascular accident (5 each), Generalised tonic-clonic seizure (3), Partial seizures and Seizure (2 each) and Myoclonic epilepsy (1).</li> </ul> <p>* Observed/Expected analysis performed for Cerebrovascular accident, Guillain-Barre syndrome, Multiple sclerosis, Multiple sclerosis relapse, Optic neuritis and Seizure/Seizure disorders. No new significant safety information was identified based on a review of these cases and of the Observed versus Expected analysis (see <a href="#">Appendix 5.1</a>).</p> <p>Conclusion: No new safety signals have emerged from review of the cases or of the O/E analyses. Surveillance will continue.</p>
<p><b>Other AESIs</b>  <i>Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Ageusia; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue;</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 2953 (20.3% of the total PM dataset, compared to 15.3% of the previous reporting period), of which 1905 medically confirmed and 1048 non-medically confirmed;</li> <li>• Country of incidence: US (1309), UK (1079), Italy (111), Germany (58), Spain (46), Israel and Poland (41 each), Romania (34), Mexico (32), Denmark (31), Canada (19), Serbia and Sweden (17 each), Iceland (15), Hungary (14), Greece (13), Portugal (12), France (8), Croatia, Lithuania and Norway (6 each), Puerto Rico (5), Czech Republic and Slovakia (4 each), Chile, Costa Rica,</li> </ul>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
<p><i>MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive</i></p>	<p>Latvia and Saudi Arabia (3 each), Bulgaria, Finland and United Arab Emirates (2 each) and the remaining 7 cases were distributed among 7 other countries;</p> <ul style="list-style-type: none"> <li>• Patients' gender (n=2817): female (2110), male (707);</li> <li>• Patients' age group (n=2627): Adult<sup>f</sup> (2341), Elderly<sup>g</sup> (277), Child, Infant (see <a href="#">Table 15</a>, respectively infant breastfeeding patients and children below 16 who experienced Pyrexia) and Adolescent (3 each);</li> <li>• Number of relevant events: 2986, of which 899 serious, 2087 non-serious;</li> <li>• Most frequently reported relevant PTs (&gt;1 occurrence) included: Pyrexia (2773), Ageusia (79), Herpes zoster (64), Inflammation (27), Oral herpes (21), Herpes virus infection (8), Multiple organ dysfunction syndrome (5) and Genital herpes and Herpes simplex (2 each);</li> <li>• Relevant event onset latency (n = 2405): Range from &lt;24 hours to 28 days, median 1 day;</li> <li>• Relevant events outcome:<sup>c</sup> fatal (23), resolved/resolving (1727), resolved with sequelae (34), not resolved (572) and unknown (655).</li> </ul> <p>Conclusion: No new safety signals have emerged based on a review of these cases. Surveillance will continue.</p>
<p><b>Pregnancy Related AESIs</b>  <i>Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia</i></p>	<p>For relevant cases, please refer to the subsection <i>Use in Pregnancy and While Breast Feeding</i> in <a href="#">Table 15</a>.</p>
<p><b>Renal AESIs</b>  <i>Search criteria: PTs Acute kidney injury; Renal failure.</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 19 cases (0.1% of the total PM dataset, in the previous reporting period there were no relevant cases), of which 16 medically confirmed, 3 non-medically confirmed;</li> <li>• Country of incidence: UK (7), Germany (6) and Belgium, France, Italy, Norway, Sweden and US (1 each);</li> <li>• Patients' gender: female (14), male (5);</li> <li>• Patients' age group (n=18): Elderly<sup>g</sup> (17), Infant (1, relevant PT Renal failure, see <a href="#">Table 15</a>, <i>Use in Paediatric Individuals &lt;16 Years of Age</i>);</li> <li>• Number of relevant events: 19, all serious;</li> <li>• Reported relevant PTs: Acute kidney injury* (13) and Renal failure (6);</li> <li>• Relevant event onset latency (n = 13): Range from 1 to 9 days, median 2 days;</li> <li>• Relevant event outcome: fatal (7), resolving (3), not resolved (5) and unknown (4).</li> </ul>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>* Observed/Expected analysis performed for Acute kidney injury.                      Conclusion: No new safety signals have emerged based on a review of these cases and of the Observed versus Expected analysis performed (see <a href="#">Appendix 5.1</a>). Surveillance will continue.</p>
<p><b>Respiratory AESIs</b>  <i>Search criteria: Lower respiratory tract infections NEC (HLT) (Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 31 cases (0.2% of the total PM dataset, compared to 0.06% of the previous reporting interval), of which 26 medically confirmed;</li> <li>• Countries of incidence: UK (10), Spain (5), Belgium, Germany (3 each), Denmark, France, Greece, US (2 each), Italy and Switzerland (1 each).</li> <li>• Patients' gender (n=31): male (16), female (15).</li> <li>• Patients's age group (n=29): Elderly<sup>g</sup> (22), Adult<sup>f</sup> (7).</li> <li>• Number of relevant events: 31 serious events, 1 non-serious.</li> <li>• Reported relevant PTs: Acute respiratory failure (10), Respiratory failure (7), Respiratory disorder (6, of which 1 non-serious), Hypoxia (5), Acute respiratory distress syndrome* (2), Severe acute respiratory syndrome (2).</li> <li>• Relevant event onset latency (n=31): range from &lt; 24 hours to 19 days.</li> <li>• Relevant events outcome:<sup>c</sup> fatal (19), Resolved/resolving (4), not recovered (4) and unknown (5).</li> <li>• Four (4) of these 31 cases [3 with fatal and 1 life threatening; PTs: Respiratory failure (1), Hypoxia (2), Respiratory failure (1), Severe acute respiratory syndrome (1)], were also reviewed among the potential relevant cases for the Risk 'VAED Including VAERD' in <a href="#">Table 12</a>.</li> </ul> <p>* Observed/Expected analysis performed for Acute respiratory distress syndrome.                      Conclusion: No new safety signals have emerged based on a review of these cases and of the Observed versus Expected analysis performed (see <a href="#">Appendix 5.1</a>). Surveillance will continue.</p>
<p><b>Thromboembolic Events</b>  <i>Search criteria: Embolism and thrombosis (HLGT) (Primary Path) OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism</i></p>	<ul style="list-style-type: none"> <li>• Number of cases: 33 (0.2% of the total PM dataset, compared to 0.03% of the previous reporting period), of which 22 medically confirmed and 11 non-medically confirmed;</li> <li>• Country of incidence: US (12), UK (10), Germany (4), Israel (3) and Austria, Belgium, Italy and Portugal (1 each);</li> <li>• Patients' gender (n= 29): female (19), male (10);</li> <li>• Patients' age group (n=27): Adult<sup>f</sup> (11), Elderly<sup>g</sup> (16);</li> <li>• Number of relevant events: 36, of which 35 serious, 1 non-serious;</li> <li>• Reported relevant PTs: Deep vein thrombosis* (12), Thrombosis (11), Pulmonary embolism (9) and Embolism, Microembolism, Peripheral embolism and Vena cava thrombosis (1 each);</li> <li>• Relevant event onset latency (n = 27): Range from &lt;24 hours to 11 days, median 3 days;</li> <li>• Relevant event outcome: fatal (4), resolved with sequelae (2) and resolved/resolving, not resolved and unknown (10 each).</li> </ul> <p>* Observed/Expected analysis performed for Deep vein thrombosis.</p>

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**Table 13. AESIs Evaluation for BNT162b2**

AESIs <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup> Total Number of Cases in the Reporting Period (N=14525)
	Conclusion: No new safety signals have emerged based on a review of these cases and of the Observed versus Expected analysis performed (see <a href="#">Appendix 5.1</a> ). Surveillance will continue.
<b>Vasculitic Events</b> <i>Search criteria: Vasculitides HLT (Primary Path) OR PTs Kawasaki's disease; Microangiopathy; Peripheral ischaemia</i>	<ul style="list-style-type: none"> <li>• Number of cases: 2 cases (0.01% of the total PM dataset, in the previous reporting period there were no relevant cases), both medically confirmed;</li> <li>• Country of incidence: Spain and UK (1 each);</li> <li>• Two female elderly<sup>g</sup> patients experienced Peripheral ischaemia, serious, 3 days after the vaccination;</li> <li>• Relevant event outcome: fatal and unknown (1 each).</li> </ul> <p>Conclusion: No new safety signals have emerged based on a review of these cases. Surveillance will continue.</p>

- a. For the complete list of the AESIs, please refer to [Appendix 5](#);
- b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- c. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
- d. Cases reporting the PTs Demyelinating polyneuropathy, Demyelination, Guillain-Barre syndrome, Multiple sclerosis, Multiple sclerosis relapse, Myelitis transverse, Narcolepsy and Optic neuritis overlapping in this category were described in the Neurological category;
- e. Fifteen additional cases were excluded from the analysis of facial paralysis because they were assessed as Category 5 according to Brighton collaboration criteria (i.e., not cases of facial paralysis); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reported;
- f. Patients with age ranged between 18 and 64 years;
- g. Patients with age equal to or above 65 years.

**9.5.3. Evaluation of Special Situations**

Table 14 below presents the evaluation of new information received during the current reporting period from post-marketing data sources for BNT162b2 in relation to special situations (Death, Lack of Efficacy and Vaccine Interactions).

**Table 14. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
Death	<b>Overview</b> <ul style="list-style-type: none"> <li>• Number of fatal cases: 409<sup>28</sup> (2.8 % of the total PM dataset, compared to 0.3% of the total PM cases received in the previous reporting period) of which 340 were medically confirmed and 69 non-medically confirmed;</li> </ul>

<sup>28</sup> During the current reporting interval there were 2 additional cases reporting patients' death. However, they were excluded from further analysis in this subsection as the death was mentioned as an incidental information only in these 2 cases, with none of the reported events presenting a fatal outcome. A third additional case was excluded as it was made invalid based on the follow up information received.

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**Table 14. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>• Country of incidence: the majority were from UK (115), Germany (83), the US (47), Norway (30), Sweden (24), France (18), Israel (14), Denmark and Spain (12 each) and Italy (11); the remaining 43 cases occurred in other 10 countries.</li> <li>• Patients' Gender: females (204), males (176), unknown (29);</li> <li>• Patients' Age: 27 to 104 years (n = 363), mean = 83.6, median = 85;</li> <li>• Adults (29), Elderly (350), patients with unknown age (30);</li> <li>• Causes of death most frequently reported (≥2%): Death (167), Sudden death (32), Cardiac arrest (27), COVID-19 (22), General physical health deterioration and Dyspnoea (16 each), Drug ineffective (15), Myocardial infarction (13), Pneumonia and Pyrexia (12 each), Cardiac failure (11), Vomiting and Acute respiratory failure (8 each).</li> <li>• PTs most frequently reported (&gt;2%): Death (166), Drug ineffective (46), COVID-19 (40), Sudden death (39), Malaise (35), Dyspnoea (33), Pyrexia (32), Cardiac arrest (29), Vomiting (27), General physical health deterioration (25), Fatigue (15), Fall (14), Diarrhoea, Myocardial infarction and Pneumonia (13 each), Oxygen saturation decreased (12), Cardiac failure (11), Circulatory collapse, Confusional state, Cough, Hypotension (10 each), Acute respiratory failure, Asthenia and Nausea (9 each).</li> <li>• Concomitant medications were reported in 165 out of 409 cases and the most frequently present (≥2%) are listed below:                      paracetamol (53), furosemide (32), acetylsalicylic acid (31), omeprazole (23), atorvastatin and levothyroxine sodium (22 each), apixaban (21), colecalciferol (20), macrogol 3350/potassium chloride/sodium bicarbonate/sodium chloride and ramipril (17 each), bisoprolol (16), oxazepam (14), amlodipine, folic acid and lactulose (13 each), mirtazapine, simvastatin and zopiclone (12 each), bisoprolol fumarate and salbutamol (10 each), calcium carbonate/colecalciferol, glyceryl trinitrate and lansoprazole (9 each), metformin, metoprolol, pantoprazole, prednisolone, pregabalin and sodium picosulfate (8 each).</li> <li>• Lot/Batch Number (#) information by Country are available in 236 cases with no related quality issues identified during investigations of the impacted lot/batch number. The list of Lot # more frequently reported (&gt;2% of total fatal cases) is presented hereinafter:                         <ul style="list-style-type: none"> <li>○ Lot # EJ6796 in 58 cases from Germany (19), Spain (10), Sweden (9), Iceland (6), Norway and Austria (5 each), Slovenia (2), Switzerland and Denmark (1), respectively</li> <li>○ Lot # EM0477 in 30 cases from Germany (12), France (8), Belgium (6), Denmark (3) and Ireland (1), respectively</li> <li>○ Lot # EJ6795 in 30 cases from Norway (19), Sweden (4), France (3), Germany (2) and Greece (1), respectively</li> <li>○ Lot # EJ1688 in 20 cases from UK</li> <li>○ Lot # EJ6797 in 17 cases from Denmark (8), Germany (6), Austria (2) and Italy (1), respectively</li> <li>○ Lot # EJ0553 in 15 cases from UK</li> </ul> </li> <li>• Time to onset of fatal events was reported for 305 patients and ranged from the day of vaccination to 23 days after vaccination:                         <ul style="list-style-type: none"> <li>○ Same day to 3 days after vaccination: 208 cases,</li> <li>○ 4-7 days after vaccination: 54 cases</li> <li>○ 8-14 days after vaccination: 28 cases</li> <li>○ 15-23 days after vaccination: 15 cases</li> </ul> </li> </ul>

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**Table 14. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>• Number of vaccine doses administered at the time of the patients' death: in 167 cases the death occurred after the administration of the first dose, in 23 cases the fatal outcome was observed after the administration of the second dose whereas in the remaining cases (219) it was not specified if the patients received the first or the second vaccine dose at the time of the fatal events.</li> <li>• Test for COVID-19 were reported for 105 patients as follows: in 41 cases patients tested positive (18 after 1<sup>st</sup> vaccine dose, 2 after 2<sup>nd</sup> vaccine dose and in 21 there was no information available about the dose they received), in 58 were negative and in 6 cases test results were unknown.</li> </ul> <p><b>Analysis</b></p> <p>Most of the cases reporting a fatal outcome (77.3%) were in subjects over 75 years of age. This reflects one of the priority groups targeted for vaccination by many countries including Europe and the US, that is, elderly (with various lower age cut-offs across countries), because of their higher risk of severe disease and mortality if infected with SARS-CoV-2.<sup>11,12</sup></p> <p>Among the total of 409 cases with a fatal outcome, when the medical history was provided (in 310 cases), the majority had multiple concomitant comorbidities. The most frequently reported medical conditions included cardiac and vascular disorders (eg Hypertension, Atrial fibrillation, Cardiac failure, Cerebrovascular accident, Myocardial ischaemia, Coronary artery disease, Myocardial infarction). Cases not describing cardiac conditions reported other significant medical histories that included Dementia, Diabetes mellitus, Chronic kidney disease, Chronic obstructive pulmonary disease and Renal failure. In some individuals, palliative care had already been initiated before vaccination. No specific pattern regarding underlying condition or cause of death have been identified. Further reports will continue to be carefully monitored.</p> <p>Please see <a href="#">Appendix 5.1</a> for Observed versus Expected analysis of Death.</p> <p>Conclusion: No new risks were identified following review of the signal of death, particularly in the comorbid elderly population.</p>
Lack of Efficacy	<ul style="list-style-type: none"> <li>• Number of cases<sup>29</sup>: 1043 (7.2 % of the total PM dataset, compared to 3.7% of the previous reporting period) of which 705 were medically confirmed and 338 non-medically confirmed;</li> <li>• Country of incidence: US (563), UK (226), Germany (113), Romania (19), Portugal (18), Israel (14), Poland (13), Italy and Mexico (11 each); the remaining 55 cases originated from 16 different countries.</li> <li>• COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (111), not resolved (116) or unknown (787) at the time of the reporting, resolved with sequelae (1); there were 28 cases where a fatal outcome was reported (see also <i>Death</i> section above in this table).</li> <li>• Number of lack of efficacy events: 1043 (PT: Drug ineffective);</li> </ul>

<sup>29</sup> Four (4) additional cases retrieved in this dataset were excluded from the analysis because they were invalid (2 cases, accordingly invalidated in the safety database after DLP) or not LOE cases (2 cases, LOE PT removed after DLP).

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**Table 14. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>• Drug ineffective seriousness: serious (1040), non-serious (3)<sup>30</sup>; seriousness criterion (more than 1 in some cases) was important medical event (1012), death (28), hospitalization (25), life threatening (15), and disability or permanent damage (14);</li> <li>• Lack of efficacy term was reported:                         <ul style="list-style-type: none"> <li>○ after the 1<sup>st</sup> dose in 652 cases</li> <li>○ after the 2<sup>nd</sup> dose in 19 cases</li> <li>○ in 372 cases it was unknown after which dose the lack of efficacy occurred.</li> </ul> </li> <li>• Latency of lack of efficacy term reported after the first dose was known for 383 cases:                         <ul style="list-style-type: none"> <li>○ Within 0 and 7 days: 190 patients.</li> <li>○ Within 8 and 14 days 1: 155 patients.</li> <li>○ Within 15 and 20 days: 33 patients.</li> <li>○ Within 21 and 40 days: 5 patients (in these cases it was not reported whether a second dose was administered in the meantime).</li> </ul> </li> <li>• Latency lack of efficacy term reported after the second dose was known for 16 cases:                         <ul style="list-style-type: none"> <li>○ Within 0 and 4 days: 13 patients.</li> <li>○ Within 8 and 16 days: 3 patients (in 1 case the 1<sup>st</sup> and the 2<sup>nd</sup> dose were not properly spaced, in the 2<sup>nd</sup> and the 3<sup>rd</sup> case the interval between the 1<sup>st</sup> and the 2<sup>nd</sup> dose was not provided).</li> </ul> </li> <li>• Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 187 cases:                         <ul style="list-style-type: none"> <li>○ Within 0 and 7 days after vaccination: 136 patients.</li> <li>○ Within 8 and 14 days after vaccination: 39 patients.</li> <li>○ Within 15 and 31 day after vaccination: 12 patients.</li> </ul> </li> </ul> <p>According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 670 cases where lack of efficacy was reported after the 1<sup>st</sup> dose or the 2<sup>nd</sup> dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.</p> <p>Conclusion: No new safety signals have emerged based on a review of these cases.</p> <p>Company conventions for coding cases indicative of lack of efficacy:</p> <ul style="list-style-type: none"> <li>• PT “Vaccination failure” is coded when ALL of the following criteria are met:                         <ul style="list-style-type: none"> <li>○ The patient has received the appropriate series of two doses based on the labeling.</li> <li>○ At least 7 days have elapsed since the second dose of vaccine has been administered.</li> <li>○ The patient experiences COVID-19 infection (confirmed laboratory tests).</li> </ul> </li> <li>• PT “Drug ineffective” is coded when a reporter states or implies LOE in a patient who experiences a potential/confirmed COVID-19 infection and either of the following applies:</li> </ul>

<sup>30</sup> Event seriousness of PTs, indicative of possible lack of therapeutic effect captured at the DLP, was upgraded to serious as per case processing convention at completion of the case.

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**Table 14. Evaluation of Special Situations for BNT162b2**

Topic	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>○ The patient has not received the appropriate series of two doses based on the labeling or it is unknown;</li> <li>○ It has NOT been 7 days since the second dose of the vaccine has been administered or the time since the last dose is unknown;</li> <li>○ The infection is not confirmed as COVID 19 through laboratory tests.</li> </ul>
Vaccine Interactions	<ul style="list-style-type: none"> <li>• Number of cases: 12 (0.08% of the total PM dataset, compared to 0.03% of the previous reporting period) of which, 6 cases were medically confirmed and 6 cases were non-medically confirmed.</li> <li>• Country of incidence: US (8), Denmark, Germany, Greece, and Spain (1 each).</li> <li>• Patient Gender: Female (6), Male (5), and Unknown (1);</li> <li>• Patients' Age: 36 to 86 years; (n=10); mean=54.5; median 49.0;</li> <li>• Relevant reported interaction PTs: Drug interaction (11) and Inhibitory drug interaction (1);</li> <li>• Relevant event seriousness: Serious (2) and Non-serious (10);</li> <li>• Relevant event outcome: Resolved (2) and Unknown (10);</li> <li>• Co-reported events coded to the PTs (&gt;1 event): Headache (4), Malaise, Pain (3 each), Dizziness, Fatigue, and Pyrexia (2 each);</li> <li>• Reported Interacting Agents: montelukast sodium (2), amphetamine aspartate/amphetamine sulfate/dexamphetamine saccharate/dexamphetamine sulfate, apixaban, diphtheria vaccine toxoid/pertussis vaccine acellular 5-component/polio vaccine inact 3v (vero)/tetanus vaccine toxoid, famotidine, fexofenadine hydrochloride, guselkumab, ibuprofen, lithium, oxycodone hydrochloride, paroxetine, piroxicam, prednisone, sulfamethoxazole/trimethoprim, and ustekinumab (1 each);</li> <li>• Of the 12 cases, 1 case reported a potential interaction with another vaccine (increased reactogenicity to diphtheria vaccine toxoid, pertussis vaccine acellular 5-component, polio vaccine inact 3v (vero), tetanus vaccine toxoid) (see also Table 15, <i>Interaction With Other Vaccines</i>).</li> </ul> <p>Conclusion: there is no indication of a safety signal of interference of immune response of vaccines noted based on a review of these cases.</p>

a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources.

**9.5.4. Evaluation of Missing Information**

Table 15 below summarises the evaluation of new information received during the current reporting period from post-marketing data sources<sup>7</sup> in relation to the Missing information associated with the use of BNT162b2.

**Table 15. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
Use in Pregnancy and While Breast Feeding <sup>b</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 199<sup>c</sup> (1.4% of the total PM dataset, compared to 1.9% of the previous reporting period) of which 129 medically confirmed and 70 non-medically confirmed;</li> <li>• Country of incidence: US (110), Canada (23), Germany (16), UK (14), Poland (11), Estonia, Portugal (4 each), Romania (3), France, Israel, Spain (2 each),</li> </ul>

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**Table 15. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>Chile, Greece, Hungary, Italy, Mexico, Netherlands, Puerto Rico, and Slovakia (1 each).</p> <p><u>Pregnancy cases:</u> 124 mother cases including:</p> <ul style="list-style-type: none"> <li>• 115 cases indicative of exposure to vaccine during pregnancy [relevant PT events Maternal exposure during pregnancy (87), Exposure during pregnancy (23) and Maternal exposure timing unspecified (5)], of which:                             <ul style="list-style-type: none"> <li>• 78 cases reported exposure in utero only without the occurrence of any clinical event; trimester of exposure was reported in 9 of these cases: 1<sup>st</sup> trimester (7 cases), 2<sup>nd</sup> trimester (2 cases);</li> <li>• 37 cases, 24 non-serious and 13 serious, reported additional clinical events, which occurred in the vaccinated mothers; the events which occurred more than once encoded to the PTs Vaccination site pain (11), Fatigue (8), Headache, Myalgia, Pain in extremity, Pyrexia (7 each), Chills (6), Lymphadenopathy (5), Drug ineffective, Nausea, Pain (4 each), Arthralgia, Chest pain, Dizziness, (3 each), COVID-19, and Oropharyngeal pain (2 each); trimester of exposure was reported in 21 of these cases: 1<sup>st</sup> trimester (13 cases), 2<sup>nd</sup> trimester (3 cases), 3<sup>rd</sup> trimester (5 cases).</li> </ul> </li> <li>• 8 serious cases reported the PT Spontaneous abortion (note that 1 of these cases reported an exposure term and was also counted in the 115 cases above). No other pregnancy outcomes were reported in any of the other pregnancy cases. Trimester of exposure was reported as 1<sup>st</sup> trimester in 4 of these cases.</li> <li>• 1 case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.</li> <li>• 1 case reported that a pregnant woman was scheduled to receive the vaccine; however, the vaccine had not been administered at the time of reporting.</li> </ul> <p><u>Breast Feeding baby cases:</u> 70, of which:</p> <ul style="list-style-type: none"> <li>• 63 cases reporting exposure to vaccine during breastfeeding without the occurrence of any clinical event;</li> <li>• 7 cases, all non-serious, reporting overall 15 additional clinical events occurred, in the subjects exposed to vaccine via breastfeeding; these events encoded to the PTs: Pyrexia (3), Rash (2), Agitation, Anxiety, Crying, Diarrhoea, Eructation, Increased appetite, Infant irritability, Infantile Vomiting, Insomnia, and Poor quality sleep.</li> </ul> <p><u>Lactation mother cases:</u> 5, of which:</p> <ul style="list-style-type: none"> <li>• 1 case was serious and reported clinical events that encoded to the PTs: Paresis, Pyrexia, and Suppressed lactation</li> <li>• 4 cases were non-serious and reported clinical events that encoded to the PTs: Suppressed lactation (3), Arthralgia, Breast milk discolouration, Breast pain, Chills, Fatigue, Headache, Menstruation irregular, Migraine, Myalgia, Nausea, Pain in extremity, Pyrexia, Scar pain, Vomiting (1 each)</li> </ul> <p>Conclusion: There were no safety signals that emerged from the review of these cases of pregnancy, lactation and breast-feeding babies.</p>
Use in Immunocompromised Patients <sup>d</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 299 (2.1% of the total PM dataset, compared to 1.7% of the previous reporting period) of which 172 were medically confirmed and 127 non-medically confirmed;</li> <li>• Case Seriousness: Serious (154), Non-Serious (145);</li> </ul>

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**Table 15. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>• Country of incidence: US (127), UK (122), Israel (9), Canada (6), Germany and Italy (5 each), Denmark (4), France and Spain (3 each), Greece, Norway and Portugal (2 each); the remaining 9 cases originated from 9 different countries;</li> <li>• Gender: females (230), males (66) and unknown (3);</li> <li>• Age (n = 280) ranged from 18 to 94 years, mean = 56.7, median = 54;</li> <li>• Relevant patients' medical histories most frequently reported (&gt;10 cases) coded to the PTs: Breast cancer (36), Hysterectomy (24), Immunodeficiency (22), Thyroid cancer and Thyroidectomy (18 each), Neoplasm malignant (16), Prostate cancer (13) and Splenectomy (11);</li> <li>• Of the 1296 clinical events overall reported, the most frequent (&gt;20 occurrences) coded to the PTs: Headache (77), Fatigue (63), Vaccination site pain (48), Pyrexia (46), Nausea (39), Chills (37), Dizziness (34), Arthralgia and Myalgia (32 each), Pain (28), Malaise and Pain in extremity (26 each) and Diarrhoea (23);</li> <li>• Case outcome: fatal (14, see <a href="#">Table 14</a>, <i>Death</i>), resolved/resolving (140), resolved with sequelae (6), not resolved (104) and unknown (35).</li> </ul> <p>Conclusion: All the most frequently reported events observed in immunocompromised patients were consistent with those observed in the overall population. The reporting proportion of cases reporting outcomes of fatal (4.7%), not resolved (34.8%) and resolved with sequelae (2%) in immunocompromised patients is similar to the reporting proportions observed in the overall population (2.8% for fatal outcome, 26.9% for outcome of not resolved and 1% for outcome of resolved with sequelae). No safety signals have emerged that would be considered specific to this population</p>
Use in Patients With Autoimmune or Inflammatory Disorders <sup>d</sup>	<ul style="list-style-type: none"> <li>• Number of cases: 893 (6.1% of the total PM dataset, compared to 6.5% of the previous reporting period) of which 584 were medically confirmed and 309 non-medically confirmed;</li> <li>• Case Seriousness: Serious (345), Non-Serious (548);</li> <li>• Country of incidence: US (477), UK (297), Israel (20), Italy (18), Canada and Germany (15 each), Portugal (6), Spain (5), France (4), Denmark, Finland, Greece, Hungary and Romania (3 each) and Bulgaria, Chile, Iceland, Poland, Puerto Rico and Sweden (2 each); the remaining 9 cases originated from 9 different countries;</li> <li>• Gender: Females (773), Males (112) and Unknown (8);</li> <li>• Age (n = 854) ranged from 17 to 98 years, mean = 49 years, median = 48 years;</li> <li>• Relevant patients' medical histories most frequently reported (&gt;15 cases) coded to the PTs: Hypothyroidism (214), Rheumatoid arthritis (71), Arthritis (68), Autoimmune thyroiditis (53), Psoriasis (51), Type 1 diabetes mellitus (42), Coeliac disease (37), Thyroid disorder (35), Crohn's disease (32), Multiple sclerosis (30), Systemic lupus erythematosus (28), Basedow's disease (27), Autoimmune disorder (26), Raynaud's phenomenon (25), Colitis ulcerative (24), Psoriatic arthropathy (22);</li> <li>• Of the 4027 events overall reported, the most frequent (&gt;40 occurrences) coded to the PTs: Headache (284), Fatigue (205), Pyrexia (184), Chills (154), Pain (151), Nausea (142), Pain in extremity (131), Vaccination site pain (123), Myalgia (116), Arthralgia (107), Dizziness (83), Malaise (66), Lymphadenopathy (51), Paraesthesia (50), Dyspnoea, Influenza like illness and Rash (42 each);</li> </ul>

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**Table 15. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<ul style="list-style-type: none"> <li>Case outcome: fatal (5 see <a href="#">Table 14, Death</a>), resolved/resolving (452), resolved with sequelae (15), not resolved (313) and unknown (108).</li> </ul> <p>The reporting proportion of outcomes of “not resolved” (33.2% in the previous reporting period and 35.1% in the current reporting period) and of “resolved with sequelae” (0.9% in the previous reporting period and 1.7% in the current reporting period) in patients with autoimmune or inflammatory disorders is similar to the reporting proportion observed in the overall population (26.9% for outcome of not resolved and 1% for outcome of resolved with sequelae). There were no cases with fatal outcomes involving patients with autoimmune and inflammatory disorders in the previous reporting period, and the reporting proportion of cases with fatal outcome in patients with autoimmune or inflammatory conditions (0.6%) for this reporting period is below the reporting proportion of cases with fatal outcome in the overall population (2.8%).</p> <p>Per company procedures, there is a minimum of 2 follow-up attempts for all non-clinical study cases, regardless of product, event or population involved. The MAH acknowledges that quality and completeness of information obtained is important for individual case assessment and critical for signal detection and evaluation. Reports should contain information on demographics, vaccine brand, batch number, vaccination and adverse event dates, outcome, concomitant drugs, etc. When contact with the reporter has been successfully established, if the reported event has not resolved at the time of the initial report, follow up attempts are pursued until the outcome has been established or the condition has stabilized.</p> <p>Conclusion: The most frequently reported events observed in patients with autoimmune or inflammatory disorders were consistent with those observed in the overall population. No safety signals have emerged that would be considered specific to this population</p>
Use in Frail Patients With Co-morbidities (e.g. COPD, Diabetes, Chronic Neurological Disease, Cardiovascular Disorders) <sup>d</sup>	<ul style="list-style-type: none"> <li>Number of cases: 1343 (9.2% of the total PM dataset, compared to 7.6% of the previous reporting period) of which 903 were medically confirmed and 440 non-medically confirmed;</li> <li>Case Seriousness: Serious (787), Non-Serious (556);</li> <li>Country of incidence: UK (523), US (497), Germany (74), Sweden (36), Norway (29), Italy (25), Denmark (23), Spain (20), France (19), Israel (17), Iceland (11), Austria and Belgium (8 each), Portugal (6), Canada, Greece and Switzerland (5 each), Croatia, Czech Republic and Romania (3 each), Bulgaria, Finland, Hungary, Latvia, Puerto Rico, Saudi Arabia and Slovenia (2 each); the remaining 9 cases originated from 9 different countries;</li> <li>Gender: Females (960), Males (371) and Unknown (12);</li> <li>Age (n = 1303) ranged from 2 months to 100 years, mean = 60.4, median = 57;</li> <li>Relevant patients’ medical histories most frequently reported (&gt;20 cases) coded to the PTs: Asthma (609), Diabetes mellitus (229), Type 2 diabetes mellitus (137), Dementia (118), COPD (95), Cardiac failure (63), Chronic kidney disease (54), Dementia Alzheimer’s type (43), Renal failure (24), Parkinson’s disease (23) and Vascular dementia (22);</li> <li>Of the 5649 events overall reported, the most frequent (&gt;60 occurrences) coded to the PTs: Headache (310), Pyrexia (287), Fatigue (248), Chills (191), Nausea (170), Vaccination site pain (168), Myalgia (153), Pain (151), Arthralgia, Malaise and Pain in extremity (115 each), Dizziness (103), Dyspnoea (108),</li> </ul>

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**Table 15. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>Drug ineffective (85), Asthenia (77), Vomiting (76), Death (71), Cough (68) and Diarrhoea (62); all these events were consistent with the most frequent events observed in the overall population except for Death;</p> <ul style="list-style-type: none"> <li>Case outcome: fatal (219, see <a href="#">Table 14 Death</a>), resolved/resolving (535), resolved with sequelae (18), not resolved (424) and unknown (147).</li> </ul> <p>The reporting proportion of “not resolved” cases (31.6%) and cases resolved with sequelae (1.3%) in frail patients is similar to the reporting proportion observed in the overall population (26.9% for outcome of not resolved, 1% for outcome of resolved with sequelae).</p> <p>The reporting proportion of cases reporting fatal outcome (16.3%) in frail patients is higher than the reporting proportion of cases reporting fatal outcome in the overall population (2.8%). This is expected, considering that most of the cases reporting a fatal outcome (87.7%) were in subjects over 75 years of age who, due to their advanced age and underlying comorbidities are more likely to die than younger individuals. Underlying comorbidities are likely to be contributory to their deaths.</p> <p>Conclusion: Overall, no risks based on patient frailty have been identified for the vaccine.</p> <p>With regard to follow-up activities in place please see subsection <i>Use in Patients With Autoimmune or Inflammatory Disorders</i> above in this Table.</p>
Interaction With Other Vaccines <sup>d</sup>	There was 1 case reporting an interaction with other vaccines during the reporting interval (please refer to <a href="#">Table 14, Vaccine Interactions</a> ).
Long-Term Safety Data <sup>d</sup>	Not applicable
Use in Paediatric Individuals <16 Years of Age <sup>e</sup>	<ul style="list-style-type: none"> <li>Number of cases: 15<sup>f</sup> (0.1% of the total PM dataset, compared to 0.08% of the previous reporting period), of which 9 were medically confirmed and 6 were non-medically confirmed, and indicative of erroneous administration in paediatric subjects &lt;16 years of age (relevant PT Product administered to patient of inappropriate age,<sup>g</sup> see <a href="#">Section 7 Medication Errors</a>);</li> <li>Country of incidence: UK (8), US (5), Andorra and Italy (1 each);</li> <li>Cases Seriousness: Serious (7), Non-Serious (8);</li> <li>Gender: Females (9), Males (5) and Unknown (1);</li> <li>Age (n=15) ranged from 2 months to 15 years, mean = 6.2, median = 5;</li> <li>Of the 40 reported events,                         <ul style="list-style-type: none"> <li>The most frequently reported AEs (&gt;1 case) were coded to the PTs Product administered to patient of inappropriate age (11)<sup>g</sup>, Off label use and Pyrexia (3 each).</li> <li>The remaining 23 AEs were single occurrences and coded to the PTs Abdominal pain upper, Blood pressure increased, Blood urine present, Cough, Decreased appetite, Dizziness exertional, Dyspnoea, Exertional headache, Feeling abnormal, Headache, Hyperhidrosis, Illness, Lethargy, Malaise, Myalgia, Nausea, Oropharyngeal pain, Product use issue, Rash, Rash pruritic, Renal failure, Vaccination site pain and Vomiting;</li> <li>Unlisted AEs were reported in 2 cases:<sup>h</sup> <ul style="list-style-type: none"> <li>Limited information was provided in the case involving renal failure (serious) blood in urine (non-serious) and hyperhidrosis (non-serious) in a female patient of 1 years of</li> </ul> </li> </ul> </li> </ul>

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**Table 15. Evaluation of Missing Information for BNT162b2**

Missing Information	Post-Marketing Cases Evaluation <sup>a</sup> Total Number of Cases in the Reporting Period (N=14525)
	<p>age (as reported) with suspected COVID-19 infection. A meaningful medical assessment of causality cannot be made as clinical details, complete medical history and concomitant medications were not reported.</p> <ul style="list-style-type: none"> <li>▪ A male patient of 2 months of age (as reported) with a history of hypertension experienced serious increase in blood pressure (serious; blood pressure not reported). The patient received treatment (unspecified), and the SAE was recovering at the time of the report.</li> </ul> <ul style="list-style-type: none"> <li>• Case outcome: resolved/resolving and not resolved (4 each) and unknown (7).</li> </ul> <p>No new significant safety information was identified based on a review of these cases.</p>
Vaccine effectiveness <sup>e</sup>	Relevant cases for vaccine effectiveness during the reporting interval are reviewed in <a href="#">Table 14, Lack of Efficacy</a> .

- a. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
- b. Missing information as per both the EU-RMP Version 1.0, dated 21 December 2020 and the US PVP, Version 0.2, dated 05 December 2020;
- c. One case was excluded from the analysis as it did not involve pregnancy;
- d. Missing information as per the EU-RMP Version 1.0, dated 21 December 2020;
- e. Missing information as per the US PVP, Version 0.2, dated 05 December 2020;
- f. Upon review, 13 cases were excluded from analysis as the data reported (e.g., clinical details, height, weight, etc.) were not consistent for paediatric patients;
- g. Applicable Medication Error PT Product administered to patient of inappropriate age was added to 4 of the 15 cases after the data-lock point;
- h. Details provided in these 2 individual case safety reports received from the UK MHRA seem incongruent with a pediatric age, but no follow-up is possible for clarification.

**Search Criteria for the Search and Inclusion of the Reports in the Special Populations of Immunocompromised Patients, Patients With Autoimmune or Inflammatory Disorders and Frail Patients With Co-Morbidities**

*As per EMA PRAC assessment report (Product No. EMEA/H/C/005735/MEA/002) received on the first SMSR, the MAH was asked to clarify the criteria for the search and inclusion of the reports in the special population of immunocompromised subjects to ensure proper evaluation of the vaccine safety profile.*

Criteria for the search and inclusion of the reports in the special population of Immunocompromised Patients

Patients with Medical history of PTs included in SMQ Malignancy related conditions (Narrow and Broad); SMQ Malignancy related therapeutic and diagnostic procedures; SMQ Malignant or unspecified tumours; HLGT Immunodeficiency syndromes (Primary Path); HLT Retroviral infections (Primary Path); or of PTs Heart transplant; Pancreas islet cell transplant; Small intestine transplant; Allogenic bone marrow transplantation therapy; Allogenic stem cell transplantation; Autologous bone marrow transplantation therapy;

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Autologous haematopoietic stem cell transplant; Cord blood transplant therapy; Bone marrow transplant; Stem cell transplant; Liver transplant; Renal transplant; Lung transplant.

Criteria for the search and inclusion of the reports in the special population of Patients with Autoimmune or Inflammatory Disorders

Patients with Medical history of PTs included in HLTG Autoimmune disorders (Primary Path); Immune disorders NEC (Primary Path); in HLT Neuromuscular junction dysfunction (Primary Path); in SMQ Immune-mediated/autoimmune disorders (Narrow and Broad).

Criteria for the search and inclusion of the reports in the special population of Frail Patients With Co-Morbidities

Patients with Medical history of PTs included in HLTGs (Primary Path when applicable) Bronchial disorders (excl neoplasms), Heart failures, Mental impairment disorders, Movement disorders (incl parkinsonism), Nephropathies, Pulmonary vascular disorders and Renal disorders (excl nephropathies) and in HLTs (Primary Path when applicable) Autonomic nervous system disorders, Diabetes mellitus (incl subtypes), Hepatic failure and associated disorders, Hepatic fibrosis and cirrhosis, Motor neurone diseases, Muscle tone abnormal, Neuromuscular disorders NEC, Pulmonary hypertensions, Respiratory failures (excl. neonatal).

Criteria for Inclusion of Reports Overlapping Among Different Categories (Immunocompromised Patients, Patients with Autoimmune or Inflammatory, Frail Patients with Co-morbidities)

- Frail patients of 70 years of age and older were considered frail even if they had also an autoimmune/inflammatory or immunocompromised condition;
- Any immunocompromised condition outweighed an autoimmune/inflammatory condition if both were present and the patient was below the age of 70 years;
- For any frail patient below the age of 70 years, medical histories conditions were reviewed to evaluate which condition was the most relevant between the autoimmune conditions or other co-morbidities.

## 10. OVERALL BENEFIT-RISK EVALUATION

### 10.1. Benefits

BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.

In the Phase 2/3 portion, approximately 44,000 participants were randomised equally and were to receive 2 doses of COVID-19 mRNA Vaccine or placebo (normal saline) separated by 21 days. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. Participants are planned to be followed for up to 24 months after Dose 2, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. In addition, 134 participants were between the ages of 16 to 17 years of age (66 in the COVID-19 mRNA Vaccine group and 68 in the placebo group) and 1616 participants 75 years of age and older (804 in the COVID-19 mRNA Vaccine group and 812 in the placebo group).

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for in total 2,214 person-years for the COVID-19 mRNA Vaccine and in total 2,222 person-years in the placebo group. There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g. asthma, body mass index (BMI)  $\geq$  30 kg/m<sup>2</sup>, chronic pulmonary disease, diabetes mellitus, hypertension).

The vaccine efficacy information is presented in Table 16.

**Table 16. Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population**

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	COVID-19 mRNA Vaccine N <sup>a</sup> = 18,198 Cases n <sup>1</sup> <sup>b</sup> Surveillance time <sup>c</sup> (n <sup>2</sup> <sup>d</sup> )	Placebo N <sup>a</sup> = 18,325 Cases n <sup>1</sup> <sup>b</sup> Surveillance time <sup>c</sup> (n <sup>2</sup> <sup>d</sup> )	Vaccine efficacy % (95% CI) <sup>f</sup>
All subjects <sup>e</sup>	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.0, 97.9)
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)



**Table 16. Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population**

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	COVID-19 mRNA Vaccine N <sup>a</sup> = 18,198 Cases n1 <sup>b</sup> Surveillance time <sup>c</sup> (n2 <sup>d</sup> )	Placebo N <sup>a</sup> = 18,325 Cases n1 <sup>b</sup> Surveillance time <sup>c</sup> (n2 <sup>d</sup> )	Vaccine efficacy % (95% CI) <sup>f</sup>
65 to 74 years	1 0.406 (3074)	14 0.406 (3095)	92.9 (53.1, 99.8)
75 years and older	0 0.102 (774)	5 0.106 (785)	100.0 (-13.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 [\*Case definition: (at least 1 of) fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhoea or vomiting.]

\* Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by nucleic acid amplification tests (NAAT) [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- a. N = number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of subjects at risk for the endpoint.
- e. No confirmed cases were identified in participants 12 to 15 years of age.
- f. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time. CI not adjusted for multiplicity.

In the second primary analysis, compared to placebo, efficacy of COVID-19 mRNA Vaccine in participants from first COVID-19 occurrence from 7 days after Dose 2 compared to participants with or without evidence of prior infection with SARS-CoV-2 was 94.6% (95% credible interval of 89.9% to 97.3%) in participants 16 years of age and older.

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

## 10.2. Risks

As per the EU RMP Version 1.0, dated 21 December 2020, traceability is part of the routine pharmacovigilance activities in place. During the reporting period improving of the design of

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traceability tools upon EMA request was implemented with the first pre-printed stickers with batch/lot information delivered to 8 European markets (see [Appendix 7](#)).

Based on pharmacovigilance monitoring activities, since first authorisation, anaphylaxis has been recognised as an important identified risk. Facial paralysis, pain in extremity, insomnia, injection site pruritus and hypersensitivity (less severe than anaphylaxis) were included in the EU SmPC as adverse reactions in Section 4.8 at the request of the EMA at the time of conditional approval of the vaccine. The relevant signals, except for Facial paralysis that it is still under evaluation, were evaluated and closed during the reporting period; according to the Core Position, Hypersensitivity reactions (not Anaphylaxis) was also included after the data-lock point of this SMSR as adverse reaction in the EUA Fact Sheet for the HCP and Full EUA PI and is to be added in the CDS, Pain in extremity will be added to the EUA Fact Sheet for the HCP and Full EUA PI and to the CDS, while Injection site pruritus and Insomnia were considered as no risks with no further action warranted. Diarrhoea and Vomiting were re-opened and evaluated as signals during the reporting period, they were closed after the data-lock point of this SMSR and according to the Core Position they will be added to labelling as adverse reactions.

Based on all available safety and efficacy data for BNT162b2 the benefit-risk profile of the vaccine remains favorable.

### **10.3. Overall Benefit-Risk**

The identified risks associated with the use of BNT162b2 are minimized through provision of relevant product information in the RSI to support safe use of the product. Risks have been evaluated in the context of the enumerated benefits of the product. Based on the available safety and efficacy data for BNT162b2, the overall benefit-risk profile of BNT162b2 remains favourable.

## **11. CONCLUSION AND ACTIONS**

The MAH will continue to review the safety of BNT162b2, including all reports of adverse experiences and will revise the product documents if an evaluation of the safety data yields significant new information.

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**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

## 1. NAME OF THE MEDICINAL PRODUCT

Comirnaty concentrate for dispersion for injection  
COVID-19 mRNA Vaccine (nucleoside modified)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see sections 4.2 and 6.6.

1 dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Concentrate for dispersion for injection (sterile concentrate).  
The vaccine is a white to off-white frozen dispersion (pH: 6.9 - 7.9).

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Comirnaty is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

### 4.2 Posology and method of administration

#### Posology

##### *Individuals 16 years of age and older*

Comirnaty is administered intramuscularly after dilution as a course of 2 doses (0.3 mL each). It is recommended to administer the second dose 3 weeks after the first dose (see sections 4.4 and 5.1).

There are no data available on the interchangeability of Comirnaty with other COVID-19 vaccines to complete the vaccination course. Individuals who have received 1 dose of Comirnaty should receive a second dose of Comirnaty to complete the vaccination course.

##### *Paediatric population*

The safety and efficacy of Comirnaty in children and adolescents aged less than 16 years of age have not yet been established. Limited data are available.

### *Elderly population*

No dosage adjustment is required in elderly individuals  $\geq 65$  years of age.

### Method of administration

Comirnaty should be administered intramuscularly after dilution (see section 6.6).

After dilution, vials of Comirnaty contain six doses of 0.3 mL of vaccine. In order to extract six doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

The preferred site is the deltoid muscle of the upper arm.

Do not inject the vaccine intravascularly, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see section 4.4.

For instructions regarding thawing, handling and disposal of the vaccine, see section 6.6.

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### **4.4 Special warnings and precautions for use**

#### Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

#### General recommendations

##### *Hypersensitivity and anaphylaxis*

Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Comirnaty.

##### *Anxiety-related reactions*

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

### *Concurrent illness*

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.

### *Thrombocytopenia and coagulation disorders*

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

### *Immunocompromised individuals*

The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Comirnaty may be lower in immunosuppressed individuals.

### *Duration of protection*

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

### *Limitations of vaccine effectiveness*

As with any vaccine, vaccination with Comirnaty may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.

### Excipients

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

Concomitant administration of Comirnaty with other vaccines has not been studied.

## **4.6 Fertility, pregnancy and lactation**

### Pregnancy

There is limited experience with use of Comirnaty in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). Administration of Comirnaty in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

### Breast-feeding

It is unknown whether Comirnaty is excreted in human milk.

### Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

#### 4.7 Effects on ability to drive and use machines

Comirnaty has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

#### 4.8 Undesirable effects

##### Summary of safety profile

The safety of Comirnaty was evaluated in participants 16 years of age and older in 2 clinical studies that included 21,744 participants that have received at least one dose of Comirnaty.

In Study 2, a total of 21,720 participants 16 years of age or older received at least 1 dose of Comirnaty and a total of 21,728 participants 16 years of age or older received placebo (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively). A total of 20,519 participants 16 years of age or older received 2 doses of Comirnaty.

At the time of the analysis of Study 2, a total of 19,067 (9,531 Comirnaty and 9,536 placebo) participants 16 years of age or older were evaluated for safety for at least 2 months after the second dose of Comirnaty. This included a total of 10,727 (5,350 Comirnaty and 5,377 placebo) participants 16 to 55 years of age and a total of 8,340 (4,181 Comirnaty and 4,159 placebo) participants 56 years and older.

The most frequent adverse reactions in participants 16 years of age and older were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia and chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.

##### Tabulated list of adverse reactions from clinical studies

Adverse reactions observed during clinical studies are listed below according to the following frequency categories:

Very common ( $\geq 1/10$ ),

Common ( $\geq 1/100$  to  $< 1/10$ ),

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ),

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ),

Very rare ( $< 1/10,000$ ),

Not known (cannot be estimated from the available data).

**Table 1: Adverse reactions from Comirnaty clinical trials**

System Organ Class	Very common ( $\geq 1/10$ )	Common ( $\geq 1/100$ to $< 1/10$ )	Uncommon ( $\geq 1/1,000$ to $< 1/100$ )	Rare ( $\geq 1/10,000$ to $< 1/1,000$ )	Not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy		
Immune system disorders					Anaphylaxis; hypersensitivity
Psychiatric disorders			Insomnia		

System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Not known (cannot be estimated from the available data)
Nervous system disorders	Headache			Acute peripheral facial paralysis <sup>†</sup>	
Gastrointestinal disorders		Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; myalgia		Pain in extremity		
General disorders and administration site conditions	Injection site pain; fatigue; chills; pyrexia*; injection site swelling	Injection site redness	Malaise; injection site pruritus		

\* A higher frequency of pyrexia was observed after the 2<sup>nd</sup> dose.

† Throughout the safety follow-up period to date, acute peripheral facial paralysis (or palsy) was reported by four participants in the COVID-19 mRNA Vaccine group. Onset was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of acute peripheral facial paralysis (or palsy) were reported in the placebo group.

The safety profile in 545 subjects receiving Comirnaty, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in [Appendix V](#) and include batch/Lot number if available.

#### **4.9 Overdose**

Overdose data is available from 52 study participants included in the clinical trial that due to an error in dilution received 58 micrograms of Comirnaty. The vaccine recipients did not report an increase in reactogenicity or adverse reactions.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.



## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, other viral vaccines, ATC code: J07BX03

#### Mechanism of action

The nucleoside-modified messenger RNA in Comirnaty is formulated in lipid nanoparticles, which enable delivery of the non replicating RNA into host cells to direct transient expression of the SARS-CoV-2 S antigen. The mRNA codes for membrane-anchored, full-length S with two point mutations within the central helix. Mutation of these two amino acids to proline locks S in an antigenically preferred prefusion conformation. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.

#### Efficacy

Study 2 is a multicentre, multinational, Phase 1/2/3 randomised, placebo-controlled, observer-blind dose-finding, vaccine candidate selection and efficacy study in participants 12 years of age and older. Randomisation was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the  $\geq 56$ -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrolment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV) or hepatitis B virus (HBV). At the time of the analysis of Study 2, information presented is based on participants 16 years and older.

#### Efficacy in participants 16 years of age and older

In the Phase 2/3 portion, approximately 44,000 participants were randomised equally and were to receive 2 doses of COVID-19 mRNA Vaccine or placebo separated by 21 days. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. The majority (93.1%) of vaccine recipients received the second dose 19 days to 23 days after Dose 1. Participants are planned to be followed for up to 24 months after Dose 2, for assessments of safety and efficacy against COVID-19. In the clinical study, participants were required to observe a minimum interval of 14 days before and after administration of an influenza vaccine in order to receive either placebo or COVID-19 mRNA Vaccine. In the clinical study, participants were required to observe a minimum interval of 60 days before or after receipt of blood/plasma products or immunoglobulins within through conclusion of the study in order to receive either placebo or COVID-19 mRNA Vaccine.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the COVID-19 mRNA Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. In addition, 134 participants were between the ages of 16 to 17 years of age (66 in the COVID-19 mRNA Vaccine group and 68 in the placebo group) and 1,616 participants 75 years of age and older (804 in the COVID-19 mRNA Vaccine group and 812 in the placebo group).

#### Efficacy against COVID-19

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for in total 2,214 person-years for the COVID-19 mRNA Vaccine and in total 2,222 person-years in the placebo group.

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g. asthma, body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>, chronic pulmonary disease, diabetes mellitus, hypertension).

The vaccine efficacy information is presented in Table 2.

**Table 2: Vaccine efficacy – First COVID-19 occurrence from 7 days after Dose 2, by age subgroup – participants without evidence of infection prior to 7 days after Dose 2 – evaluable efficacy (7 days) population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*</b>			
<b>Subgroup</b>	<b>COVID-19 mRNA Vaccine</b> <b>N<sup>a</sup> = 18,198</b> <b>Cases</b> <b>n1<sup>b</sup></b> <b>Surveillance time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Placebo</b> <b>N<sup>a</sup> = 18,325</b> <b>Cases</b> <b>n1<sup>b</sup></b> <b>Surveillance time<sup>c</sup> (n2<sup>d</sup>)</b>	<b>Vaccine efficacy</b> <b>% (95% CI)<sup>f</sup></b>
All subjects <sup>e</sup>	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.0, 97.9)
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)
65 to 74 years	1 0.406 (3074)	14 0.406 (3095)	92.9 (53.1, 99.8)
75 years and older	0 0.102 (774)	5 0.106 (785)	100.0 (-13.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 [\*Case definition: (at least 1 of) fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhoea or vomiting.]

\* Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by nucleic acid amplification tests (NAAT) [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- N = number of participants in the specified group.
- n1 = Number of participants meeting the endpoint definition.
- Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- n2 = Number of subjects at risk for the endpoint.
- No confirmed cases were identified in participants 12 to 15 years of age.
- Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time. CI not adjusted for multiplicity.

In the second primary analysis, compared to placebo, efficacy of COVID-19 mRNA Vaccine in participants from first COVID-19 occurrence from 7 days after Dose 2 compared to participants with or without evidence of prior infection with SARS-CoV-2 was 94.6% (95% credible interval of 89.9% to 97.3%) in participants 16 years of age and older.

Additionally, subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across genders, ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.

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### Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with Comirnaty in the paediatric population in prevention of COVID-19 (see section 4.2 for information on paediatric use).

This medicinal product has been authorised under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited. The European Medicines Agency will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

### **5.2 Pharmacokinetic properties**

Not applicable.

### **5.3 Preclinical safety data**

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproductive and developmental toxicity.

### General toxicity

Rats intramuscularly administered Comirnaty (receiving 3 full human doses once weekly, generating relatively higher levels in rats due to body weight differences) demonstrated some injection site oedema and erythema and increases in white blood cells (including basophils and eosinophils) consistent with an inflammatory response as well as vacuolation of portal hepatocytes without evidence of liver injury. All effects were reversible.

### Genotoxicity/Carcinogenicity

Neither genotoxicity nor carcinogenicity studies were performed. The components of the vaccine (lipids and mRNA) are not expected to have genotoxic potential.

### Reproductive toxicity

Reproductive and developmental toxicity were investigated in rats in a combined fertility and developmental toxicity study where female rats were intramuscularly administered Comirnaty prior to mating and during gestation (receiving 4 full human doses that generate relatively higher levels in rat due to body weight differences, spanning between pre-mating day 21 and gestational day 20). SARS-CoV-2 neutralizing antibody responses were present in maternal animals from prior to mating to the end of the study on postnatal day 21 as well as in foetuses and offspring. There were no vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development. No Comirnaty data are available on vaccine placental transfer or excretion in milk.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)

2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)

1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)

Cholesterol

Potassium chloride

Potassium dihydrogen phosphate

Sodium chloride

Disodium phosphate dihydrate  
Sucrose  
Water for injections

## 6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

## 6.3 Shelf life

### Unopened vial

6 months at -90 °C to -60 °C.

Once removed from the freezer, the unopened vaccine can be stored for up to 5 days at 2 °C to 8 °C, and up to 2 hours at temperatures up to 30 °C, prior to use.

Once thawed, the vaccine should not be re-frozen.

Closed-lid vial trays containing 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for up to 5 minutes for transfer between ultra-low-temperature environments. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

### Diluted medicinal product

Chemical and physical in-use stability has been demonstrated for 6 hours at 2 °C to 30 °C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

## 6.4 Special precautions for storage

Store in a freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thawed vials can be handled in room light conditions.

When you are ready to thaw or use the vaccine

- Open-lid vial trays, or vial trays containing less than 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for up to 3 minutes to remove vials or for transfer between ultra-low-temperature environments.
- Once a vial is removed from the vial tray, it should be thawed for use.
- After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

For storage conditions after thawing and dilution of the medicinal product, see section 6.3.

## 6.5 Nature and contents of container


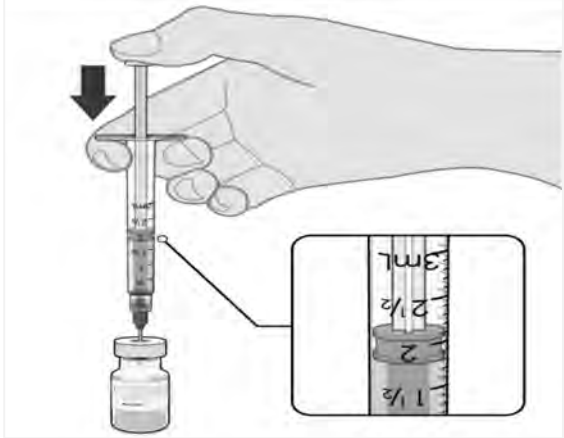
2 mL clear multidose vial (type I glass) with a stopper (synthetic bromobutyl rubber) and a flip-off plastic cap with aluminium seal. Each vial contains 6 doses, see section 6.6.

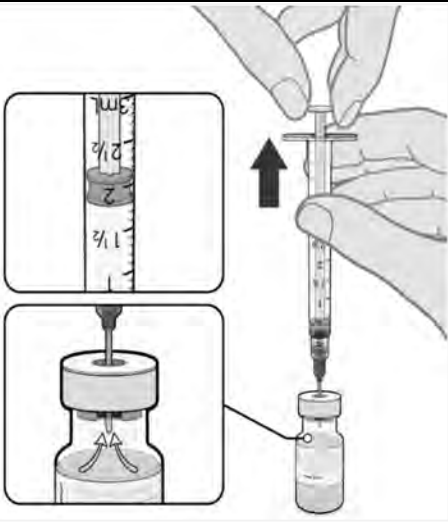
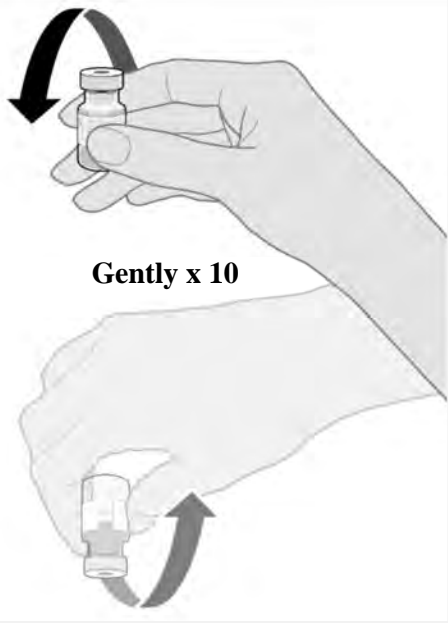
Pack size: 195 vials


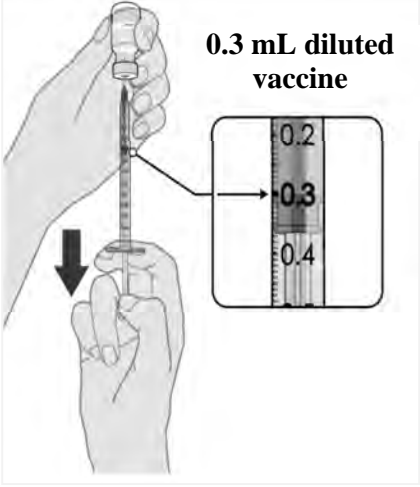
## 6.6 Special precautions for disposal and other handling

### Handling instructions

Comirnaty should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

<b>THAWING PRIOR TO DILUTION</b>	
 <p><b>No more than 2 hours at room temperature (up to 30 °C)</b></p>	<ul style="list-style-type: none"><li>• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.</li><li>• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.</li><li>• Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.</li></ul>
<b>DILUTION</b>	
 <p><b>1.8 mL of 0.9% sodium chloride injection</b></p>	<ul style="list-style-type: none"><li>• The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.</li></ul>

 <p><b>Pull back plunger to 1.8 mL to remove air from vial</b></p>	<ul style="list-style-type: none"><li>• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.</li></ul>
 <p><b>Gently x 10</b></p>	<ul style="list-style-type: none"><li>• Gently invert the diluted dispersion 10 times. Do not shake.</li><li>• The diluted vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.</li></ul>

 <p><b>Record appropriate date and time. Use within 6 hours after dilution</b></p>	<ul style="list-style-type: none"> <li>• The diluted vials should be marked with the appropriate date and time.</li> <li>• Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.</li> </ul>
<b>PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY</b>	
	<ul style="list-style-type: none"> <li>• After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.</li> <li>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.</li> <li>• Withdraw 0.3 mL of Comirnaty.</li> </ul> <p>Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.</p> <p>If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.</p> <ul style="list-style-type: none"> <li>• Each dose must contain 0.3 mL of vaccine.</li> <li>• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.</li> <li>• Discard any unused vaccine within 6 hours after dilution.</li> </ul>

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz  
Germany  
Phone: +49 6131 90840  
Fax: +49 6131 9084390  
info@biontech.de

**8. MARKETING AUTHORISATION NUMBER(S)**

EU/1/20/1528

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 21 December 2020

**10. DATE OF REVISION OF THE TEXT**

Detailed information on this medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.



**ANNEX II**

- A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**
- D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**
- E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION**

**A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturers of the biological active substance(s)

BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz  
Germany

Rentschler Biopharma SE  
Erwin-Rentschler-Strasse 21  
88471 Laupheim  
Germany

Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC  
1 Burtt Road  
Andover, MA 01810  
USA

Name and address of the manufacturers responsible for batch release

BioNTech Manufacturing GmbH  
Kupferbergterrasse 17 - 19  
55116 Mainz  
Germany

Pfizer Manufacturing Belgium NV  
Rijksweg 12  
2870 Puurs  
Belgium

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

In view of the declared Public Health Emergency of International Concern and in order to ensure early supply this medicinal product is subject to a time-limited exemption allowing reliance on batch control testing conducted in the registered site(s) that are located in a third country. This exemption ceases to be valid on 31 August 2021. Implementation of EU based batch control arrangements, including the necessary variations to the terms of the marketing authorisation, has to be completed by 31 August 2021 at the latest, in line with the agreed plan for this transfer of testing. Progress reports have to be submitted on 31 March 2021 and included in the annual renewal application.

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Medicinal product subject to medical prescription.

• **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

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### C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

### D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

### E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data.	July 2021. Interim reports: 31 March 2021
In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications.	July 2021. Interim reports: March 2021
In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional validation data.	March 2021
In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0315.	July 2021. Interim reports: January 2021, April 2021
In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0159.	July 2021. Interim reports: January 2021, April 2021

<b>Description</b>	<b>Due date</b>
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001.	December 2023

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

**A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON BOX LABEL**

**1. NAME OF THE MEDICINAL PRODUCT**

COMIRNATY concentrate for dispersion for injection  
COVID-19 mRNA Vaccine (nucleoside modified)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

After dilution each vial contains 6 doses of 0.3 mL.

**3. LIST OF EXCIPIENTS**

Excipients: ALC-0315, ALC-0159, DSPC, cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium phosphate dihydrate, sucrose, water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Concentrate for dispersion for injection  
195 multidose vials

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use after dilution.  
Read the package leaflet before use.

Scan QR code for more information.

Dilute before use: Dilute each vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP



**9. SPECIAL STORAGE CONDITIONS**

Storage:

Prior to dilution, store at -90 °C to -60 °C in the original package in order to protect from light.

After dilution, store the vaccine at 2 °C to 30 °C and use within 6 hours. Discard any unused vaccine.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

**12. MARKETING AUTHORISATION NUMBER(S)**

EU/1/20/1528

**13. BATCH NUMBER**

LOT

**14. GENERAL CLASSIFICATION FOR SUPPLY**

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

Justification for not including Braille accepted.

**17. UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included.

**18. UNIQUE IDENTIFIER - HUMAN READABLE DATA**

PC  
SN  
NN

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**VIAL LABEL**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

COMIRNATY sterile concentrate  
COVID-19 mRNA Vaccine  
IM

**2. METHOD OF ADMINISTRATION**

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

LOT

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

6 doses after dilution

**6. OTHER**

Discard date/time:

**B. PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Comirnaty is and what it is used for
2. What you need to know before you receive Comirnaty
3. How Comirnaty is given
4. Possible side effects
5. How to store Comirnaty
6. Contents of the pack and other information

#### 1. What Comirnaty is and what it is used for

Comirnaty is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

Comirnaty is given to adults and adolescents from 16 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty does not contain the virus to produce immunity, it cannot give you COVID-19.

#### 2. What you need to know before you receive Comirnaty

##### Comirnaty should not be given

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

##### Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Comirnaty in the past.
- you have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system

As with any vaccine, the 2-dose vaccination course of Comirnaty may not fully protect all those who receive it and it is not known how long you will be protected.

### **Children and adolescents**

Comirnaty is not recommended for children aged under 16 years.

### **Other medicines and Comirnaty**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

### **Driving and using machines**

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

### **Comirnaty contains potassium and sodium**

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## **3. How Comirnaty is given**

Comirnaty is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 2 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose to complete the vaccination course.

If you have any further questions on the use of Comirnaty, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

**Very common side effects:** may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- joint pain
- chills, fever

**Common side effects:** may affect up to 1 in 10 people

- injection site redness
- nausea

**Uncommon side effects:** may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- pain in limb
- insomnia
- injection site itching

**Rare side effects:** may affect up to 1 in 1,000 people

- temporary one sided facial drooping

**Not known** (cannot be estimated from the available data)

- severe allergic reaction

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#) and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Comirnaty**

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 5 days at 2 °C to 8 °C, or up to 2 hours at temperatures up to 30 °C, prior to use.

After dilution, store the vaccine at 2 °C to 30 °C and use within 6 hours. Discard any unused vaccine.

Once removed from the freezer and diluted, the vials should be marked with the new discard date and time. Once thawed, the vaccine cannot be re-frozen.

Do not use this vaccine if you notice particulates in the dilution or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Comirnaty contains

- The active substance is COVID-19 mRNA Vaccine. After dilution, the vial contains 6 doses of 0.3 mL with 30 micrograms mRNA each.
- The other ingredients are:
  - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
  - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
  - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
  - cholesterol
  - potassium chloride
  - potassium dihydrogen phosphate
  - sodium chloride
  - disodium phosphate dihydrate
  - sucrose
  - water for injections

### What Comirnaty looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a flip-off plastic cap with aluminium seal.

Pack size: 195 vials

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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**This leaflet was last revised in {MM/YYYY}**

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Scan the code with a mobile device to get the package leaflet in different languages.



URL: [www.comirnatyglobal.com](http://www.comirnatyglobal.com)

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

This package leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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**The following information is intended for healthcare professionals only:**


Administer Comirnaty intramuscularly after dilution as a course of 2 doses (0.3 mL each) 3 weeks apart.

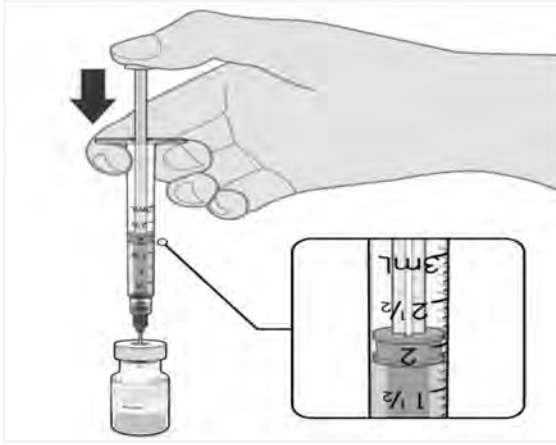
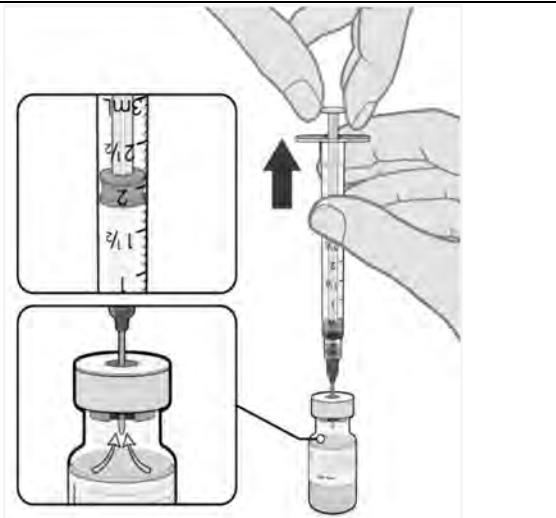
Traceability

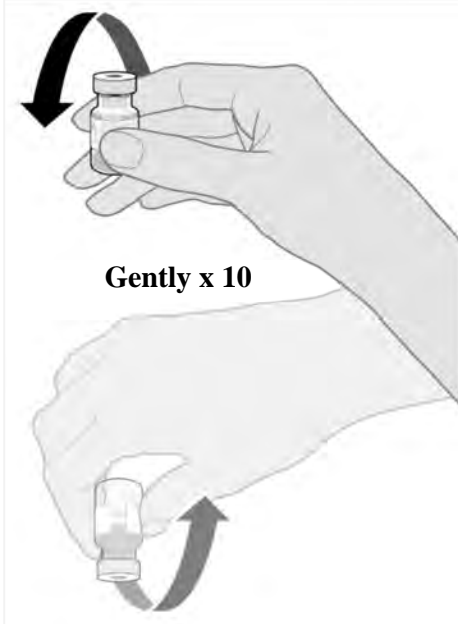

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

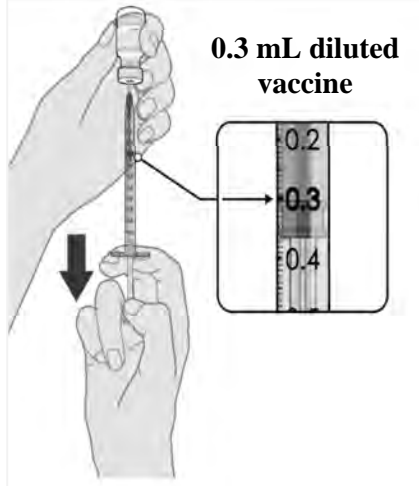
**Handling instructions**

Comirnaty should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

THAWING PRIOR TO DILUTION	
 <p><b>No more than 2 hours at room temperature (up to 30 °C)</b></p>	<ul style="list-style-type: none"> <li>• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.</li> <li>• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.</li> <li>• Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.</li> </ul>

<b>DILUTION</b>	
 <p><b>1.8 mL of 0.9% sodium chloride injection</b></p>	<ul style="list-style-type: none"><li>• The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.</li></ul>
 <p><b>Pull back plunger to 1.8 mL to remove air from vial</b></p>	<ul style="list-style-type: none"><li>• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.</li></ul>

 <p><b>Gently x 10</b></p>	<ul style="list-style-type: none"><li>• Gently invert the diluted dispersion 10 times. Do not shake.</li><li>• The diluted vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.</li></ul>
 <p><b>Record appropriate date and time. Use within 6 hours after dilution</b></p>	<ul style="list-style-type: none"><li>• The diluted vials should be marked with the appropriate date and time.</li><li>• Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.</li></ul>

**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY**

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 6 hours after dilution.

**Disposal**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE  
(VACCINATION PROVIDERS)**

**EMERGENCY USE AUTHORIZATION (EUA) OF  
THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS  
DISEASE 2019 (COVID-19)**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

**SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS**

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

**DESCRIPTION OF COVID-19**

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

## DOSAGE AND ADMINISTRATION

### Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

#### Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

#### Thawed Vials Before Dilution

##### *Thawed Under Refrigeration*

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

##### *Transportation at 2°C to 8°C (35°F to 46°F)*

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).

##### *Thawed at Room Temperature*

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

## Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

## **Dosing and Schedule**

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

## Dose Preparation

### *Prior to Dilution*

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] (*see Storage and Handling*).
- Refer to thawing instructions in the panels below.



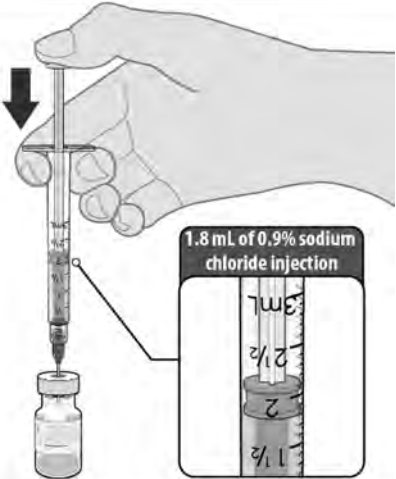
### *Dilution*

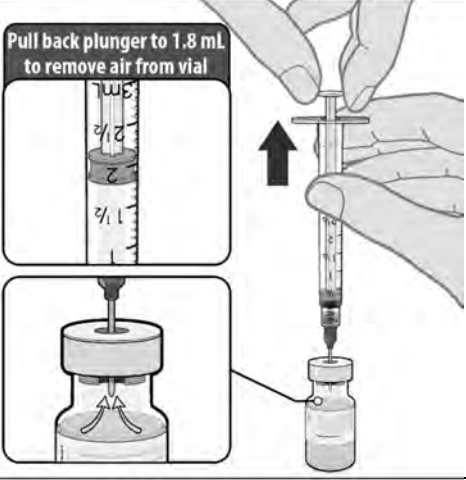

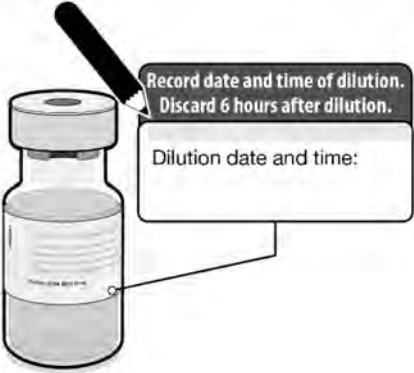
Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.

After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.


- Refer to dilution and dose preparation instructions in the panels below.



THAWING PRIOR TO DILUTION	
	<ul style="list-style-type: none"> <li>• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: <ul style="list-style-type: none"> <li>○ Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).</li> <li>○ Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.</li> </ul> </li> <li>• Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.</li> </ul>
	<ul style="list-style-type: none"> <li>• Before dilution invert vaccine vial gently 10 times.</li> <li>• <u>Do not shake.</u></li> <li>• Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.</li> <li>• Do not use if liquid is discolored or if other particles are observed.</li> </ul>
DILUTION	
	<ul style="list-style-type: none"> <li>• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.</li> <li>• Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).</li> <li>• Cleanse the vaccine vial stopper with a single-use antiseptic swab.</li> <li>• Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.</li> </ul>

	<ul style="list-style-type: none"> <li>• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.</li> </ul>
	<ul style="list-style-type: none"> <li>• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.</li> <li>• <u>Do not shake.</u></li> <li>• Inspect the vaccine in the vial.</li> <li>• The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.</li> </ul>
	<ul style="list-style-type: none"> <li>• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.</li> <li>• Store between 2°C to 25°C (35°F to 77°F).</li> <li>• Discard any unused vaccine 6 hours after dilution.</li> </ul>

## PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE

	<ul style="list-style-type: none"> <li>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.3 mL</u> of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.</li> <li>• Each dose must contain 0.3 mL of vaccine.</li> <li>• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.</li> <li>• Administer immediately.</li> </ul>
---	---

### Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

### Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine (*see Full EUA Prescribing Information*).

## Warnings

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

## Adverse Reactions

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy (see *Full EUA Prescribing Information*).

Severe allergic reactions, including anaphylaxis, have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

## Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

## INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website [www.cvdvaccine.com](http://www.cvdvaccine.com) to obtain the Fact Sheet) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.

- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

### **MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION**

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
  - vaccine administration errors whether or not associated with an adverse event,
  - serious adverse events\* (irrespective of attribution to vaccination),

- cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
- cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

\* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

#### **OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.**

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.


To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

<b>Website</b>	<b>Fax number</b>	<b>Telephone number</b>
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

## ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
<p data-bbox="363 573 669 604"><a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a></p> 	<p data-bbox="997 619 1211 646">1-877-829-2619</p> <p data-bbox="976 667 1232 699">(1-877-VAX-CO19)</p>

## AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

## AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 16 years of age and older.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

## The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp), email [cicp@hrsa.gov](mailto:cicp@hrsa.gov), or call: 1-855-266-2427.



Manufactured by  
Pfizer Inc., New York, NY 10017

**BIONTECH**

Manufactured for  
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An der Goldgrube 12  
55131 Mainz, Germany

LAB-1450-5.0

Revised: January 2021

END SHORT VERSION FACT SHEET  
Long Version (Full EUA Prescribing Information) Begins On Next Page

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**FULL EMERGENCY USE  
AUTHORIZATION (EUA) PRESCRIBING  
INFORMATION**

**PFIZER-BIONTECH COVID-19 VACCINE**

**FULL EMERGENCY USE AUTHORIZATION  
PRESCRIBING INFORMATION: CONTENTS\***

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\* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

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# FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

## 1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

## 2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

### 2.1 Preparation for Administration

#### Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] [*see How Supplied/Storage and Handling (19)*].
- Refer to thawing instructions in the panels below.

#### Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. Do not add more than 1.8 mL of diluent.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.

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## THAWING PRIOR TO DILUTION

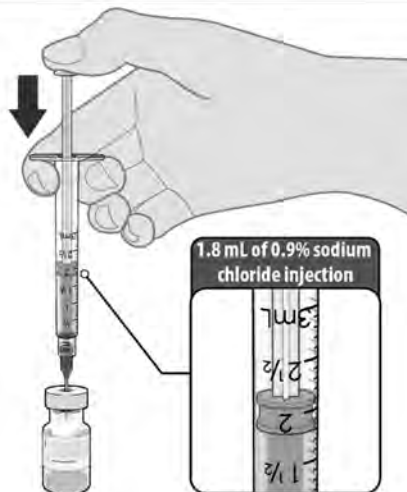


- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

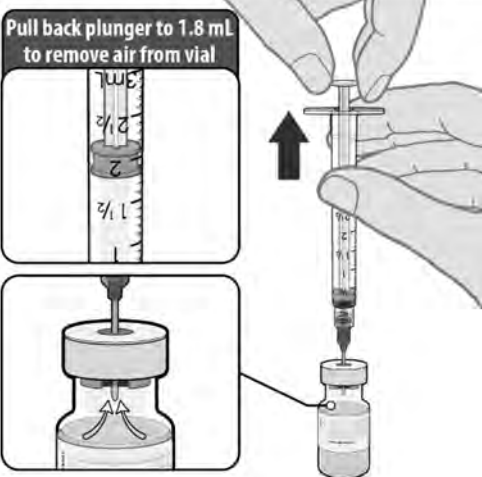
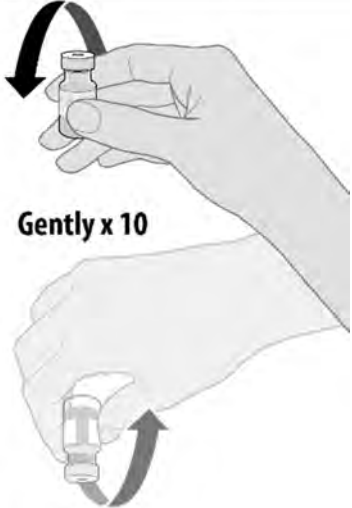



- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

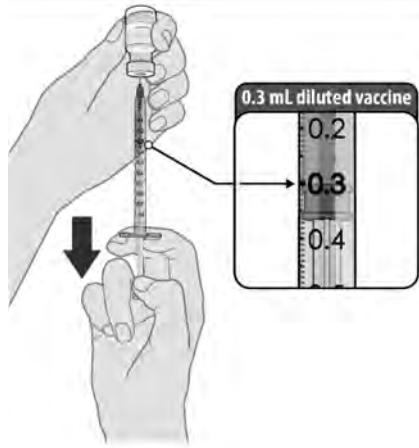
## DILUTION



- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	<ul style="list-style-type: none"> <li>Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.</li> </ul>
	<ul style="list-style-type: none"> <li>Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.</li> <li><u>Do not shake.</u></li> <li>Inspect the vaccine in the vial.</li> <li>The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.</li> </ul>
	<ul style="list-style-type: none"> <li>Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.</li> <li>Store between 2°C to 25°C (35°F to 77°F).</li> <li>Discard any unused vaccine 6 hours after dilution.</li> </ul>

## PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE



- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately.

### 2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

### 2.3 Vaccination Schedule for Individuals 16 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

## 3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

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## 4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine [see Description (13)].

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>).

### 5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

### 5.3 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

## 6 OVERALL SAFETY SUMMARY

**It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.**

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

Severe allergic reactions, including anaphylaxis, have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

### 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

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The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 16 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 44,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively).

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older have been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020. Participants 18 years and older in the reactogenicity subset are monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

#### Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo in the subset of participants 18 to 55 years of age included in the EUA safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo for participants 56 years of age and older.

Across both age groups, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

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**Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age<sup>‡</sup> – Reactogenicity Subset of the Safety Population\***

	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 1 N<sup>a</sup>=2291 n<sup>b</sup> (%)</b>	<b>Placebo Dose 1 N<sup>a</sup>=2298 n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 2 N<sup>a</sup>=2098 n<sup>b</sup> (%)</b>	<b>Placebo Dose 2 N<sup>a</sup>=2103 n<sup>b</sup> (%)</b>
<b>Redness<sup>c</sup></b>				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
<b>Swelling<sup>c</sup></b>				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
<b>Pain at the injection site<sup>d</sup></b>				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

<sup>‡</sup> Eight participants were between 16 and 17 years of age.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

**Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age<sup>‡</sup> – Safety Population\***

	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 1 N<sup>a</sup>=2291 n<sup>b</sup> (%)</b>	<b>Placebo Dose 1 N<sup>a</sup>=2298 n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 2 N<sup>a</sup>=2098 n<sup>b</sup> (%)</b>	<b>Placebo Dose 2 N<sup>a</sup>=2103 n<sup>b</sup> (%)</b>
<b>Fever</b>				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
<b>Fatigue<sup>c</sup></b>				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)

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	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 1 N<sup>a</sup>=2291 n<sup>b</sup> (%)</b>	<b>Placebo Dose 1 N<sup>a</sup>=2298 n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 2 N<sup>a</sup>=2098 n<sup>b</sup> (%)</b>	<b>Placebo Dose 2 N<sup>a</sup>=2103 n<sup>b</sup> (%)</b>
<b>Headache<sup>c</sup></b>				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
<b>Chills<sup>c</sup></b>				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)
<b>Vomiting<sup>d</sup></b>				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
<b>Diarrhea<sup>e</sup></b>				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
<b>New or worsened muscle pain<sup>c</sup></b>				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
<b>New or worsened joint pain<sup>c</sup></b>				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
<b>Use of antipyretic or pain medication<sup>f</sup></b>	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

‡ Eight participants were between 16 and 17 years of age.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

**Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Safety Population\***

	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 1 N<sup>a</sup>=1802 n<sup>b</sup> (%)</b>	<b>Placebo Dose 1 N<sup>a</sup>=1792 n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 2 N<sup>a</sup>=1660 n<sup>b</sup> (%)</b>	<b>Placebo Dose 2 N<sup>a</sup>=1646 n<sup>b</sup> (%)</b>
<b>Redness<sup>c</sup></b>				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
<b>Swelling<sup>c</sup></b>				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
<b>Pain at the injection site<sup>d</sup></b>				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

**Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population\***

	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 1 N<sup>a</sup>=1802 n<sup>b</sup> (%)</b>	<b>Placebo Dose 1 N<sup>a</sup>=1792 n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 2 N<sup>a</sup>=1660 n<sup>b</sup> (%)</b>	<b>Placebo Dose 2 N<sup>a</sup>=1646 n<sup>b</sup> (%)</b>
<b>Fever</b>				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Fatigue<sup>c</sup></b>				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 1 N<sup>a</sup>=1802 n<sup>b</sup> (%)</b>	<b>Placebo Dose 1 N<sup>a</sup>=1792 n<sup>b</sup> (%)</b>	<b>Pfizer-BioNTech COVID-19 Vaccine Dose 2 N<sup>a</sup>=1660 n<sup>b</sup> (%)</b>	<b>Placebo Dose 2 N<sup>a</sup>=1646 n<sup>b</sup> (%)</b>
Headache <sup>c</sup>				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills <sup>c</sup>				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting <sup>d</sup>				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea <sup>e</sup>				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain <sup>c</sup>				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain <sup>c</sup>				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

\* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

## Unsolicited Adverse Events

### *Serious Adverse Events*

In Study 2, among participants 16 to 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7960, placebo = 7934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

### *Non-Serious Adverse Events*

Overall in Study 2 in which 10,841 participants 16 to 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. The higher frequency of reported unsolicited non-serious adverse events among Pfizer BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

## **8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS**

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

Revised: 1/2021

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events\* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

\*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

### Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to [info@vaers.org](mailto:info@vaers.org).

**IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:**

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
  - a. Write “Pfizer-BioNTech COVID-19 Vaccine EUA” as the first line.
  - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.

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3. Contact information:

- a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
- b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
- c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

**10 DRUG INTERACTIONS**

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

**11 USE IN SPECIFIC POPULATIONS**

**11.1 Pregnancy**

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

**11.2 Lactation**

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

**11.3 Pediatric Use**

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 16 and 17 years of age is based on extrapolation of safety and effectiveness from adults 18 years of age and older. Emergency Use Authorization of Pfizer BioNTech COVID-19 Vaccine does not include use in individuals younger than 16 years of age.

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## 11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy [see *Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)*]. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

## 13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

## 14 CLINICAL PHARMACOLOGY

### 14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

## 18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

### 18.1 Efficacy in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the  $\geq 56$ -year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 5 presents the specific demographic characteristics in the studied population.

**Table 5: Demographics (population for the primary efficacy endpoint)<sup>a</sup>**

	<b>Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)</b>	<b>Placebo (N=18,379) n (%)</b>
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other <sup>b</sup>	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities <sup>c</sup>		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

b. Includes multiracial and not reported.

c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease

- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index  $\geq 30$  kg/m<sup>2</sup>)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

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Efficacy Against COVID-19

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 to 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 to 17 years of age began enrollment from September 16, 2020 and 12 to 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 6.

**Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population**

<b>First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*</b>			
<b>Subgroup</b>	<b>Pfizer-BioNTech COVID-19 Vaccine N<sup>a</sup>=18,198 Cases n<sup>1</sup><sup>b</sup> Surveillance Time<sup>c</sup> (n<sup>2</sup><sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=18,325 Cases n<sup>1</sup><sup>b</sup> Surveillance Time<sup>c</sup> (n<sup>2</sup><sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
All subjects <sup>c</sup>	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6) <sup>f</sup>
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1) <sup>g</sup>
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9) <sup>g</sup>
<b>First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection</b>			
<b>Subgroup</b>	<b>Pfizer-BioNTech COVID-19 Vaccine N<sup>a</sup>=19,965 Cases n<sup>1</sup><sup>b</sup> Surveillance Time<sup>c</sup> (n<sup>2</sup><sup>d</sup>)</b>	<b>Placebo N<sup>a</sup>=20,172 Cases n<sup>1</sup><sup>b</sup> Surveillance Time<sup>c</sup> (n<sup>2</sup><sup>d</sup>)</b>	<b>Vaccine Efficacy % (95% CI)</b>
All subjects <sup>c</sup>	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3) <sup>f</sup>
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7) <sup>g</sup>
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9) <sup>g</sup>

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

\* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

- a. N = number of participants in the specified group.
- b. n1 = Number of participants meeting the endpoint definition.
- c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
- d. n2 = Number of participants at risk for the endpoint.

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- e. No confirmed cases were identified in participants 12 to 15 years of age.
  - f. Credible interval for VE was calculated using a beta-binomial model with a beta (0.700102, 1) prior for  $\theta=r(1-VE)/(1+r(1-VE))$ , where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
  - g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

## 19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2). After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

### Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light, in the original cartons, until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

### Thawed Vials Before Dilution

#### *Thawed Under Refrigeration*

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

#### *Transportation at 2°C to 8°C (35°F to 46°F)*

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).

#### *Thawed at Room Temperature*

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions.

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Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.


**20 PATIENT COUNSELING INFORMATION**

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

**21 CONTACT INFORMATION**

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
<a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> 	<p>1-877-829-2619 (1-877-VAX-CO19)</p>

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see [www.cvdvaccine.com](http://www.cvdvaccine.com).



Manufactured by  
Pfizer Inc., New York, NY 10017



Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

LAB-1457-5.0

Revised: January 2021

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**GLOBAL LABELING MANAGEMENT  
EUA Fact Sheet for HCP and Full EUA PI Safety Updates Log**

**PRODUCT NAME: Pfizer-BioNTech COVID-19 Vaccine**

**Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers and Full EUA Prescribing Information Version History for the Reporting Period 1 January 2021 to 31 January 2021:**

Version number	Effective Date	Sections Changed
<b>Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers</b>		
LAB-1450-5.0	25-Jan-2021	Adverse Reactions
<b>Full EUA Prescribing Information</b>		
LAB-1457-5.0	25-Jan-2021	6 OVERALL SAFETY SUMMARY

**Emergency Use Authorization Fact Sheet for Healthcare Providers**

**EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)**

No safety changes during the reporting period

**SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDER**

No safety changes during the reporting period

**DESCRIPTION OF COVID-19**

No safety changes during the reporting period

**DOSAGE AND ADMINISTRATION - Storage and Handling**

No safety changes during the reporting period

**DOSAGE AND ADMINISTRATION - Dosing and Schedule**

No safety changes during the reporting period

**DOSAGE AND ADMINISTRATION - Administration**

No safety changes during the reporting period

**Contraindications**

No safety changes during the reporting period

**PFIZER CONFIDENTIAL**

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Please refer to the EUA Fact Sheet for the Healthcare Provider and the Full EUA Product Information as the original source of labeling information.

FDA-CBER-2021-5683-1079392

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**GLOBAL LABELING MANAGEMENT  
EUA Fact Sheet for HCP and Full EUA PI Safety Updates Log**

**PRODUCT NAME: Pfizer-BioNTech COVID-19 Vaccine**

**Warnings**

No safety changes during the reporting period

**Adverse Reactions**

<b>LAB-1450-5.0</b>	<b>25-Jan-2021</b>	<b>2021-0066980</b>
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**Safety/Non-safety: Safety**

**Content change:**

Severe allergic reactions, including anaphylaxis, have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

**Use with Other Vaccines**

No safety changes during the reporting period

**INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS**

No safety changes during the reporting period

**MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION**

No safety changes during the reporting period

**OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.**

No safety changes during the reporting period

**ADDITIONAL INFORMATION**

No safety changes during the reporting period

**AVAILABLE ALTERNATIVES**

No safety changes during the reporting period

**AUTHORITY FOR ISSUANCE OF THE EUA**

No safety changes during the reporting period

**The Countermeasures Injury Compensation Program**

No safety changes during the reporting period

**PFIZER CONFIDENTIAL**

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Please refer to the EUA Fact Sheet for the Healthcare Provider and the Full EUA Product Information as the original source of labeling information.

FDA-CBER-2021-5683-1079393

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**GLOBAL LABELING MANAGEMENT  
EUA Fact Sheet for HCP and Full EUA PI Safety Updates Log**

**PRODUCT NAME: Pfizer-BioNTech COVID-19 Vaccine**

**Full Emergency Use Authorization Prescribing Information**

**1 AUTHORIZED USE**

No safety changes during the reporting period

**2 DOSAGE AND ADMINISTRATION**

No safety changes during the reporting period

**3 DOSAGE FORMS AND STRENGTHS**

No safety changes during the reporting period

**4 CONTRAINDICATIONS**

No safety changes during the reporting period

**5 WARNINGS AND PRECAUTIONS**

No safety changes during the reporting period

**6 OVERALL SAFETY SUMMARY**

<b>LAB-1457-5.0</b>	<b>25-Jan-2021</b>	<b>2021-0066980</b>
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**Safety/Non-safety: Safety**

**Content change:**

Severe allergic reactions, including anaphylaxis, have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

**8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERROR**

No safety changes during the reporting period

**10 DRUG INTERACTIONS**

No safety changes during the reporting period

**11 USE IN SPECIFIC POPULATION**

No safety changes during the reporting period

**PFIZER CONFIDENTIAL**

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Please refer to the EUA Fact Sheet for the Healthcare Provider and the Full EUA Product Information as the original source of labeling information.

FDA-CBER-2021-5683-1079394

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**GLOBAL LABELING MANAGEMENT**  
**EUA Fact Sheet for HCP and Full EUA PI Safety Updates Log**

**PRODUCT NAME: Pfizer-BioNTech COVID-19 Vaccine**

**13 DESCRIPTION**

No safety changes during the reporting period

**14 CLINICAL PHARMACOLOGY**

No safety changes during the reporting period

**18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA**

No safety changes during the reporting period

**19 HOW SUPPLIED/STORAGE AND HANDLING**

No safety changes during the reporting period

**20 PATIENT COUNSELING INFORMATION**

No safety changes during the reporting period

**21 CONTACT INFORMATION**

No safety changes during the reporting period

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**PFIZER CONFIDENTIAL**

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Please refer to the EUA Fact Sheet for the Healthcare Provider and the Full EUA Product Information as the original source of labeling information.

FDA-CBER-2021-5683-1079395



**APPENDIX 2 Interval Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non-Medically Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

PF-07302048 - ALL

Reporting Period: 01-JAN-2021 Through 31-JAN-2021  
Total Number of Cases: 14525 (100%) (ALL) / 14525 (OVERALL)  
Total Number of Adverse Events (PT): 51765 (ALL)

**NON CT**

Total Number of Cases: 14525  
Total Number of Adverse Events (PT): 51765

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		Number of Cases	Percentage (%)
<b>Sex</b>			
	FEMALE	10011	68.9 %
	MALE	3093	21.3 %
	NO DATA	1421	9.8 %
<b>Age Range</b>			
Min = 0.01 Years	0 to 27 days	4	0.0 %
Max = 104.0 Years	28 days to 23 months	32	0.2 %
Mean = 49.1	2 to 11 years	20	0.1 %
Median = 46.0	12 to 17 years	14	0.1 %
Standard Deviation = 18.6	18 - 30 years	1764	12.1 %
n = 11294	31 - 50 years	4809	33.1 %
	51 - 64 years	2552	17.6 %
	65 - 74 years	686	4.7 %
	Greater than or equal to 75 years	1473	10.1 %
	Unknown	3171	21.8 %
<b>Country Where Event Occurred</b>			
	UNITED STATES	6352	43.7 %
	UNITED KINGDOM	4551	31.3 %
	GERMANY	713	4.9 %
	ITALY	654	4.5 %
	ISRAEL	292	2.0 %
	ROMANIA	227	1.6 %
	SPAIN	189	1.3 %
	PORTUGAL	166	1.1 %
	DENMARK	151	1.0 %
	CANADA	139	1.0 %
	SWEDEN	126	0.9 %
	POLAND	125	0.9 %
	GREECE	116	0.8 %
	MEXICO	111	0.8 %
	FRANCE	102	0.7 %
	HUNGARY	57	0.4 %
	NORWAY	55	0.4 %
	ICELAND	41	0.3 %
	SERBIA	30	0.2 %
	BELGIUM	27	0.2 %





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		Number of Cases	Percentage (%)
<b>Country Where Event Occured</b>			
	SLOVAKIA	23	0.2 %
	AUSTRIA	21	0.1 %
	BULGARIA	20	0.1 %
	FINLAND	20	0.1 %
	LATVIA	20	0.1 %
	CZECH REPUBLIC	19	0.1 %
	CHILE	18	0.1 %
	PUERTO RICO	17	0.1 %
	CROATIA	15	0.1 %
	COSTA RICA	14	0.1 %
	SWITZERLAND	14	0.1 %
	ESTONIA	13	0.1 %
	NETHERLANDS	11	0.1 %
	CYPRUS	10	0.1 %
	LITHUANIA	10	0.1 %
	UNITED ARAB EMIRATES	10	0.1 %
	IRELAND	8	0.1 %
	SAUDI ARABIA	8	0.1 %
	SINGAPORE	7	0.0 %
	SLOVENIA	7	0.0 %
	MALTA	5	0.0 %
	NORTHERN MARIANA ISLANDS	2	0.0 %
	UNITED STATES MINOR OUTLYING ISLANDS	2	0.0 %
	ANDORRA	1	0.0 %
	BAHRAIN	1	0.0 %
	BERMUDA	1	0.0 %
	COLOMBIA	1	0.0 %
	KUWAIT	1	0.0 %
	LUXEMBOURG	1	0.0 %
	QATAR	1	0.0 %
<b>Source</b>			
	Clinical Study	13	0.1 %
	Literature - Study	14	0.1 %
	Solicited	1	0.0 %
	Spontaneous	14497	99.8 %
<b>Case Seriousness</b>			
	SERIOUS	5506	37.9 %
	NONSERIOUS	9019	62.1 %
<b>HP/Medically Confirmed</b>			
	Yes	9193	63.3 %
	No	5332	36.7 %
<b>Special Populations</b>			
	<b>Pregnant/Breastfeeding Women</b>		
	Yes	200	1.4 %
	<b>Pediatric Non EIU</b>		
	Yes	37	0.3 %



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	Number of Cases	Percentage (%)
<b>Elderly</b>		
Yes	2159	14.9 %
<b>Race/Ethnicity</b>		
ASIAN - HISPANIC OR LATINO	9	0.1 %
ASIAN - NO DATA	176	1.2 %
ASIAN - NOT HISPANIC OR LATINO	195	1.3 %
ASIAN - OTHER	1	0.0 %
BLACK - HISPANIC OR LATINO	7	0.0 %
BLACK - NO DATA	139	1.0 %
BLACK - NOT HISPANIC OR LATINO	87	0.6 %
CAUCASIAN - HISPANIC OR LATINO	146	1.0 %
CAUCASIAN - NO DATA	1296	8.9 %
CAUCASIAN - NOT HISPANIC OR LATINO	1733	11.9 %
CAUCASIAN - OTHER	3	0.0 %
NATIVE AMERICAN - HISPANIC OR LATINO	5	0.0 %
NATIVE AMERICAN - NO DATA	25	0.2 %
NATIVE AMERICAN - NOT HISPANIC OR LATINO	10	0.1 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO	1	0.0 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA	3	0.0 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO	9	0.1 %
NO DATA - HISPANIC OR LATINO	236	1.6 %
NO DATA - NO DATA	10363	71.3 %
NO DATA - NOT HISPANIC OR LATINO	55	0.4 %
NO DATA - OTHER	26	0.2 %

**APPENDIX 2 Interval Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non-Medically Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

PF-07302048 - ALL

Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14525 (100%) (ALL) / 14525 (OVERALL)

Total Number of Adverse Events (PT): 51765 (ALL)

**NON CT**

Total Number of Cases: 14525

Total Number of Adverse Events (PT): 51765

Preferred Term	System Organ Class (SOC)	Number of Cases
Headache	Nervous system disorders	3512 (24.18%)
Pyrexia	General disorders and administration site conditions	2773 (19.09%)
Fatigue	General disorders and administration site conditions	2401 (16.53%)
Chills	General disorders and administration site conditions	2087 (14.37%)
Vaccination site pain	General disorders and administration site conditions	2018 (13.89%)
Nausea	Gastrointestinal disorders	1722 (11.86%)
Myalgia	Musculoskeletal and connective tissue disorders	1628 (11.21%)
Pain in extremity	Musculoskeletal and connective tissue disorders	1472 (10.13%)
Pain	General disorders and administration site conditions	1454 (10.01%)
Arthralgia	Musculoskeletal and connective tissue disorders	1173 (8.08%)
Dizziness	Nervous system disorders	1107 (7.62%)
Drug ineffective	General disorders and administration site conditions	1046 (7.20%)
Malaise	General disorders and administration site conditions	924 (6.36%)
Lymphadenopathy	Blood and lymphatic system disorders	711 (4.90%)
COVID-19	Infections and infestations	688 (4.74%)
Asthenia	General disorders and administration site conditions	597 (4.11%)
Diarrhoea	Gastrointestinal disorders	574 (3.95%)
Vomiting	Gastrointestinal disorders	509 (3.50%)
Dyspnoea	Respiratory, thoracic and mediastinal disorders	497 (3.42%)
Rash	Skin and subcutaneous tissue disorders	471 (3.24%)
Pruritus	Skin and subcutaneous tissue disorders	460 (3.17%)
Paraesthesia	Nervous system disorders	445 (3.06%)
Vaccination site erythema	General disorders and administration site conditions	364 (2.51%)
Cough	Respiratory, thoracic and mediastinal disorders	350 (2.41%)
Vaccination site swelling	General disorders and administration site conditions	350 (2.41%)
Influenza like illness	General disorders and administration site conditions	344 (2.37%)
Hypoaesthesia	Nervous system disorders	332 (2.29%)
Urticaria	Skin and subcutaneous tissue disorders	311 (2.14%)
Inappropriate schedule of product administration	Injury, poisoning and procedural complications	297 (2.04%)
Erythema	Skin and subcutaneous tissue disorders	296 (2.04%)
Feeling abnormal	General disorders and administration site conditions	295 (2.03%)
Oropharyngeal pain	Respiratory, thoracic and mediastinal disorders	289 (1.99%)
Off label use	Injury, poisoning and procedural complications	288 (1.98%)
Hyperhidrosis	Skin and subcutaneous tissue disorders	285 (1.96%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Tachycardia	Cardiac disorders	272 (1.87%)
Back pain	Musculoskeletal and connective tissue disorders	270 (1.86%)
Neck pain	Musculoskeletal and connective tissue disorders	267 (1.84%)
Product use issue	Injury, poisoning and procedural complications	264 (1.82%)
Feeling hot	General disorders and administration site conditions	262 (1.80%)
SARS-CoV-2 test positive	Investigations	252 (1.73%)
Heart rate increased	Investigations	236 (1.62%)
Peripheral swelling	General disorders and administration site conditions	234 (1.61%)
Tremor	Nervous system disorders	233 (1.60%)
Migraine	Nervous system disorders	221 (1.52%)
Palpitations	Cardiac disorders	219 (1.51%)
Chest discomfort	General disorders and administration site conditions	203 (1.40%)
Feeling cold	General disorders and administration site conditions	201 (1.38%)
Paraesthesia oral	Gastrointestinal disorders	197 (1.36%)
Lethargy	Nervous system disorders	195 (1.34%)
Chest pain	General disorders and administration site conditions	193 (1.33%)
Decreased appetite	Metabolism and nutrition disorders	192 (1.32%)
Somnolence	Nervous system disorders	178 (1.23%)
Insomnia	Psychiatric disorders	177 (1.22%)
Swelling	General disorders and administration site conditions	172 (1.18%)
Death	General disorders and administration site conditions	167 (1.15%)
Dysgeusia	Nervous system disorders	166 (1.14%)
Vaccination site warmth	General disorders and administration site conditions	164 (1.13%)
Anaphylactic reaction	Immune system disorders	162 (1.12%)
Hypersensitivity	Immune system disorders	161 (1.11%)
Lymph node pain	Blood and lymphatic system disorders	151 (1.04%)
Abdominal pain upper	Gastrointestinal disorders	147 (1.01%)
Poor quality product administered	Injury, poisoning and procedural complications	145 (1.00%)
Flushing	Vascular disorders	144 (0.99%)
Abdominal pain	Gastrointestinal disorders	142 (0.98%)
Hypertension	Vascular disorders	141 (0.97%)
Syncope	Nervous system disorders	139 (0.96%)
Musculoskeletal stiffness	Musculoskeletal and connective tissue disorders	138 (0.95%)
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders	138 (0.95%)
Illness	General disorders and administration site conditions	136 (0.94%)
Vaccination site pruritus	General disorders and administration site conditions	136 (0.94%)
Hypoaesthesia oral	Gastrointestinal disorders	129 (0.89%)
Limb discomfort	Musculoskeletal and connective tissue disorders	126 (0.87%)
Vertigo	Ear and labyrinth disorders	126 (0.87%)
Blood pressure increased	Investigations	124 (0.85%)
Body temperature increased	Investigations	120 (0.83%)
Swelling face	General disorders and administration site conditions	119 (0.82%)
Muscular weakness	Musculoskeletal and connective tissue disorders	118 (0.81%)
Axillary pain	General disorders and administration site conditions	116 (0.80%)
Suspected COVID-19	Infections and infestations	115 (0.79%)
Underdose	Injury, poisoning and procedural complications	113 (0.78%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Throat tightness	Respiratory, thoracic and mediastinal disorders	107 (0.74%)
Presyncope	Nervous system disorders	106 (0.73%)
Vision blurred	Eye disorders	106 (0.73%)
Facial paralysis	Nervous system disorders	105 (0.72%)
Nasal congestion	Respiratory, thoracic and mediastinal disorders	102 (0.70%)
Muscle spasms	Musculoskeletal and connective tissue disorders	98 (0.67%)
Rash pruritic	Skin and subcutaneous tissue disorders	97 (0.67%)
Nasopharyngitis	Infections and infestations	96 (0.66%)
Anxiety	Psychiatric disorders	95 (0.65%)
Eye pain	Eye disorders	94 (0.65%)
Hot flush	Vascular disorders	92 (0.63%)
Rash erythematous	Skin and subcutaneous tissue disorders	91 (0.63%)
Swollen tongue	Gastrointestinal disorders	89 (0.61%)
Throat irritation	Respiratory, thoracic and mediastinal disorders	88 (0.61%)
Maternal exposure during pregnancy	Injury, poisoning and procedural complications	87 (0.60%)
Incorrect route of product administration	Injury, poisoning and procedural complications	85 (0.59%)
Product preparation issue	Injury, poisoning and procedural complications	85 (0.59%)
Dysphagia	Gastrointestinal disorders	84 (0.58%)
Burning sensation	Nervous system disorders	83 (0.57%)
Hypotension	Vascular disorders	83 (0.57%)
Lip swelling	Gastrointestinal disorders	83 (0.57%)
Product preparation error	Injury, poisoning and procedural complications	81 (0.56%)
Ageusia	Nervous system disorders	79 (0.54%)
Cold sweat	Skin and subcutaneous tissue disorders	77 (0.53%)
Confusional state	Psychiatric disorders	77 (0.53%)
Ear pain	Ear and labyrinth disorders	76 (0.52%)
Pharyngeal swelling	Respiratory, thoracic and mediastinal disorders	76 (0.52%)
Circumstance or information capable of leading to medication error	Injury, poisoning and procedural complications	75 (0.52%)
Loss of consciousness	Nervous system disorders	75 (0.52%)
Night sweats	Skin and subcutaneous tissue disorders	74 (0.51%)
Discomfort	General disorders and administration site conditions	71 (0.49%)
Dry mouth	Gastrointestinal disorders	71 (0.49%)
Anosmia	Nervous system disorders	70 (0.48%)
Exposure via breast milk	Injury, poisoning and procedural complications	70 (0.48%)
Influenza	Infections and infestations	68 (0.47%)
Gait disturbance	General disorders and administration site conditions	67 (0.46%)
Tinnitus	Ear and labyrinth disorders	67 (0.46%)
Condition aggravated	General disorders and administration site conditions	66 (0.45%)
Abdominal discomfort	Gastrointestinal disorders	65 (0.45%)
Bone pain	Musculoskeletal and connective tissue disorders	65 (0.45%)
Rash macular	Skin and subcutaneous tissue disorders	65 (0.45%)
Herpes zoster	Infections and infestations	64 (0.44%)
Overdose	Injury, poisoning and procedural complications	62 (0.43%)
Eye swelling	Eye disorders	61 (0.42%)
Vaccination site mass	General disorders and administration site conditions	58 (0.40%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Pallor	Vascular disorders	54 (0.37%)
Fall	Injury, poisoning and procedural complications	51 (0.35%)
Sleep disorder	Psychiatric disorders	51 (0.35%)
Peripheral coldness	Vascular disorders	50 (0.34%)
Mobility decreased	Musculoskeletal and connective tissue disorders	49 (0.34%)
Feeling of body temperature change	General disorders and administration site conditions	47 (0.32%)
Sneezing	Respiratory, thoracic and mediastinal disorders	47 (0.32%)
Vaccination site movement impairment	General disorders and administration site conditions	47 (0.32%)
Vaccination site rash	General disorders and administration site conditions	47 (0.32%)
Wrong technique in product usage process	Injury, poisoning and procedural complications	47 (0.32%)
Balance disorder	Nervous system disorders	45 (0.31%)
Dizziness postural	Nervous system disorders	45 (0.31%)
Oxygen saturation decreased	Investigations	45 (0.31%)
Allergy to vaccine	Immune system disorders	44 (0.30%)
Wheezing	Respiratory, thoracic and mediastinal disorders	44 (0.30%)
Pain in jaw	Musculoskeletal and connective tissue disorders	43 (0.30%)
Vaccination site bruising	General disorders and administration site conditions	43 (0.30%)
Cerebrovascular accident	Nervous system disorders	41 (0.28%)
Disturbance in attention	Nervous system disorders	41 (0.28%)
Vaccination site induration	General disorders and administration site conditions	41 (0.28%)
Epistaxis	Respiratory, thoracic and mediastinal disorders	40 (0.28%)
Head discomfort	Nervous system disorders	40 (0.28%)
Angioedema	Skin and subcutaneous tissue disorders	39 (0.27%)
Facial pain	General disorders and administration site conditions	39 (0.27%)
Sudden death	General disorders and administration site conditions	39 (0.27%)
Cardiac arrest	Cardiac disorders	38 (0.26%)
Exposure to SARS-CoV-2	Injury, poisoning and procedural complications	38 (0.26%)
Joint swelling	Musculoskeletal and connective tissue disorders	38 (0.26%)
Seizure	Nervous system disorders	38 (0.26%)
Photophobia	Eye disorders	37 (0.25%)
Vaccination site reaction	General disorders and administration site conditions	37 (0.25%)
Disease recurrence	General disorders and administration site conditions	36 (0.25%)
Dysphonia	Respiratory, thoracic and mediastinal disorders	36 (0.25%)
Product colour issue	Product issues	36 (0.25%)
Eye pruritus	Eye disorders	35 (0.24%)
Hypersomnia	Nervous system disorders	35 (0.24%)
Movement disorder	Nervous system disorders	35 (0.24%)
Visual impairment	Eye disorders	35 (0.24%)
Dehydration	Metabolism and nutrition disorders	34 (0.23%)
Thirst	General disorders and administration site conditions	33 (0.23%)
Vaccination site discomfort	General disorders and administration site conditions	33 (0.23%)
Asthma	Respiratory, thoracic and mediastinal disorders	32 (0.22%)
General physical health deterioration	General disorders and administration site conditions	32 (0.22%)
Joint range of motion decreased	Musculoskeletal and connective tissue disorders	32 (0.22%)
Loss of personal independence in daily activities	Social circumstances	32 (0.22%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Neuralgia	Nervous system disorders	32 (0.22%)
Product administered at inappropriate site	Injury, poisoning and procedural complications	32 (0.22%)
Restlessness	Psychiatric disorders	32 (0.22%)
Taste disorder	Nervous system disorders	31 (0.21%)
Tenderness	General disorders and administration site conditions	31 (0.21%)
Vaccination site inflammation	General disorders and administration site conditions	31 (0.21%)
Anaphylactic shock	Immune system disorders	30 (0.21%)
Contusion	Injury, poisoning and procedural complications	30 (0.21%)
Dyspepsia	Gastrointestinal disorders	30 (0.21%)
Eye irritation	Eye disorders	30 (0.21%)
Muscle tightness	Musculoskeletal and connective tissue disorders	30 (0.21%)
Tension headache	Nervous system disorders	30 (0.21%)
Pneumonia	Infections and infestations	29 (0.20%)
Poor quality sleep	Nervous system disorders	29 (0.20%)
Skin burning sensation	Skin and subcutaneous tissue disorders	29 (0.20%)
Circulatory collapse	Vascular disorders	28 (0.19%)
Dry throat	Respiratory, thoracic and mediastinal disorders	28 (0.19%)
Lacrimation increased	Eye disorders	28 (0.19%)
Muscle twitching	Musculoskeletal and connective tissue disorders	28 (0.19%)
Musculoskeletal pain	Musculoskeletal and connective tissue disorders	28 (0.19%)
Atrial fibrillation	Cardiac disorders	27 (0.19%)
Blood pressure decreased	Investigations	27 (0.19%)
Inflammation	General disorders and administration site conditions	27 (0.19%)
Arthritis	Musculoskeletal and connective tissue disorders	26 (0.18%)
Hyperaesthesia	Nervous system disorders	26 (0.18%)
Nervousness	Psychiatric disorders	26 (0.18%)
Myocardial infarction	Cardiac disorders	25 (0.17%)
Ocular hyperaemia	Eye disorders	25 (0.17%)
Product temperature excursion issue	Product issues	25 (0.17%)
Blood glucose increased	Investigations	24 (0.17%)
Musculoskeletal discomfort	Musculoskeletal and connective tissue disorders	24 (0.17%)
Rash papular	Skin and subcutaneous tissue disorders	24 (0.17%)
Sensation of foreign body	General disorders and administration site conditions	24 (0.17%)
Vaccination site urticaria	General disorders and administration site conditions	24 (0.17%)
Blister	Skin and subcutaneous tissue disorders	23 (0.16%)
Breast pain	Reproductive system and breast disorders	23 (0.16%)
Ear discomfort	Ear and labyrinth disorders	23 (0.16%)
Exposure during pregnancy	Injury, poisoning and procedural complications	23 (0.16%)
Injection site pain	General disorders and administration site conditions	23 (0.16%)
Joint stiffness	Musculoskeletal and connective tissue disorders	23 (0.16%)
Pain of skin	Skin and subcutaneous tissue disorders	23 (0.16%)
Retching	Gastrointestinal disorders	23 (0.16%)
Speech disorder	Nervous system disorders	23 (0.16%)
Vaccination site paraesthesia	General disorders and administration site conditions	23 (0.16%)
Lip oedema	Gastrointestinal disorders	22 (0.15%)
Middle insomnia	Psychiatric disorders	22 (0.15%)



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Preferred Term	System Organ Class (SOC)	Number of Cases
Respiratory distress	Respiratory, thoracic and mediastinal disorders	22 (0.15%)
Skin discolouration	Skin and subcutaneous tissue disorders	22 (0.15%)
Body temperature abnormal	Investigations	21 (0.14%)
Eye disorder	Eye disorders	21 (0.14%)
Gait inability	General disorders and administration site conditions	21 (0.14%)
Hallucination	Psychiatric disorders	21 (0.14%)
Laryngeal oedema	Respiratory, thoracic and mediastinal disorders	21 (0.14%)
Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	21 (0.14%)
Oral herpes	Infections and infestations	21 (0.14%)
Productive cough	Respiratory, thoracic and mediastinal disorders	21 (0.14%)
Skin warm	Skin and subcutaneous tissue disorders	21 (0.14%)
Swelling of eyelid	Eye disorders	21 (0.14%)
Agitation	Psychiatric disorders	20 (0.14%)
Dysstasia	Nervous system disorders	20 (0.14%)
Cellulitis	Infections and infestations	19 (0.13%)
Delirium	Psychiatric disorders	19 (0.13%)
Disorientation	Psychiatric disorders	19 (0.13%)
Renal pain	Renal and urinary disorders	19 (0.13%)
Tachypnoea	Respiratory, thoracic and mediastinal disorders	19 (0.13%)
Unresponsive to stimuli	Nervous system disorders	19 (0.13%)
Vaccination site hypoaesthesia	General disorders and administration site conditions	19 (0.13%)
Vaccination site oedema	General disorders and administration site conditions	19 (0.13%)
Acute myocardial infarction	Cardiac disorders	18 (0.12%)
Gastrointestinal disorder	Gastrointestinal disorders	18 (0.12%)
Incorrect dose administered	Injury, poisoning and procedural complications	18 (0.12%)
Sensory disturbance	Nervous system disorders	18 (0.12%)
Sinus pain	Respiratory, thoracic and mediastinal disorders	18 (0.12%)
Spinal pain	Musculoskeletal and connective tissue disorders	18 (0.12%)
Weight decreased	Investigations	18 (0.12%)
Abnormal dreams	Psychiatric disorders	17 (0.12%)
Crying	General disorders and administration site conditions	17 (0.12%)
Depressed level of consciousness	Nervous system disorders	17 (0.12%)
Dermatitis allergic	Skin and subcutaneous tissue disorders	17 (0.12%)
Oedema	General disorders and administration site conditions	17 (0.12%)
Parosmia	Nervous system disorders	17 (0.12%)
Pharyngeal paraesthesia	Respiratory, thoracic and mediastinal disorders	17 (0.12%)
Stomatitis	Gastrointestinal disorders	17 (0.12%)
Bradycardia	Cardiac disorders	16 (0.11%)
Cardiac failure	Cardiac disorders	16 (0.11%)
Deafness	Ear and labyrinth disorders	16 (0.11%)
Dysarthria	Nervous system disorders	16 (0.11%)
Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	16 (0.11%)
Feeling drunk	General disorders and administration site conditions	16 (0.11%)
Head injury	Injury, poisoning and procedural complications	16 (0.11%)
Muscle fatigue	Musculoskeletal and connective tissue disorders	16 (0.11%)
Oropharyngeal discomfort	Respiratory, thoracic and mediastinal disorders	16 (0.11%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Rash maculo-papular	Skin and subcutaneous tissue disorders	16 (0.11%)
Vaccination site joint movement impairment	General disorders and administration site conditions	16 (0.11%)
Abdominal distension	Gastrointestinal disorders	15 (0.10%)
Accidental overdose	Injury, poisoning and procedural complications	15 (0.10%)
Hypoacusis	Ear and labyrinth disorders	15 (0.10%)
Memory impairment	Nervous system disorders	15 (0.10%)
Petechiae	Skin and subcutaneous tissue disorders	15 (0.10%)
Sinus congestion	Respiratory, thoracic and mediastinal disorders	15 (0.10%)
Urinary tract infection	Infections and infestations	15 (0.10%)
Arrhythmia	Cardiac disorders	14 (0.10%)
Local reaction	General disorders and administration site conditions	14 (0.10%)
Mouth ulceration	Gastrointestinal disorders	14 (0.10%)
Respiratory rate increased	Investigations	14 (0.10%)
Sensory loss	Nervous system disorders	14 (0.10%)
Sepsis	Infections and infestations	14 (0.10%)
Sinus headache	Nervous system disorders	14 (0.10%)
Sinusitis	Infections and infestations	14 (0.10%)
Sinus tachycardia	Cardiac disorders	14 (0.10%)
Toothache	Gastrointestinal disorders	14 (0.10%)
Upper respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	14 (0.10%)
Vaccination site discolouration	General disorders and administration site conditions	14 (0.10%)
Vaccination site nodule	General disorders and administration site conditions	14 (0.10%)
		14 (0.10%)
Acute kidney injury	Renal and urinary disorders	13 (0.09%)
Axillary mass	Musculoskeletal and connective tissue disorders	13 (0.09%)
C-reactive protein increased	Investigations	13 (0.09%)
Depressed mood	Psychiatric disorders	13 (0.09%)
Dermatitis	Skin and subcutaneous tissue disorders	13 (0.09%)
Facial paresis	Nervous system disorders	13 (0.09%)
Feeding disorder	Metabolism and nutrition disorders	13 (0.09%)
Hemiparesis	Nervous system disorders	13 (0.09%)
Hypertensive crisis	Vascular disorders	13 (0.09%)
Infection	Infections and infestations	13 (0.09%)
Irritability	Psychiatric disorders	13 (0.09%)
Lower respiratory tract infection	Infections and infestations	13 (0.09%)
Lymphadenitis	Blood and lymphatic system disorders	13 (0.09%)
Neuropathy peripheral	Nervous system disorders	13 (0.09%)
Oedema peripheral	General disorders and administration site conditions	13 (0.09%)
Paralysis	Nervous system disorders	13 (0.09%)
Product administered to patient of inappropriate age	Injury, poisoning and procedural complications	13 (0.09%)
Product administration error	Injury, poisoning and procedural complications	13 (0.09%)
Rash vesicular	Skin and subcutaneous tissue disorders	13 (0.09%)
Sensitive skin	Skin and subcutaneous tissue disorders	13 (0.09%)
Therapeutic response unexpected	General disorders and administration site conditions	13 (0.09%)
Abdominal pain lower	Gastrointestinal disorders	12 (0.08%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Asthenopia	Eye disorders	12 (0.08%)
Body temperature decreased	Investigations	12 (0.08%)
Bronchospasm	Respiratory, thoracic and mediastinal disorders	12 (0.08%)
Cardiovascular disorder	Cardiac disorders	12 (0.08%)
COVID-19 pneumonia	Infections and infestations	12 (0.08%)
Cyanosis	Vascular disorders	12 (0.08%)
Deep vein thrombosis	Vascular disorders	12 (0.08%)
Diplopia	Eye disorders	12 (0.08%)
Drug hypersensitivity	Immune system disorders	12 (0.08%)
Flatulence	Gastrointestinal disorders	12 (0.08%)
Glossodynia	Gastrointestinal disorders	12 (0.08%)
Hypoglycaemia	Metabolism and nutrition disorders	12 (0.08%)
Lymphoedema	Vascular disorders	12 (0.08%)
Mental impairment	Nervous system disorders	12 (0.08%)
Nightmare	Psychiatric disorders	12 (0.08%)
Odynophagia	Gastrointestinal disorders	12 (0.08%)
Pollakiuria	Renal and urinary disorders	12 (0.08%)
SARS-CoV-2 antibody test negative	Investigations	12 (0.08%)
Tongue discomfort	Gastrointestinal disorders	12 (0.08%)
Tongue oedema	Gastrointestinal disorders	12 (0.08%)
Tongue pruritus	Gastrointestinal disorders	12 (0.08%)
Vaccination site lymphadenopathy	General disorders and administration site conditions	12 (0.08%)
Drug interaction	General disorders and administration site conditions	11 (0.08%)
Exposure via skin contact	Injury, poisoning and procedural complications	11 (0.08%)
Fear	Psychiatric disorders	11 (0.08%)
Gingival pain	Gastrointestinal disorders	11 (0.08%)
Groin pain	Musculoskeletal and connective tissue disorders	11 (0.08%)
Hangover	General disorders and administration site conditions	11 (0.08%)
Hyperglycaemia	Metabolism and nutrition disorders	11 (0.08%)
Hyperventilation	Respiratory, thoracic and mediastinal disorders	11 (0.08%)
Incomplete course of vaccination	Injury, poisoning and procedural complications	11 (0.08%)
Ocular discomfort	Eye disorders	11 (0.08%)
Periorbital swelling	Eye disorders	11 (0.08%)
Skin disorder	Skin and subcutaneous tissue disorders	11 (0.08%)
Skin exfoliation	Skin and subcutaneous tissue disorders	11 (0.08%)
Skin irritation	Skin and subcutaneous tissue disorders	11 (0.08%)
Thrombosis	Vascular disorders	11 (0.08%)
Vaccination site haemorrhage	General disorders and administration site conditions	11 (0.08%)
Vaginal haemorrhage	Reproductive system and breast disorders	11 (0.08%)
Accidental exposure to product	Injury, poisoning and procedural complications	10 (0.07%)
Acute respiratory failure	Respiratory, thoracic and mediastinal disorders	10 (0.07%)
Bedridden	Social circumstances	10 (0.07%)
Blood pressure systolic increased	Investigations	10 (0.07%)
Constipation	Gastrointestinal disorders	10 (0.07%)
Depression	Psychiatric disorders	10 (0.07%)
Dry skin	Skin and subcutaneous tissue disorders	10 (0.07%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Face oedema	General disorders and administration site conditions	10 (0.07%)
Formication	Nervous system disorders	10 (0.07%)
Gastrointestinal pain	Gastrointestinal disorders	10 (0.07%)
Haemoptysis	Respiratory, thoracic and mediastinal disorders	10 (0.07%)
Heart rate irregular	Investigations	10 (0.07%)
Lip pruritus	Gastrointestinal disorders	10 (0.07%)
Mouth swelling	Gastrointestinal disorders	10 (0.07%)
No adverse event	General disorders and administration site conditions	10 (0.07%)
Paranasal sinus discomfort	Respiratory, thoracic and mediastinal disorders	10 (0.07%)
Pulse abnormal	Investigations	10 (0.07%)
Respiratory arrest	Respiratory, thoracic and mediastinal disorders	10 (0.07%)
Rhinitis	Infections and infestations	10 (0.07%)
SARS-CoV-2 antibody test positive	Investigations	10 (0.07%)
Stress	Psychiatric disorders	10 (0.07%)
Sweating fever	Infections and infestations	10 (0.07%)
Thrombocytopenia	Blood and lymphatic system disorders	10 (0.07%)
Vaccination site vesicles	General disorders and administration site conditions	10 (0.07%)
Aphasia	Nervous system disorders	9 (0.06%)
Dry eye	Eye disorders	9 (0.06%)
Ear pruritus	Ear and labyrinth disorders	9 (0.06%)
Feeling jittery	General disorders and administration site conditions	9 (0.06%)
Gastroesophageal reflux disease	Gastrointestinal disorders	9 (0.06%)
Heart rate decreased	Investigations	9 (0.06%)
Ischaemic stroke	Nervous system disorders	9 (0.06%)
Menstruation irregular	Reproductive system and breast disorders	9 (0.06%)
Muscle contractions involuntary	Nervous system disorders	9 (0.06%)
Musculoskeletal disorder	Musculoskeletal and connective tissue disorders	9 (0.06%)
Oral discomfort	Gastrointestinal disorders	9 (0.06%)
Pharyngeal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	9 (0.06%)
Pulmonary embolism	Respiratory, thoracic and mediastinal disorders	9 (0.06%)
Respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	9 (0.06%)
Sinus disorder	Respiratory, thoracic and mediastinal disorders	9 (0.06%)
Skin lesion	Skin and subcutaneous tissue disorders	9 (0.06%)
Tongue disorder	Gastrointestinal disorders	9 (0.06%)
Transient ischaemic attack	Nervous system disorders	9 (0.06%)
Vaccination complication	Injury, poisoning and procedural complications	9 (0.06%)
Vaccination site cellulitis	Infections and infestations	9 (0.06%)
Vaccination site joint pain	General disorders and administration site conditions	9 (0.06%)
Abortion spontaneous	Pregnancy, puerperium and perinatal conditions	8 (0.06%)
Amnesia	Nervous system disorders	8 (0.06%)
Angina pectoris	Cardiac disorders	8 (0.06%)
Aphthous ulcer	Gastrointestinal disorders	8 (0.06%)
Cardiac disorder	Cardiac disorders	8 (0.06%)
Chromaturia	Renal and urinary disorders	8 (0.06%)
Cluster headache	Nervous system disorders	8 (0.06%)
Eczema	Skin and subcutaneous tissue disorders	8 (0.06%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Epilepsy	Nervous system disorders	8 (0.06%)
Eructation	Gastrointestinal disorders	8 (0.06%)
Hallucination, visual	Psychiatric disorders	8 (0.06%)
Herpes virus infection	Infections and infestations	8 (0.06%)
Hypokinesia	Nervous system disorders	8 (0.06%)
Hypothermia	General disorders and administration site conditions	8 (0.06%)
Injected limb mobility decreased	General disorders and administration site conditions	8 (0.06%)
International normalised ratio increased	Investigations	8 (0.06%)
Liquid product physical issue	Product issues	8 (0.06%)
Menstrual disorder	Reproductive system and breast disorders	8 (0.06%)
Mental fatigue	Psychiatric disorders	8 (0.06%)
Neck mass	Musculoskeletal and connective tissue disorders	8 (0.06%)
Oral pain	Gastrointestinal disorders	8 (0.06%)
Panic attack	Psychiatric disorders	8 (0.06%)
Pharyngeal inflammation	Respiratory, thoracic and mediastinal disorders	8 (0.06%)
Upper-airway cough syndrome	Respiratory, thoracic and mediastinal disorders	8 (0.06%)
Vaccination site infection	Infections and infestations	8 (0.06%)
Anaphylactoid reaction	Immune system disorders	7 (0.05%)
Aura	Nervous system disorders	7 (0.05%)
Blood urine present	Investigations	7 (0.05%)
Cerebral haemorrhage	Nervous system disorders	7 (0.05%)
Cognitive disorder	Nervous system disorders	7 (0.05%)
Conjunctivitis	Infections and infestations	7 (0.05%)
Dyskinesia	Nervous system disorders	7 (0.05%)
Eating disorder	Psychiatric disorders	7 (0.05%)
Gingival swelling	Gastrointestinal disorders	7 (0.05%)
Gout	Metabolism and nutrition disorders	7 (0.05%)
Haematemesis	Gastrointestinal disorders	7 (0.05%)
Haematochezia	Gastrointestinal disorders	7 (0.05%)
Leukocytosis	Blood and lymphatic system disorders	7 (0.05%)
Mass	General disorders and administration site conditions	7 (0.05%)
Migraine with aura	Nervous system disorders	7 (0.05%)
Muscle swelling	Musculoskeletal and connective tissue disorders	7 (0.05%)
Nasal oedema	Respiratory, thoracic and mediastinal disorders	7 (0.05%)
Pericarditis	Cardiac disorders	7 (0.05%)
Peripheral vascular disorder	Vascular disorders	7 (0.05%)
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders	7 (0.05%)
Pharyngeal oedema	Respiratory, thoracic and mediastinal disorders	7 (0.05%)
Pneumonia aspiration	Respiratory, thoracic and mediastinal disorders	7 (0.05%)
Respiratory failure	Respiratory, thoracic and mediastinal disorders	7 (0.05%)
Rhinalgia	Respiratory, thoracic and mediastinal disorders	7 (0.05%)
Salivary hypersecretion	Gastrointestinal disorders	7 (0.05%)
Skin reaction	Skin and subcutaneous tissue disorders	7 (0.05%)
Supraventricular tachycardia	Cardiac disorders	7 (0.05%)
Tongue ulceration	Gastrointestinal disorders	7 (0.05%)
Tonsillar hypertrophy	Respiratory, thoracic and mediastinal disorders	7 (0.05%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Urinary incontinence	Renal and urinary disorders	7 (0.05%)
Urinary retention	Renal and urinary disorders	7 (0.05%)
Abnormal faeces	Gastrointestinal disorders	6 (0.04%)
Abnormal sensation in eye	Eye disorders	6 (0.04%)
Anger	Psychiatric disorders	6 (0.04%)
Blepharospasm	Eye disorders	6 (0.04%)
Blindness	Eye disorders	6 (0.04%)
Blood glucose decreased	Investigations	6 (0.04%)
Blood pressure fluctuation	Vascular disorders	6 (0.04%)
Breast swelling	Reproductive system and breast disorders	6 (0.04%)
Cardio-respiratory arrest	Cardiac disorders	6 (0.04%)
Choking	Respiratory, thoracic and mediastinal disorders	6 (0.04%)
Dysuria	Renal and urinary disorders	6 (0.04%)
Eye contusion	Injury, poisoning and procedural complications	6 (0.04%)
Eye haemorrhage	Eye disorders	6 (0.04%)
Eye movement disorder	Eye disorders	6 (0.04%)
Frequent bowel movements	Gastrointestinal disorders	6 (0.04%)
Gingival bleeding	Gastrointestinal disorders	6 (0.04%)
Haematoma	Vascular disorders	6 (0.04%)
Hyperpyrexia	General disorders and administration site conditions	6 (0.04%)
Hypophagia	Metabolism and nutrition disorders	6 (0.04%)
Impaired work ability	Social circumstances	6 (0.04%)
Increased upper airway secretion	Respiratory, thoracic and mediastinal disorders	6 (0.04%)
Nasal discomfort	Respiratory, thoracic and mediastinal disorders	6 (0.04%)
Nerve compression	Nervous system disorders	6 (0.04%)
Occupational exposure to SARS-CoV-2	Injury, poisoning and procedural complications	6 (0.04%)
Oral mucosal blistering	Gastrointestinal disorders	6 (0.04%)
Oral pruritus	Gastrointestinal disorders	6 (0.04%)
Painful respiration	Respiratory, thoracic and mediastinal disorders	6 (0.04%)
Product leakage	Product issues	6 (0.04%)
Renal failure	Renal and urinary disorders	6 (0.04%)
Respiratory disorder	Respiratory, thoracic and mediastinal disorders	6 (0.04%)
Restless legs syndrome	Nervous system disorders	6 (0.04%)
Skin swelling	Skin and subcutaneous tissue disorders	6 (0.04%)
Skin tightness	Skin and subcutaneous tissue disorders	6 (0.04%)
Sleep disorder due to a general medical condition	Psychiatric disorders	6 (0.04%)
Sluggishness	General disorders and administration site conditions	6 (0.04%)
Stridor	Respiratory, thoracic and mediastinal disorders	6 (0.04%)
Thinking abnormal	Psychiatric disorders	6 (0.04%)
Tonsillitis	Infections and infestations	6 (0.04%)
Vaccination site haematoma	General disorders and administration site conditions	6 (0.04%)
Wrong product administered	Injury, poisoning and procedural complications	6 (0.04%)
Alanine aminotransferase increased	Investigations	5 (0.03%)
Alopecia	Skin and subcutaneous tissue disorders	5 (0.03%)
Apathy	Psychiatric disorders	5 (0.03%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Appendicitis	Infections and infestations	5 (0.03%)
Arthropathy	Musculoskeletal and connective tissue disorders	5 (0.03%)
Asymptomatic COVID-19	Infections and infestations	5 (0.03%)
Body height decreased	Investigations	5 (0.03%)
Body temperature fluctuation	Investigations	5 (0.03%)
Bronchitis	Infections and infestations	5 (0.03%)
Cardiac flutter	Cardiac disorders	5 (0.03%)
Dysmenorrhoea	Reproductive system and breast disorders	5 (0.03%)
Ear disorder	Ear and labyrinth disorders	5 (0.03%)
Extrasystoles	Cardiac disorders	5 (0.03%)
Eye inflammation	Eye disorders	5 (0.03%)
Eyelid oedema	Eye disorders	5 (0.03%)
Eye oedema	Eye disorders	5 (0.03%)
Fibromyalgia	Musculoskeletal and connective tissue disorders	5 (0.03%)
Flank pain	Musculoskeletal and connective tissue disorders	5 (0.03%)
Gastritis	Gastrointestinal disorders	5 (0.03%)
Generalised tonic-clonic seizure	Nervous system disorders	5 (0.03%)
Haemorrhage	Vascular disorders	5 (0.03%)
Heart rate abnormal	Investigations	5 (0.03%)
Hunger	General disorders and administration site conditions	5 (0.03%)
Hyperacusis	Ear and labyrinth disorders	5 (0.03%)
Hypopnoea	Respiratory, thoracic and mediastinal disorders	5 (0.03%)
Hyposmia	Nervous system disorders	5 (0.03%)
Hypotonia	Nervous system disorders	5 (0.03%)
Hypoxia	Respiratory, thoracic and mediastinal disorders	5 (0.03%)
Initial insomnia	Psychiatric disorders	5 (0.03%)
Injection site erythema	General disorders and administration site conditions	5 (0.03%)
Irritable bowel syndrome	Gastrointestinal disorders	5 (0.03%)
Limb injury	Injury, poisoning and procedural complications	5 (0.03%)
Maternal exposure timing unspecified	Injury, poisoning and procedural complications	5 (0.03%)
Motion sickness	Ear and labyrinth disorders	5 (0.03%)
Multiple organ dysfunction syndrome	General disorders and administration site conditions	5 (0.03%)
Multiple sclerosis relapse	Nervous system disorders	5 (0.03%)
Muscle discomfort	Musculoskeletal and connective tissue disorders	5 (0.03%)
Muscle rigidity	Musculoskeletal and connective tissue disorders	5 (0.03%)
Myocarditis	Cardiac disorders	5 (0.03%)
Needle issue	Product issues	5 (0.03%)
Neuritis	Nervous system disorders	5 (0.03%)
Papule	Skin and subcutaneous tissue disorders	5 (0.03%)
Pelvic pain	Reproductive system and breast disorders	5 (0.03%)
Periarthritis	Musculoskeletal and connective tissue disorders	5 (0.03%)
Photosensitivity reaction	Skin and subcutaneous tissue disorders	5 (0.03%)
Piloerection	Skin and subcutaneous tissue disorders	5 (0.03%)
Platelet count increased	Investigations	5 (0.03%)
Polyuria	Renal and urinary disorders	5 (0.03%)
Pulmonary oedema	Respiratory, thoracic and mediastinal disorders	5 (0.03%)



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Preferred Term	System Organ Class (SOC)	Number of Cases
Rales	Respiratory, thoracic and mediastinal disorders	5 (0.03%)
Rheumatoid arthritis	Musculoskeletal and connective tissue disorders	5 (0.03%)
SARS-CoV-2 test false positive	Investigations	5 (0.03%)
Sciatica	Nervous system disorders	5 (0.03%)
Type IV hypersensitivity reaction	Immune system disorders	5 (0.03%)
Vaccination site hyperaesthesia	General disorders and administration site conditions	5 (0.03%)
Ventricular extrasystoles	Cardiac disorders	5 (0.03%)
Ventricular fibrillation	Cardiac disorders	5 (0.03%)
Vertigo positional	Ear and labyrinth disorders	5 (0.03%)
Acne	Skin and subcutaneous tissue disorders	4 (0.03%)
Acute coronary syndrome	Cardiac disorders	4 (0.03%)
Aphonia	Respiratory, thoracic and mediastinal disorders	4 (0.03%)
Arthropod bite	Injury, poisoning and procedural complications	4 (0.03%)
Blood lactic acid increased	Investigations	4 (0.03%)
Blood pressure abnormal	Investigations	4 (0.03%)
Blood pressure diastolic decreased	Investigations	4 (0.03%)
Breast discomfort	Reproductive system and breast disorders	4 (0.03%)
Conjunctival haemorrhage	Eye disorders	4 (0.03%)
Coordination abnormal	Nervous system disorders	4 (0.03%)
Dermatitis contact	Skin and subcutaneous tissue disorders	4 (0.03%)
Diabetes mellitus	Metabolism and nutrition disorders	4 (0.03%)
Dysaesthesia	Nervous system disorders	4 (0.03%)
Ear infection	Infections and infestations	4 (0.03%)
Enlarged uvula	Gastrointestinal disorders	4 (0.03%)
Episcleritis	Eye disorders	4 (0.03%)
Erythema of eyelid	Eye disorders	4 (0.03%)
Euphoric mood	Psychiatric disorders	4 (0.03%)
Eyelid ptosis	Eye disorders	4 (0.03%)
Eyelids pruritus	Eye disorders	4 (0.03%)
Fluid intake reduced	Metabolism and nutrition disorders	4 (0.03%)
Gastric disorder	Gastrointestinal disorders	4 (0.03%)
Glossitis	Gastrointestinal disorders	4 (0.03%)
Grip strength decreased	Investigations	4 (0.03%)
Haemoglobin decreased	Investigations	4 (0.03%)
Haemorrhage intracranial	Nervous system disorders	4 (0.03%)
Haemorrhagic stroke	Nervous system disorders	4 (0.03%)
Huntington's disease	Congenital, familial and genetic disorders	4 (0.03%)
Hyperthermia	General disorders and administration site conditions	4 (0.03%)
Hypoaesthesia eye	Eye disorders	4 (0.03%)
Impaired driving ability	Social circumstances	4 (0.03%)
Induration	General disorders and administration site conditions	4 (0.03%)
Jaundice	Hepatobiliary disorders	4 (0.03%)
Joint effusion	Musculoskeletal and connective tissue disorders	4 (0.03%)
Lip pain	Gastrointestinal disorders	4 (0.03%)
Livedo reticularis	Skin and subcutaneous tissue disorders	4 (0.03%)
Localised infection	Infections and infestations	4 (0.03%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Localised oedema	General disorders and administration site conditions	4 (0.03%)
Lung disorder	Respiratory, thoracic and mediastinal disorders	4 (0.03%)
Menorrhagia	Reproductive system and breast disorders	4 (0.03%)
Metrorrhagia	Reproductive system and breast disorders	4 (0.03%)
Monoplegia	Nervous system disorders	4 (0.03%)
Motor dysfunction	Nervous system disorders	4 (0.03%)
Neurogenic shock	Vascular disorders	4 (0.03%)
Nipple pain	Reproductive system and breast disorders	4 (0.03%)
Nystagmus	Nervous system disorders	4 (0.03%)
Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	4 (0.03%)
Occupational exposure to product	Injury, poisoning and procedural complications	4 (0.03%)
Oedema mouth	Gastrointestinal disorders	4 (0.03%)
Oral disorder	Gastrointestinal disorders	4 (0.03%)
Orthostatic hypotension	Vascular disorders	4 (0.03%)
Palatal swelling	Gastrointestinal disorders	4 (0.03%)
Panic reaction	Psychiatric disorders	4 (0.03%)
Parotitis	Infections and infestations	4 (0.03%)
Pharyngeal disorder	Respiratory, thoracic and mediastinal disorders	4 (0.03%)
Pharyngitis	Infections and infestations	4 (0.03%)
Photopsia	Eye disorders	4 (0.03%)
Pleural effusion	Respiratory, thoracic and mediastinal disorders	4 (0.03%)
Pleuritic pain	Respiratory, thoracic and mediastinal disorders	4 (0.03%)
Pulmonary pain	Respiratory, thoracic and mediastinal disorders	4 (0.03%)
Purpura	Skin and subcutaneous tissue disorders	4 (0.03%)
Reaction to excipient	Immune system disorders	4 (0.03%)
Rectal haemorrhage	Gastrointestinal disorders	4 (0.03%)
Red blood cell sedimentation rate increased	Investigations	4 (0.03%)
Respiratory tract infection	Infections and infestations	4 (0.03%)
Scratch	Injury, poisoning and procedural complications	4 (0.03%)
Seasonal allergy	Immune system disorders	4 (0.03%)
Sleep disorder due to general medical condition, insomnia type	Psychiatric disorders	4 (0.03%)
Sudden hearing loss	Ear and labyrinth disorders	4 (0.03%)
Suppressed lactation	Reproductive system and breast disorders	4 (0.03%)
Tachyarrhythmia	Cardiac disorders	4 (0.03%)
Tachyphrenia	Psychiatric disorders	4 (0.03%)
Temperature regulation disorder	General disorders and administration site conditions	4 (0.03%)
Tongue dry	Gastrointestinal disorders	4 (0.03%)
Tongue erythema	Gastrointestinal disorders	4 (0.03%)
Trismus	Musculoskeletal and connective tissue disorders	4 (0.03%)
Vaccination site extravasation	General disorders and administration site conditions	4 (0.03%)
Vaccination site irritation	General disorders and administration site conditions	4 (0.03%)
Vaccination site macule	General disorders and administration site conditions	4 (0.03%)
Visual field defect	Nervous system disorders	4 (0.03%)
Vomiting projectile	Gastrointestinal disorders	4 (0.03%)
White blood cell count increased	Investigations	4 (0.03%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Abdominal tenderness	Gastrointestinal disorders	3 (0.02%)
Adverse event	General disorders and administration site conditions	3 (0.02%)
Aggression	Psychiatric disorders	3 (0.02%)
Allodynia	Nervous system disorders	3 (0.02%)
Anal incontinence	Gastrointestinal disorders	3 (0.02%)
Arrhythmia supraventricular	Cardiac disorders	3 (0.02%)
Aspiration	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Bladder discomfort	Renal and urinary disorders	3 (0.02%)
Blood potassium decreased	Investigations	3 (0.02%)
Blood pressure diastolic increased	Investigations	3 (0.02%)
Body temperature	Investigations	3 (0.02%)
Bone swelling	Musculoskeletal and connective tissue disorders	3 (0.02%)
Breath odour	Gastrointestinal disorders	3 (0.02%)
Chapped lips	Gastrointestinal disorders	3 (0.02%)
Chronic obstructive pulmonary disease	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Coma	Nervous system disorders	3 (0.02%)
Coma scale abnormal	Investigations	3 (0.02%)
Contraindicated product administered	Injury, poisoning and procedural complications	3 (0.02%)
Coronavirus infection	Infections and infestations	3 (0.02%)
Coronavirus test positive	Investigations	3 (0.02%)
Costochondritis	Musculoskeletal and connective tissue disorders	3 (0.02%)
Cystitis	Infections and infestations	3 (0.02%)
Deafness neurosensory	Ear and labyrinth disorders	3 (0.02%)
Dementia	Nervous system disorders	3 (0.02%)
Depersonalisation/derealisation disorder	Psychiatric disorders	3 (0.02%)
Derealisation	Psychiatric disorders	3 (0.02%)
Diet refusal	Metabolism and nutrition disorders	3 (0.02%)
Dissociation	Psychiatric disorders	3 (0.02%)
Dizziness exertional	Nervous system disorders	3 (0.02%)
Drug eruption	Skin and subcutaneous tissue disorders	3 (0.02%)
Ear congestion	Ear and labyrinth disorders	3 (0.02%)
Electrocardiogram abnormal	Investigations	3 (0.02%)
Emotional disorder	Psychiatric disorders	3 (0.02%)
Emotional distress	Psychiatric disorders	3 (0.02%)
Energy increased	General disorders and administration site conditions	3 (0.02%)
Enuresis	Psychiatric disorders	3 (0.02%)
Eye allergy	Eye disorders	3 (0.02%)
Eyelid irritation	Eye disorders	3 (0.02%)
Eyelid pain	Eye disorders	3 (0.02%)
Face injury	Injury, poisoning and procedural complications	3 (0.02%)
Facial spasm	Nervous system disorders	3 (0.02%)
Faeces discoloured	Gastrointestinal disorders	3 (0.02%)
Fibrin D dimer increased	Investigations	3 (0.02%)
Fine motor skill dysfunction	Nervous system disorders	3 (0.02%)
Fungal infection	Infections and infestations	3 (0.02%)
Gastroenteritis viral	Infections and infestations	3 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Gastrointestinal sounds abnormal	Gastrointestinal disorders	3 (0.02%)
Guillain-Barre syndrome	Nervous system disorders	3 (0.02%)
Hepatic enzyme increased	Investigations	3 (0.02%)
Hordeolum	Infections and infestations	3 (0.02%)
Hyperaesthesia teeth	Gastrointestinal disorders	3 (0.02%)
Hypogeusia	Nervous system disorders	3 (0.02%)
Hypokalaemia	Metabolism and nutrition disorders	3 (0.02%)
Hypothyroidism	Endocrine disorders	3 (0.02%)
Immune thrombocytopenia	Blood and lymphatic system disorders	3 (0.02%)
Incontinence	Renal and urinary disorders	3 (0.02%)
Injection site swelling	General disorders and administration site conditions	3 (0.02%)
Intestinal ischaemia	Gastrointestinal disorders	3 (0.02%)
Intraocular pressure increased	Investigations	3 (0.02%)
Labyrinthitis	Infections and infestations	3 (0.02%)
Laryngospasm	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Limb mass	Musculoskeletal and connective tissue disorders	3 (0.02%)
Lip blister	Gastrointestinal disorders	3 (0.02%)
Lip disorder	Gastrointestinal disorders	3 (0.02%)
Lip dry	Gastrointestinal disorders	3 (0.02%)
Lymphopenia	Blood and lymphatic system disorders	3 (0.02%)
Mastitis	Infections and infestations	3 (0.02%)
Mean cell haemoglobin decreased	Investigations	3 (0.02%)
Mechanical urticaria	Skin and subcutaneous tissue disorders	3 (0.02%)
Medication error	Injury, poisoning and procedural complications	3 (0.02%)
Mental disorder	Psychiatric disorders	3 (0.02%)
Miliaria	Skin and subcutaneous tissue disorders	3 (0.02%)
Mononeuropathy	Nervous system disorders	3 (0.02%)
Monoparesis	Nervous system disorders	3 (0.02%)
Mood altered	Psychiatric disorders	3 (0.02%)
Multiple sclerosis	Nervous system disorders	3 (0.02%)
Muscle strain	Injury, poisoning and procedural complications	3 (0.02%)
Nasal dryness	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Nasal obstruction	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Neuralgic amyotrophy	Nervous system disorders	3 (0.02%)
Nodule	General disorders and administration site conditions	3 (0.02%)
Nuchal rigidity	Musculoskeletal and connective tissue disorders	3 (0.02%)
Oral candidiasis	Infections and infestations	3 (0.02%)
Oral mucosal eruption	Gastrointestinal disorders	3 (0.02%)
Oropharyngeal blistering	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Palmar erythema	Skin and subcutaneous tissue disorders	3 (0.02%)
Pancreatitis	Gastrointestinal disorders	3 (0.02%)
Paresis	Nervous system disorders	3 (0.02%)
Parotid gland enlargement	Gastrointestinal disorders	3 (0.02%)
Periorbital oedema	Eye disorders	3 (0.02%)
Petit mal epilepsy	Nervous system disorders	3 (0.02%)
Pleurisy	Respiratory, thoracic and mediastinal disorders	3 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pneumonitis	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Polydipsia	Metabolism and nutrition disorders	3 (0.02%)
Post viral fatigue syndrome	Infections and infestations	3 (0.02%)
Product label confusion	Injury, poisoning and procedural complications	3 (0.02%)
Psychomotor hyperactivity	Nervous system disorders	3 (0.02%)
Pulmonary congestion	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Pustule	Infections and infestations	3 (0.02%)
Radiculopathy	Nervous system disorders	3 (0.02%)
Renal disorder	Renal and urinary disorders	3 (0.02%)
Respiration abnormal	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Rhabdomyolysis	Musculoskeletal and connective tissue disorders	3 (0.02%)
Skin laceration	Injury, poisoning and procedural complications	3 (0.02%)
Skin mass	Skin and subcutaneous tissue disorders	3 (0.02%)
Sputum discoloured	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Systemic inflammatory response syndrome	General disorders and administration site conditions	3 (0.02%)
Tendonitis	Musculoskeletal and connective tissue disorders	3 (0.02%)
Throat clearing	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Tongue eruption	Gastrointestinal disorders	3 (0.02%)
Trigeminal neuralgia	Nervous system disorders	3 (0.02%)
Troponin increased	Investigations	3 (0.02%)
Tunnel vision	Nervous system disorders	3 (0.02%)
Upper respiratory tract infection	Infections and infestations	3 (0.02%)
Urosepsis	Infections and infestations	3 (0.02%)
Vaccination site discharge	General disorders and administration site conditions	3 (0.02%)
Vaccination site hypersensitivity	General disorders and administration site conditions	3 (0.02%)
Vaccination site scab	General disorders and administration site conditions	3 (0.02%)
Viral rash	Infections and infestations	3 (0.02%)
Abnormal behaviour	Psychiatric disorders	2 (0.01%)
Abscess	Infections and infestations	2 (0.01%)
Acidosis	Metabolism and nutrition disorders	2 (0.01%)
Acute disseminated encephalomyelitis	Nervous system disorders	2 (0.01%)
Acute respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Administration site pain	General disorders and administration site conditions	2 (0.01%)
Adverse drug reaction	General disorders and administration site conditions	2 (0.01%)
Allergic cough	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Allergic oedema	Immune system disorders	2 (0.01%)
Anaesthesia	Nervous system disorders	2 (0.01%)
Aortic dissection	Vascular disorders	2 (0.01%)
Arteriosclerosis	Vascular disorders	2 (0.01%)
Arthritis reactive	Musculoskeletal and connective tissue disorders	2 (0.01%)
Aspartate aminotransferase increased	Investigations	2 (0.01%)
Asphyxia	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Auricular swelling	Ear and labyrinth disorders	2 (0.01%)
Bladder pain	Renal and urinary disorders	2 (0.01%)
Blood alkaline phosphatase increased	Investigations	2 (0.01%)
Blood chloride increased	Investigations	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Blood creatine phosphokinase increased	Investigations	2 (0.01%)
Blood glucose abnormal	Investigations	2 (0.01%)
Blood glucose fluctuation	Investigations	2 (0.01%)
Blood sodium decreased	Investigations	2 (0.01%)
Blood thyroid stimulating hormone increased	Investigations	2 (0.01%)
Booster dose missed	Injury, poisoning and procedural complications	2 (0.01%)
Bowel movement irregularity	Gastrointestinal disorders	2 (0.01%)
Brain injury	Nervous system disorders	2 (0.01%)
Brain oedema	Nervous system disorders	2 (0.01%)
Breast mass	Reproductive system and breast disorders	2 (0.01%)
Breast tenderness	Reproductive system and breast disorders	2 (0.01%)
Cardiac failure congestive	Cardiac disorders	2 (0.01%)
Cerebellar haemorrhage	Nervous system disorders	2 (0.01%)
Cerebral infarction	Nervous system disorders	2 (0.01%)
Chillblains	Injury, poisoning and procedural complications	2 (0.01%)
Choking sensation	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Circumoral swelling	Skin and subcutaneous tissue disorders	2 (0.01%)
Colitis ulcerative	Gastrointestinal disorders	2 (0.01%)
Conjunctivitis allergic	Eye disorders	2 (0.01%)
Contraindication to vaccination	Social circumstances	2 (0.01%)
Coronary artery disease	Cardiac disorders	2 (0.01%)
Costovertebral angle tenderness	Renal and urinary disorders	2 (0.01%)
Cranial nerve disorder	Nervous system disorders	2 (0.01%)
Crepitations	General disorders and administration site conditions	2 (0.01%)
Cyst	General disorders and administration site conditions	2 (0.01%)
Deafness unilateral	Ear and labyrinth disorders	2 (0.01%)
Decreased interest	Psychiatric disorders	2 (0.01%)
Defaecation urgency	Gastrointestinal disorders	2 (0.01%)
Delusional perception	Psychiatric disorders	2 (0.01%)
Demyelination	Nervous system disorders	2 (0.01%)
Dental restoration failure	Injury, poisoning and procedural complications	2 (0.01%)
Diabetic ketoacidosis	Metabolism and nutrition disorders	2 (0.01%)
Discoloured vomit	Gastrointestinal disorders	2 (0.01%)
Disease progression	General disorders and administration site conditions	2 (0.01%)
Drooling	Nervous system disorders	2 (0.01%)
Dystonia	Nervous system disorders	2 (0.01%)
Ear swelling	Ear and labyrinth disorders	2 (0.01%)
Eosinophil count increased	Investigations	2 (0.01%)
Eosinophilia	Blood and lymphatic system disorders	2 (0.01%)
Epicondylitis	Injury, poisoning and procedural complications	2 (0.01%)
Erectile dysfunction	Reproductive system and breast disorders	2 (0.01%)
Erythema multiforme	Skin and subcutaneous tissue disorders	2 (0.01%)
Expired product administered	Injury, poisoning and procedural complications	2 (0.01%)
Extremity contracture	Musculoskeletal and connective tissue disorders	2 (0.01%)
Eyelid rash	Eye disorders	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Eye paraesthesia	Eye disorders	2 (0.01%)
Facial discomfort	General disorders and administration site conditions	2 (0.01%)
Facial nerve disorder	Nervous system disorders	2 (0.01%)
Febrile infection	Infections and infestations	2 (0.01%)
Food refusal	Metabolism and nutrition disorders	2 (0.01%)
Foreign body sensation in eyes	Eye disorders	2 (0.01%)
Frustration tolerance decreased	Psychiatric disorders	2 (0.01%)
Furuncle	Infections and infestations	2 (0.01%)
Gastroenteritis	Infections and infestations	2 (0.01%)
Genital herpes	Infections and infestations	2 (0.01%)
Gingival blister	Gastrointestinal disorders	2 (0.01%)
Gingival erythema	Gastrointestinal disorders	2 (0.01%)
Glassy eyes	General disorders and administration site conditions	2 (0.01%)
Glaucoma	Eye disorders	2 (0.01%)
Haemolytic anaemia	Blood and lymphatic system disorders	2 (0.01%)
Hallucination, auditory	Psychiatric disorders	2 (0.01%)
Hand-eye coordination impaired	Nervous system disorders	2 (0.01%)
Hepatitis	Hepatobiliary disorders	2 (0.01%)
Herpes simplex	Infections and infestations	2 (0.01%)
Hiccups	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Hypertensive emergency	Vascular disorders	2 (0.01%)
Hypertonia	Nervous system disorders	2 (0.01%)
Hypocalcaemia	Metabolism and nutrition disorders	2 (0.01%)
Hyponatraemia	Metabolism and nutrition disorders	2 (0.01%)
Hyporeflexia	Nervous system disorders	2 (0.01%)
Immunisation anxiety related reaction	Psychiatric disorders	2 (0.01%)
Incoherent	Nervous system disorders	2 (0.01%)
Increased appetite	Metabolism and nutrition disorders	2 (0.01%)
Increased viscosity of upper respiratory secretion	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Infantile vomiting	Gastrointestinal disorders	2 (0.01%)
Inflammatory marker increased	Investigations	2 (0.01%)
Injection related reaction	Injury, poisoning and procedural complications	2 (0.01%)
Injection site rash	General disorders and administration site conditions	2 (0.01%)
Injury	Injury, poisoning and procedural complications	2 (0.01%)
Intranasal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Intranasal paraesthesia	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Iridocyclitis	Eye disorders	2 (0.01%)
Irritability postvaccinal	General disorders and administration site conditions	2 (0.01%)
Jaw clicking	Musculoskeletal and connective tissue disorders	2 (0.01%)
Joint noise	Musculoskeletal and connective tissue disorders	2 (0.01%)
Lacunar infarction	Nervous system disorders	2 (0.01%)
Laryngeal pain	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Ligament injury	Injury, poisoning and procedural complications	2 (0.01%)
Ligament sprain	Injury, poisoning and procedural complications	2 (0.01%)
Lip injury	Injury, poisoning and procedural complications	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Liver function test abnormal	Investigations	2 (0.01%)
Liver function test increased	Investigations	2 (0.01%)
Liver injury	Hepatobiliary disorders	2 (0.01%)
Lung infiltration	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Lymph node palpable	Investigations	2 (0.01%)
Mastication disorder	Musculoskeletal and connective tissue disorders	2 (0.01%)
Menopausal symptoms	Reproductive system and breast disorders	2 (0.01%)
Monocyte count increased	Investigations	2 (0.01%)
Mucosal disorder	General disorders and administration site conditions	2 (0.01%)
Muscle contracture	Musculoskeletal and connective tissue disorders	2 (0.01%)
Muscle disorder	Musculoskeletal and connective tissue disorders	2 (0.01%)
Mydriasis	Eye disorders	2 (0.01%)
Myocardial ischaemia	Cardiac disorders	2 (0.01%)
Myoclonus	Nervous system disorders	2 (0.01%)
Myositis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Nail discolouration	Skin and subcutaneous tissue disorders	2 (0.01%)
Nasal injury	Injury, poisoning and procedural complications	2 (0.01%)
Nervous system disorder	Nervous system disorders	2 (0.01%)
Neutrophil count increased	Investigations	2 (0.01%)
Nocturia	Renal and urinary disorders	2 (0.01%)
Oesophageal pain	Gastrointestinal disorders	2 (0.01%)
Optic neuritis	Nervous system disorders	2 (0.01%)
Oral dysaesthesia	Gastrointestinal disorders	2 (0.01%)
Oral mucosal erythema	Gastrointestinal disorders	2 (0.01%)
Oropharyngeal oedema	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Oropharyngeal swelling	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Orthopnoea	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Otitis media	Infections and infestations	2 (0.01%)
Palatal oedema	Gastrointestinal disorders	2 (0.01%)
Pancytopenia	Blood and lymphatic system disorders	2 (0.01%)
Paranasal sinus hypersecretion	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Paranoia	Psychiatric disorders	2 (0.01%)
Peripheral ischaemia	Vascular disorders	2 (0.01%)
Peroneal nerve palsy	Nervous system disorders	2 (0.01%)
Personality change	Psychiatric disorders	2 (0.01%)
Pharyngitis streptococcal	Infections and infestations	2 (0.01%)
Phlebitis	Vascular disorders	2 (0.01%)
Platelet count decreased	Investigations	2 (0.01%)
PO2 decreased	Investigations	2 (0.01%)
Polymenorrhoea	Reproductive system and breast disorders	2 (0.01%)
Polymyalgia rheumatica	Musculoskeletal and connective tissue disorders	2 (0.01%)
Polyneuropathy	Nervous system disorders	2 (0.01%)
Poor peripheral circulation	Vascular disorders	2 (0.01%)
Pre-existing condition improved	General disorders and administration site conditions	2 (0.01%)
Primary cough headache	Nervous system disorders	2 (0.01%)
Procedural pain	Injury, poisoning and procedural complications	2 (0.01%)



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Preferred Term	System Organ Class (SOC)	Number of Cases
Product dose omission issue	Injury, poisoning and procedural complications	2 (0.01%)
Product prescribing error	Injury, poisoning and procedural complications	2 (0.01%)
Psoriasis	Skin and subcutaneous tissue disorders	2 (0.01%)
Psoriatic arthropathy	Musculoskeletal and connective tissue disorders	2 (0.01%)
Pulmonary thrombosis	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Pupil fixed	Eye disorders	2 (0.01%)
Pupils unequal	Eye disorders	2 (0.01%)
Q fever	Infections and infestations	2 (0.01%)
Rash pustular	Infections and infestations	2 (0.01%)
Raynaud's phenomenon	Vascular disorders	2 (0.01%)
Respiratory rate decreased	Investigations	2 (0.01%)
Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Rhonchi	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Rosacea	Skin and subcutaneous tissue disorders	2 (0.01%)
Sacroiliitis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Salivary gland pain	Gastrointestinal disorders	2 (0.01%)
Scar	Injury, poisoning and procedural complications	2 (0.01%)
Screaming	General disorders and administration site conditions	2 (0.01%)
Sedation	Nervous system disorders	2 (0.01%)
Septic shock	Infections and infestations	2 (0.01%)
Serotonin syndrome	Nervous system disorders	2 (0.01%)
Severe acute respiratory syndrome	Infections and infestations	2 (0.01%)
Skin erosion	Skin and subcutaneous tissue disorders	2 (0.01%)
Skin sensitisation	Skin and subcutaneous tissue disorders	2 (0.01%)
Skin ulcer	Skin and subcutaneous tissue disorders	2 (0.01%)
Sleep attacks	Psychiatric disorders	2 (0.01%)
Sleep talking	Psychiatric disorders	2 (0.01%)
Slow response to stimuli	Nervous system disorders	2 (0.01%)
Snoring	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Stevens-Johnson syndrome	Skin and subcutaneous tissue disorders	2 (0.01%)
Stupor	Nervous system disorders	2 (0.01%)
Subarachnoid haemorrhage	Nervous system disorders	2 (0.01%)
Sudden cardiac death	General disorders and administration site conditions	2 (0.01%)
Sunburn	Injury, poisoning and procedural complications	2 (0.01%)
Superficial vein prominence	Vascular disorders	2 (0.01%)
Systemic lupus erythematosus	Musculoskeletal and connective tissue disorders	2 (0.01%)
Systolic hypertension	Vascular disorders	2 (0.01%)
Tachycardia paroxysmal	Cardiac disorders	2 (0.01%)
Tearfulness	Psychiatric disorders	2 (0.01%)
Temporomandibular joint syndrome	Musculoskeletal and connective tissue disorders	2 (0.01%)
Tendon pain	Musculoskeletal and connective tissue disorders	2 (0.01%)
Tension	Psychiatric disorders	2 (0.01%)
Terminal insomnia	Psychiatric disorders	2 (0.01%)
Thyroid disorder	Endocrine disorders	2 (0.01%)
Tongue discolouration	Gastrointestinal disorders	2 (0.01%)
Tongue haematoma	Gastrointestinal disorders	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Tongue movement disturbance	Gastrointestinal disorders	2 (0.01%)
Tonsillar erythema	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Torticollis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Tuberculosis	Infections and infestations	2 (0.01%)
Upper gastrointestinal haemorrhage	Gastrointestinal disorders	2 (0.01%)
Vaccination site ulcer	General disorders and administration site conditions	2 (0.01%)
Vaginal discharge	Reproductive system and breast disorders	2 (0.01%)
Varicose vein	Vascular disorders	2 (0.01%)
Vasculitis	Vascular disorders	2 (0.01%)
Vasodilatation	Vascular disorders	2 (0.01%)
Viral infection	Infections and infestations	2 (0.01%)
Vulvovaginal candidiasis	Infections and infestations	2 (0.01%)
Vulvovaginal pruritus	Reproductive system and breast disorders	2 (0.01%)
Weight increased	Investigations	2 (0.01%)
Wound	Injury, poisoning and procedural complications	2 (0.01%)
Abdominal adhesions	Gastrointestinal disorders	1 (0.01%)
Abdominal rigidity	Gastrointestinal disorders	1 (0.01%)
Acarodermatitis	Infections and infestations	1 (0.01%)
Accidental underdose	Injury, poisoning and procedural complications	1 (0.01%)
Acute cardiac event	Cardiac disorders	1 (0.01%)
Acute pulmonary oedema	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Administration site reaction	General disorders and administration site conditions	1 (0.01%)
Adnexa uteri pain	Reproductive system and breast disorders	1 (0.01%)
Adverse reaction	General disorders and administration site conditions	1 (0.01%)
Aerophagia	Gastrointestinal disorders	1 (0.01%)
Affect lability	Psychiatric disorders	1 (0.01%)
African trypanosomiasis	Infections and infestations	1 (0.01%)
Age-related macular degeneration	Eye disorders	1 (0.01%)
Akathisia	Nervous system disorders	1 (0.01%)
Allergic respiratory symptom	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Allergy to chemicals	Immune system disorders	1 (0.01%)
Altered state of consciousness	Nervous system disorders	1 (0.01%)
Amblyopia	Eye disorders	1 (0.01%)
Anal haemorrhage	Gastrointestinal disorders	1 (0.01%)
Aneurysm	Vascular disorders	1 (0.01%)
Angle closure glaucoma	Eye disorders	1 (0.01%)
Angular cheilitis	Gastrointestinal disorders	1 (0.01%)
Animal bite	Injury, poisoning and procedural complications	1 (0.01%)
Ankylosing spondylitis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Antibody test positive	Investigations	1 (0.01%)
Anticholinergic syndrome	Nervous system disorders	1 (0.01%)
Anticoagulation drug level increased	Investigations	1 (0.01%)
Aortic aneurysm	Vascular disorders	1 (0.01%)
Aortic aneurysm rupture	Vascular disorders	1 (0.01%)
Appetite disorder	Metabolism and nutrition disorders	1 (0.01%)
Arteriospasm coronary	Cardiac disorders	1 (0.01%)



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Preferred Term	System Organ Class (SOC)	Number of Cases
Asthma prophylaxis	Surgical and medical procedures	1 (0.01%)
Atrioventricular block complete	Cardiac disorders	1 (0.01%)
Atypical pneumonia	Infections and infestations	1 (0.01%)
Auscultation	Investigations	1 (0.01%)
Autoimmune disorder	Immune system disorders	1 (0.01%)
Autoimmune thyroiditis	Endocrine disorders	1 (0.01%)
Autonomic nervous system imbalance	Nervous system disorders	1 (0.01%)
Axonal neuropathy	Nervous system disorders	1 (0.01%)
Bacteraemia	Infections and infestations	1 (0.01%)
Band sensation	Nervous system disorders	1 (0.01%)
Basal ganglia haemorrhage	Nervous system disorders	1 (0.01%)
Bile duct stone	Hepatobiliary disorders	1 (0.01%)
Biliary sepsis	Infections and infestations	1 (0.01%)
Bilirubin urine present	Investigations	1 (0.01%)
Bite	Injury, poisoning and procedural complications	1 (0.01%)
Blepharitis	Eye disorders	1 (0.01%)
Blepharochalasis	Eye disorders	1 (0.01%)
Blood creatinine increased	Investigations	1 (0.01%)
Blood disorder	Blood and lymphatic system disorders	1 (0.01%)
Blood electrolytes increased	Investigations	1 (0.01%)
Blood iron decreased	Investigations	1 (0.01%)
Blood ketone body present	Investigations	1 (0.01%)
Blood pH increased	Investigations	1 (0.01%)
Blood potassium abnormal	Investigations	1 (0.01%)
Blood pressure inadequately controlled	Vascular disorders	1 (0.01%)
Blood pressure orthostatic abnormal	Investigations	1 (0.01%)
Blood pressure systolic decreased	Investigations	1 (0.01%)
Blood test abnormal	Investigations	1 (0.01%)
Blood testosterone decreased	Investigations	1 (0.01%)
Blood urea increased	Investigations	1 (0.01%)
Blood uric acid increased	Investigations	1 (0.01%)
Bone disorder	Musculoskeletal and connective tissue disorders	1 (0.01%)
Brachial plexopathy	Nervous system disorders	1 (0.01%)
Bradyphrenia	Psychiatric disorders	1 (0.01%)
Breast abscess	Infections and infestations	1 (0.01%)
Breast milk discolouration	Reproductive system and breast disorders	1 (0.01%)
Bronchial disorder	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Bronchial obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Bruxism	Psychiatric disorders	1 (0.01%)
Bundle branch block right	Cardiac disorders	1 (0.01%)
Burning sensation mucosal	Nervous system disorders	1 (0.01%)
Burn oral cavity	Injury, poisoning and procedural complications	1 (0.01%)
Buttock injury	Injury, poisoning and procedural complications	1 (0.01%)
Candida infection	Infections and infestations	1 (0.01%)
Cardiac fibrillation	Cardiac disorders	1 (0.01%)
Cardiac valve disease	Cardiac disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cardiac valve sclerosis	Cardiac disorders	1 (0.01%)
Cardiogenic shock	Cardiac disorders	1 (0.01%)
Cardiopulmonary failure	Cardiac disorders	1 (0.01%)
Cardio-respiratory distress	Cardiac disorders	1 (0.01%)
Cardiovascular insufficiency	Cardiac disorders	1 (0.01%)
Central nervous system lesion	Nervous system disorders	1 (0.01%)
Central vision loss	Eye disorders	1 (0.01%)
Cerebellar infarction	Nervous system disorders	1 (0.01%)
Cerebellar stroke	Nervous system disorders	1 (0.01%)
Cerebral ischaemia	Nervous system disorders	1 (0.01%)
Cerebral venous sinus thrombosis	Nervous system disorders	1 (0.01%)
Cervix oedema	Reproductive system and breast disorders	1 (0.01%)
Chalazion	Eye disorders	1 (0.01%)
Cheilitis	Gastrointestinal disorders	1 (0.01%)
Cholecystitis	Hepatobiliary disorders	1 (0.01%)
Cholecystitis infective	Infections and infestations	1 (0.01%)
Chronic kidney disease	Renal and urinary disorders	1 (0.01%)
Circumoral oedema	Skin and subcutaneous tissue disorders	1 (0.01%)
Circumstance or information capable of leading to device use error	Injury, poisoning and procedural complications	1 (0.01%)
Clinical death	General disorders and administration site conditions	1 (0.01%)
Clostridium difficile colitis	Infections and infestations	1 (0.01%)
Clumsiness	Nervous system disorders	1 (0.01%)
Coagulation time prolonged	Investigations	1 (0.01%)
Coagulopathy	Blood and lymphatic system disorders	1 (0.01%)
Communication disorder	Psychiatric disorders	1 (0.01%)
Concomitant disease aggravated	General disorders and administration site conditions	1 (0.01%)
Conjunctival hyperaemia	Eye disorders	1 (0.01%)
Conjunctival irritation	Eye disorders	1 (0.01%)
Conjunctival oedema	Eye disorders	1 (0.01%)
Conjunctivitis viral	Infections and infestations	1 (0.01%)
Consciousness fluctuating	Nervous system disorders	1 (0.01%)
Contrast media allergy	Immune system disorders	1 (0.01%)
Corneal bleeding	Eye disorders	1 (0.01%)
Corneal oedema	Eye disorders	1 (0.01%)
Cortisol decreased	Investigations	1 (0.01%)
Crystal urine	Investigations	1 (0.01%)
Culture negative	Investigations	1 (0.01%)
Deafness bilateral	Ear and labyrinth disorders	1 (0.01%)
Decreased activity	General disorders and administration site conditions	1 (0.01%)
Delusion	Psychiatric disorders	1 (0.01%)
Dementia of the Alzheimer's type, with delirium	Nervous system disorders	1 (0.01%)
Demyelinating polyneuropathy	Nervous system disorders	1 (0.01%)
Dermatitis bullous	Skin and subcutaneous tissue disorders	1 (0.01%)
Dermatitis exfoliative	Skin and subcutaneous tissue disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Dermatitis exfoliative generalised	Skin and subcutaneous tissue disorders	1 (0.01%)
Device breakage	Product issues	1 (0.01%)
Diabetes mellitus inadequate control	Metabolism and nutrition disorders	1 (0.01%)
Diabetic complication	Metabolism and nutrition disorders	1 (0.01%)
Diastolic hypertension	Vascular disorders	1 (0.01%)
Dilatation ventricular	Cardiac disorders	1 (0.01%)
Disorganised speech	Psychiatric disorders	1 (0.01%)
Distractibility	Psychiatric disorders	1 (0.01%)
Drug administered in wrong device	Injury, poisoning and procedural complications	1 (0.01%)
Dyschromatopsia	Eye disorders	1 (0.01%)
Dysphoria	Psychiatric disorders	1 (0.01%)
Dyspnoea at rest	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Ear neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Ecchymosis	Skin and subcutaneous tissue disorders	1 (0.01%)
Electrocardiogram ST segment abnormal	Investigations	1 (0.01%)
Electrocardiogram ST segment elevation	Investigations	1 (0.01%)
Embolism	Vascular disorders	1 (0.01%)
Encephalopathy	Nervous system disorders	1 (0.01%)
Eosinophilic oesophagitis	Gastrointestinal disorders	1 (0.01%)
Epigastric discomfort	Gastrointestinal disorders	1 (0.01%)
Epiglottic oedema	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Erysipelas	Infections and infestations	1 (0.01%)
Erythema nodosum	Skin and subcutaneous tissue disorders	1 (0.01%)
Escherichia infection	Infections and infestations	1 (0.01%)
Escherichia sepsis	Infections and infestations	1 (0.01%)
Exercise lack of	Social circumstances	1 (0.01%)
Exercise tolerance decreased	General disorders and administration site conditions	1 (0.01%)
Exertional headache	Nervous system disorders	1 (0.01%)
Exophthalmos	Eye disorders	1 (0.01%)
Exposure via eye contact	Injury, poisoning and procedural complications	1 (0.01%)
Eye discharge	Eye disorders	1 (0.01%)
Eye infection	Infections and infestations	1 (0.01%)
Eye injury	Injury, poisoning and procedural complications	1 (0.01%)
Eyelid disorder	Eye disorders	1 (0.01%)
Eyelid exfoliation	Eye disorders	1 (0.01%)
Eyelid function disorder	Eye disorders	1 (0.01%)
Eyelid sensory disorder	Eye disorders	1 (0.01%)
Face crushing	Injury, poisoning and procedural complications	1 (0.01%)
Facet joint syndrome	Musculoskeletal and connective tissue disorders	1 (0.01%)
Facial asymmetry	Musculoskeletal and connective tissue disorders	1 (0.01%)
Facial neuralgia	Nervous system disorders	1 (0.01%)
Faeces pale	Gastrointestinal disorders	1 (0.01%)
Faeces soft	Gastrointestinal disorders	1 (0.01%)
Fear of death	Psychiatric disorders	1 (0.01%)
Fear of injection	Psychiatric disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Febrile convulsion	Nervous system disorders	1 (0.01%)
Febrile neutropenia	Blood and lymphatic system disorders	1 (0.01%)
Femoral neck fracture	Injury, poisoning and procedural complications	1 (0.01%)
Fixed eruption	Skin and subcutaneous tissue disorders	1 (0.01%)
Fluid imbalance	Metabolism and nutrition disorders	1 (0.01%)
Foaming at mouth	General disorders and administration site conditions	1 (0.01%)
Folliculitis	Infections and infestations	1 (0.01%)
Food aversion	Metabolism and nutrition disorders	1 (0.01%)
Food craving	Metabolism and nutrition disorders	1 (0.01%)
Fracture	Injury, poisoning and procedural complications	1 (0.01%)
Frostbite	Injury, poisoning and procedural complications	1 (0.01%)
Functional gastrointestinal disorder	Gastrointestinal disorders	1 (0.01%)
Gallbladder disorder	Hepatobiliary disorders	1 (0.01%)
Gamma-glutamyltransferase increased	Investigations	1 (0.01%)
Gastric pH decreased	Investigations	1 (0.01%)
Gastrointestinal haemorrhage	Gastrointestinal disorders	1 (0.01%)
Gastrointestinal motility disorder	Gastrointestinal disorders	1 (0.01%)
Gastrointestinal stoma complication	Injury, poisoning and procedural complications	1 (0.01%)
Gastrointestinal viral infection	Infections and infestations	1 (0.01%)
Gastrooesophageal sphincter insufficiency	Gastrointestinal disorders	1 (0.01%)
General physical condition abnormal	Investigations	1 (0.01%)
Genital blister	Reproductive system and breast disorders	1 (0.01%)
Giant cell arteritis	Vascular disorders	1 (0.01%)
Gingival disorder	Gastrointestinal disorders	1 (0.01%)
Gingivitis	Infections and infestations	1 (0.01%)
Gingivitis ulcerative	Gastrointestinal disorders	1 (0.01%)
Glare	Eye disorders	1 (0.01%)
Glomerular filtration rate decreased	Investigations	1 (0.01%)
Glycosylated haemoglobin increased	Investigations	1 (0.01%)
Grunting	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Haematocrit decreased	Investigations	1 (0.01%)
Haematoma muscle	Musculoskeletal and connective tissue disorders	1 (0.01%)
Haematuria	Renal and urinary disorders	1 (0.01%)
Haemoglobin increased	Investigations	1 (0.01%)
Haemorrhage subcutaneous	Skin and subcutaneous tissue disorders	1 (0.01%)
Haemorrhage urinary tract	Renal and urinary disorders	1 (0.01%)
Haemorrhoids	Gastrointestinal disorders	1 (0.01%)
Hair colour changes	Skin and subcutaneous tissue disorders	1 (0.01%)
Hallucination, tactile	Psychiatric disorders	1 (0.01%)
Head titubation	Nervous system disorders	1 (0.01%)
Heat illness	Injury, poisoning and procedural complications	1 (0.01%)
Heat oedema	Injury, poisoning and procedural complications	1 (0.01%)
Heat stroke	Injury, poisoning and procedural complications	1 (0.01%)
Helplessness	Psychiatric disorders	1 (0.01%)
Hemiparaesthesia	Nervous system disorders	1 (0.01%)
Hemiplegia	Nervous system disorders	1 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Hepatic artery embolism	Hepatobiliary disorders	1 (0.01%)
Hepatic pain	Hepatobiliary disorders	1 (0.01%)
Herpes zoster oticus	Infections and infestations	1 (0.01%)
Herpes zoster reactivation	Infections and infestations	1 (0.01%)
Hidradenitis	Skin and subcutaneous tissue disorders	1 (0.01%)
Hip fracture	Injury, poisoning and procedural complications	1 (0.01%)
Horner's syndrome	Nervous system disorders	1 (0.01%)
Hydrophobia	Psychiatric disorders	1 (0.01%)
Hypercalcaemia	Metabolism and nutrition disorders	1 (0.01%)
Hyperchlorhydria	Gastrointestinal disorders	1 (0.01%)
Hyperleukocytosis	Blood and lymphatic system disorders	1 (0.01%)
Hypersensitivity pneumonitis	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Hypervigilance	Psychiatric disorders	1 (0.01%)
Hypoaesthesia teeth	Gastrointestinal disorders	1 (0.01%)
Hypomagnesaemia	Metabolism and nutrition disorders	1 (0.01%)
Hyporesponsive to stimuli	Nervous system disorders	1 (0.01%)
Hypoventilation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Hypovolaemic shock	Vascular disorders	1 (0.01%)
Idiopathic intracranial hypertension	Nervous system disorders	1 (0.01%)
Ill-defined disorder	General disorders and administration site conditions	1 (0.01%)
Illness anxiety disorder	Psychiatric disorders	1 (0.01%)
Immobile	Social circumstances	1 (0.01%)
Immune system disorder	Immune system disorders	1 (0.01%)
Immunisation reaction	Immune system disorders	1 (0.01%)
Immunodeficiency	Immune system disorders	1 (0.01%)
Impaired quality of life	Social circumstances	1 (0.01%)
Impulsive behaviour	Psychiatric disorders	1 (0.01%)
Incision site haemorrhage	Injury, poisoning and procedural complications	1 (0.01%)
Increased bronchial secretion	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Indifference	Psychiatric disorders	1 (0.01%)
Infant irritability	Nervous system disorders	1 (0.01%)
Infarction	Vascular disorders	1 (0.01%)
Infection parasitic	Infections and infestations	1 (0.01%)
Infective exacerbation of chronic obstructive airways disease	Infections and infestations	1 (0.01%)
Infertility	Reproductive system and breast disorders	1 (0.01%)
Inflammatory pain	General disorders and administration site conditions	1 (0.01%)
Influenza B virus test positive	Investigations	1 (0.01%)
Infrequent bowel movements	Gastrointestinal disorders	1 (0.01%)
Inguinal mass	Musculoskeletal and connective tissue disorders	1 (0.01%)
Inhibitory drug interaction	General disorders and administration site conditions	1 (0.01%)
Injection site discomfort	General disorders and administration site conditions	1 (0.01%)
Injection site extravasation	General disorders and administration site conditions	1 (0.01%)
Injection site joint movement impairment	General disorders and administration site conditions	1 (0.01%)
Injection site muscle weakness	General disorders and administration site conditions	1 (0.01%)
Injection site pruritus	General disorders and administration site conditions	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Injection site warmth	General disorders and administration site conditions	1 (0.01%)
Injury corneal	Injury, poisoning and procedural complications	1 (0.01%)
Inspiratory capacity abnormal	Investigations	1 (0.01%)
Insulin resistance	Metabolism and nutrition disorders	1 (0.01%)
Intentional product misuse	Injury, poisoning and procedural complications	1 (0.01%)
Intentional self-injury	Psychiatric disorders	1 (0.01%)
Intercepted medication error	Injury, poisoning and procedural complications	1 (0.01%)
Intercepted product preparation error	Injury, poisoning and procedural complications	1 (0.01%)
Intercostal neuralgia	Nervous system disorders	1 (0.01%)
International normalised ratio abnormal	Investigations	1 (0.01%)
International normalised ratio decreased	Investigations	1 (0.01%)
Intervertebral disc protrusion	Musculoskeletal and connective tissue disorders	1 (0.01%)
Intestinal dilatation	Gastrointestinal disorders	1 (0.01%)
Intracardiac thrombus	Cardiac disorders	1 (0.01%)
Intrusive thoughts	Psychiatric disorders	1 (0.01%)
Iritis	Eye disorders	1 (0.01%)
Irregular breathing	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Itching scar	Skin and subcutaneous tissue disorders	1 (0.01%)
IVth nerve paralysis	Nervous system disorders	1 (0.01%)
Jaw disorder	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint ankylosis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint contracture	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint dislocation	Injury, poisoning and procedural complications	1 (0.01%)
Joint instability	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint lock	Musculoskeletal and connective tissue disorders	1 (0.01%)
Kidney infection	Infections and infestations	1 (0.01%)
Labile hypertension	Vascular disorders	1 (0.01%)
Lacunar stroke	Nervous system disorders	1 (0.01%)
Language disorder	Nervous system disorders	1 (0.01%)
Laryngitis	Infections and infestations	1 (0.01%)
Laziness	Psychiatric disorders	1 (0.01%)
Leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Leukoplakia	Skin and subcutaneous tissue disorders	1 (0.01%)
Limb immobilisation	Surgical and medical procedures	1 (0.01%)
Lip discolouration	Gastrointestinal disorders	1 (0.01%)
Lip erythema	Gastrointestinal disorders	1 (0.01%)
Lip exfoliation	Gastrointestinal disorders	1 (0.01%)
Locked-in syndrome	Nervous system disorders	1 (0.01%)
Loss of proprioception	Nervous system disorders	1 (0.01%)
Lower limb fracture	Injury, poisoning and procedural complications	1 (0.01%)
Lung consolidation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Lung neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Lung opacity	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Lymphangitis	Infections and infestations	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Lymphatic disorder	Blood and lymphatic system disorders	1 (0.01%)
Lymph gland infection	Infections and infestations	1 (0.01%)
Lymphocyte count increased	Investigations	1 (0.01%)
Lymphocytosis	Blood and lymphatic system disorders	1 (0.01%)
Macule	Skin and subcutaneous tissue disorders	1 (0.01%)
Malignant hypertension	Vascular disorders	1 (0.01%)
Malnutrition	Metabolism and nutrition disorders	1 (0.01%)
Mania	Psychiatric disorders	1 (0.01%)
Mast cell activation syndrome	Blood and lymphatic system disorders	1 (0.01%)
Masticatory pain	Musculoskeletal and connective tissue disorders	1 (0.01%)
Maternal exposure during breast feeding	Injury, poisoning and procedural complications	1 (0.01%)
Mean cell haemoglobin concentration decreased	Investigations	1 (0.01%)
Mean cell volume decreased	Investigations	1 (0.01%)
Mean platelet volume increased	Investigations	1 (0.01%)
Medication overuse headache	Nervous system disorders	1 (0.01%)
Melaena	Gastrointestinal disorders	1 (0.01%)
Meningism	Nervous system disorders	1 (0.01%)
Meningitis viral	Infections and infestations	1 (0.01%)
Mesenteric vein thrombosis	Gastrointestinal disorders	1 (0.01%)
Metabolic acidosis	Metabolism and nutrition disorders	1 (0.01%)
Metamorphopsia	Eye disorders	1 (0.01%)
Microembolism	Vascular disorders	1 (0.01%)
Micturition disorder	Renal and urinary disorders	1 (0.01%)
Micturition urgency	Renal and urinary disorders	1 (0.01%)
Middle ear inflammation	Ear and labyrinth disorders	1 (0.01%)
Mixed connective tissue disease	Musculoskeletal and connective tissue disorders	1 (0.01%)
Morning sickness	Pregnancy, puerperium and perinatal conditions	1 (0.01%)
Mouth cyst	Gastrointestinal disorders	1 (0.01%)
Mucosal dryness	General disorders and administration site conditions	1 (0.01%)
Multimorbidity	General disorders and administration site conditions	1 (0.01%)
Multi-organ disorder	General disorders and administration site conditions	1 (0.01%)
Muscle atrophy	Musculoskeletal and connective tissue disorders	1 (0.01%)
Muscle spasticity	Nervous system disorders	1 (0.01%)
Muscle tone disorder	Nervous system disorders	1 (0.01%)
Mutism	Psychiatric disorders	1 (0.01%)
Myelitis	Infections and infestations	1 (0.01%)
Myelitis transverse	Nervous system disorders	1 (0.01%)
Myocardial necrosis marker increased	Investigations	1 (0.01%)
Myopathy	Musculoskeletal and connective tissue disorders	1 (0.01%)
Myopia	Eye disorders	1 (0.01%)
Narcolepsy	Nervous system disorders	1 (0.01%)
Nasal discharge discolouration	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Nasal odour	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Nasal pruritus	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Negative thoughts	Psychiatric disorders	1 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Neoplasm skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Nephrolithiasis	Renal and urinary disorders	1 (0.01%)
Nephrotic syndrome	Renal and urinary disorders	1 (0.01%)
Nerve degeneration	Nervous system disorders	1 (0.01%)
Neurological symptom	Nervous system disorders	1 (0.01%)
Neutropenia	Blood and lymphatic system disorders	1 (0.01%)
Nipple swelling	Reproductive system and breast disorders	1 (0.01%)
Nodal rhythm	Cardiac disorders	1 (0.01%)
Noninfective encephalitis	Nervous system disorders	1 (0.01%)
Noninfective gingivitis	Gastrointestinal disorders	1 (0.01%)
Obsessive-compulsive symptom	Psychiatric disorders	1 (0.01%)
Occipital neuralgia	Nervous system disorders	1 (0.01%)
Oligodipsia	Metabolism and nutrition disorders	1 (0.01%)
Oral blood blister	Gastrointestinal disorders	1 (0.01%)
Oral mucosa erosion	Gastrointestinal disorders	1 (0.01%)
Oral papule	Gastrointestinal disorders	1 (0.01%)
Oropharyngeal spasm	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Orthostatic heart rate response increased	Investigations	1 (0.01%)
Orthostatic intolerance	Nervous system disorders	1 (0.01%)
Oscillopsia	Eye disorders	1 (0.01%)
Osteoarthritis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Osteochondritis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Otitis externa	Infections and infestations	1 (0.01%)
Overweight	Metabolism and nutrition disorders	1 (0.01%)
Oxygen consumption	Investigations	1 (0.01%)
Palatal disorder	Gastrointestinal disorders	1 (0.01%)
Palmar-plantar erythrodysesthesia syndrome	Skin and subcutaneous tissue disorders	1 (0.01%)
Pancreatitis acute	Gastrointestinal disorders	1 (0.01%)
Panic disorder	Psychiatric disorders	1 (0.01%)
Paraesthesia ear	Ear and labyrinth disorders	1 (0.01%)
Paranasal sinus inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Paraparesis	Nervous system disorders	1 (0.01%)
Paraplegia	Nervous system disorders	1 (0.01%)
Paresis cranial nerve	Nervous system disorders	1 (0.01%)
Partial seizures	Nervous system disorders	1 (0.01%)
Pathogen resistance	Infections and infestations	1 (0.01%)
Patient elopement	Nervous system disorders	1 (0.01%)
Peau d'orange	Skin and subcutaneous tissue disorders	1 (0.01%)
Pelvic fracture	Injury, poisoning and procedural complications	1 (0.01%)
Penile haemorrhage	Reproductive system and breast disorders	1 (0.01%)
Penile swelling	Reproductive system and breast disorders	1 (0.01%)
Pericardial effusion	Cardiac disorders	1 (0.01%)
Peripheral circulatory failure	Vascular disorders	1 (0.01%)
Peripheral embolism	Vascular disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Peripheral motor neuropathy	Nervous system disorders	1 (0.01%)
Peripheral sensory neuropathy	Nervous system disorders	1 (0.01%)
Peroneal nerve injury	Injury, poisoning and procedural complications	1 (0.01%)
Pharyngeal ulceration	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Phonophobia	Psychiatric disorders	1 (0.01%)
Pityriasis rosea	Skin and subcutaneous tissue disorders	1 (0.01%)
Plantar erythema	Skin and subcutaneous tissue disorders	1 (0.01%)
Plicated tongue	Gastrointestinal disorders	1 (0.01%)
Pneumonia bacterial	Infections and infestations	1 (0.01%)
Poisoning	Injury, poisoning and procedural complications	1 (0.01%)
Posterior reversible encephalopathy syndrome	Nervous system disorders	1 (0.01%)
Post lumbar puncture syndrome	Injury, poisoning and procedural complications	1 (0.01%)
Postoperative ileus	Injury, poisoning and procedural complications	1 (0.01%)
Post procedural haemorrhage	Injury, poisoning and procedural complications	1 (0.01%)
Post-traumatic stress disorder	Psychiatric disorders	1 (0.01%)
Postural orthostatic tachycardia syndrome	Cardiac disorders	1 (0.01%)
Posture abnormal	Musculoskeletal and connective tissue disorders	1 (0.01%)
Premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	1 (0.01%)
Pressure of speech	Psychiatric disorders	1 (0.01%)
Primary headache associated with sexual activity	Nervous system disorders	1 (0.01%)
Procedural nausea	Injury, poisoning and procedural complications	1 (0.01%)
Proctitis ulcerative	Gastrointestinal disorders	1 (0.01%)
Product confusion	Injury, poisoning and procedural complications	1 (0.01%)
Product packaging quantity issue	Product issues	1 (0.01%)
Product quality issue	Product issues	1 (0.01%)
Prolonged expiration	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Prostatomegaly	Reproductive system and breast disorders	1 (0.01%)
Protein urine present	Investigations	1 (0.01%)
Pruritus allergic	Skin and subcutaneous tissue disorders	1 (0.01%)
Pruritus genital	Reproductive system and breast disorders	1 (0.01%)
Pseudolymphoma	Blood and lymphatic system disorders	1 (0.01%)
Psychiatric symptom	Psychiatric disorders	1 (0.01%)
Psychological factor affecting medical condition	Psychiatric disorders	1 (0.01%)
Psychotic behaviour	Psychiatric disorders	1 (0.01%)
Pulmonary sepsis	Infections and infestations	1 (0.01%)
Pulseless electrical activity	Cardiac disorders	1 (0.01%)
Pupillary disorder	Eye disorders	1 (0.01%)
Pupillary reflex impaired	Eye disorders	1 (0.01%)
Pyelonephritis	Infections and infestations	1 (0.01%)
Rash morbilliform	Skin and subcutaneous tissue disorders	1 (0.01%)
Reaction to preservatives	Immune system disorders	1 (0.01%)
Red blood cell count decreased	Investigations	1 (0.01%)
Red blood cell count increased	Investigations	1 (0.01%)
Red blood cells urine positive	Investigations	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Reduced facial expression	Nervous system disorders	1 (0.01%)
Regurgitation	Gastrointestinal disorders	1 (0.01%)
Renal impairment	Renal and urinary disorders	1 (0.01%)
Respiratory depression	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Respiratory symptom	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Respiratory tract oedema	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Retinal migraine	Nervous system disorders	1 (0.01%)
Rhinovirus infection	Infections and infestations	1 (0.01%)
Rib fracture	Injury, poisoning and procedural complications	1 (0.01%)
Right ventricular dysfunction	Cardiac disorders	1 (0.01%)
Right ventricular enlargement	Cardiac disorders	1 (0.01%)
Rubber sensitivity	Immune system disorders	1 (0.01%)
SARS-CoV-1 test positive	Investigations	1 (0.01%)
SARS-CoV-2 test negative	Investigations	1 (0.01%)
Scar pain	Skin and subcutaneous tissue disorders	1 (0.01%)
Sciatic nerve neuropathy	Nervous system disorders	1 (0.01%)
Scleritis	Eye disorders	1 (0.01%)
Scrotal pain	Reproductive system and breast disorders	1 (0.01%)
Secretion discharge	General disorders and administration site conditions	1 (0.01%)
Sense of oppression	General disorders and administration site conditions	1 (0.01%)
Sensitisation	Immune system disorders	1 (0.01%)
Serositis	General disorders and administration site conditions	1 (0.01%)
Shock symptom	Vascular disorders	1 (0.01%)
Sinonasal obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Sinus arrhythmia	Cardiac disorders	1 (0.01%)
Sinus tarsi syndrome	Musculoskeletal and connective tissue disorders	1 (0.01%)
Sitophobia	Psychiatric disorders	1 (0.01%)
Skin abrasion	Injury, poisoning and procedural complications	1 (0.01%)
Skin cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Skin indentation	Skin and subcutaneous tissue disorders	1 (0.01%)
Skin induration	Skin and subcutaneous tissue disorders	1 (0.01%)
Skin injury	Injury, poisoning and procedural complications	1 (0.01%)
Skin odour abnormal	Skin and subcutaneous tissue disorders	1 (0.01%)
Skin weeping	Skin and subcutaneous tissue disorders	1 (0.01%)
Sleep deficit	Nervous system disorders	1 (0.01%)
Sleep paralysis	Nervous system disorders	1 (0.01%)
Sleep terror	Psychiatric disorders	1 (0.01%)
Small intestinal obstruction	Gastrointestinal disorders	1 (0.01%)
Somatic symptom disorder	Psychiatric disorders	1 (0.01%)
Spinal disorder	Musculoskeletal and connective tissue disorders	1 (0.01%)
Spinal fusion surgery	Surgical and medical procedures	1 (0.01%)
Splenomegaly	Blood and lymphatic system disorders	1 (0.01%)
Staphylococcal infection	Infections and infestations	1 (0.01%)
Staphylococcal sepsis	Infections and infestations	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Staring	Psychiatric disorders	1 (0.01%)
Status asthmaticus	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Status epilepticus	Nervous system disorders	1 (0.01%)
Stiff leg syndrome	Nervous system disorders	1 (0.01%)
Stiff tongue	Gastrointestinal disorders	1 (0.01%)
Submaxillary gland enlargement	Gastrointestinal disorders	1 (0.01%)
Substance abuse	Psychiatric disorders	1 (0.01%)
Suffocation feeling	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Superficial injury of eye	Injury, poisoning and procedural complications	1 (0.01%)
Supraventricular extrasystoles	Cardiac disorders	1 (0.01%)
Suture related complication	Injury, poisoning and procedural complications	1 (0.01%)
Symphysiolysis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Symptom recurrence	General disorders and administration site conditions	1 (0.01%)
Synovial cyst	Musculoskeletal and connective tissue disorders	1 (0.01%)
Synovial rupture	Injury, poisoning and procedural complications	1 (0.01%)
Synovitis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Syringe issue	Product issues	1 (0.01%)
Temperature intolerance	General disorders and administration site conditions	1 (0.01%)
Tendon injury	Injury, poisoning and procedural complications	1 (0.01%)
Tenosynovitis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Tetany	Metabolism and nutrition disorders	1 (0.01%)
Thrombocytosis	Blood and lymphatic system disorders	1 (0.01%)
Thunderclap headache	Nervous system disorders	1 (0.01%)
Thyroid function test abnormal	Investigations	1 (0.01%)
Tic	Psychiatric disorders	1 (0.01%)
Tongue blistering	Gastrointestinal disorders	1 (0.01%)
Tongue haemorrhage	Gastrointestinal disorders	1 (0.01%)
Tongue injury	Injury, poisoning and procedural complications	1 (0.01%)
Tonic clonic movements	Nervous system disorders	1 (0.01%)
Tonsillar inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Tonsillitis bacterial	Infections and infestations	1 (0.01%)
Tonsillolith	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Tooth infection	Infections and infestations	1 (0.01%)
Toxic epidermal necrolysis	Skin and subcutaneous tissue disorders	1 (0.01%)
Toxic skin eruption	Skin and subcutaneous tissue disorders	1 (0.01%)
Transaminases increased	Investigations	1 (0.01%)
Transient global amnesia	Nervous system disorders	1 (0.01%)
Trigeminal neuritis	Nervous system disorders	1 (0.01%)
Tri-iodothyronine decreased	Investigations	1 (0.01%)
Troponin T increased	Investigations	1 (0.01%)
Tryptase increased	Investigations	1 (0.01%)
Type I hypersensitivity	Immune system disorders	1 (0.01%)
Ulcer	General disorders and administration site conditions	1 (0.01%)
Upper airway obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Upper limb fracture	Injury, poisoning and procedural complications	1 (0.01%)
Urethral pain	Renal and urinary disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Urinary tract disorder	Renal and urinary disorders	1 (0.01%)
Urinary tract infection bacterial	Infections and infestations	1 (0.01%)
Urine analysis abnormal	Investigations	1 (0.01%)
Urine output decreased	Investigations	1 (0.01%)
Urine output increased	Investigations	1 (0.01%)
Urticaria cholinergic	Skin and subcutaneous tissue disorders	1 (0.01%)
Urticaria papular	Skin and subcutaneous tissue disorders	1 (0.01%)
Uterine contractions during pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.01%)
Uterine haemorrhage	Reproductive system and breast disorders	1 (0.01%)
Uvulitis	Gastrointestinal disorders	1 (0.01%)
Vaccination site abscess	Infections and infestations	1 (0.01%)
Vaccination site coldness	General disorders and administration site conditions	1 (0.01%)
Vaccination site dermatitis	General disorders and administration site conditions	1 (0.01%)
Vaccination site injury	General disorders and administration site conditions	1 (0.01%)
Vaccination site joint erythema	General disorders and administration site conditions	1 (0.01%)
Vaccination site joint swelling	General disorders and administration site conditions	1 (0.01%)
Vaccination site joint warmth	General disorders and administration site conditions	1 (0.01%)
Vaccination site pallor	General disorders and administration site conditions	1 (0.01%)
Vaccination site papule	General disorders and administration site conditions	1 (0.01%)
Vaccination site plaque	General disorders and administration site conditions	1 (0.01%)
Vaginal infection	Infections and infestations	1 (0.01%)
Varicella	Infections and infestations	1 (0.01%)
Vascular pain	Vascular disorders	1 (0.01%)
Vasculitic rash	Skin and subcutaneous tissue disorders	1 (0.01%)
Vasoconstriction	Vascular disorders	1 (0.01%)
Vasomotor rhinitis	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Vein discolouration	Vascular disorders	1 (0.01%)
Vein disorder	Vascular disorders	1 (0.01%)
Vein rupture	Vascular disorders	1 (0.01%)
Vena cava thrombosis	Vascular disorders	1 (0.01%)
Ventricular tachycardia	Cardiac disorders	1 (0.01%)
Vestibular disorder	Ear and labyrinth disorders	1 (0.01%)
Vestibular migraine	Nervous system disorders	1 (0.01%)
Vestibular neuronitis	Infections and infestations	1 (0.01%)
Viral labyrinthitis	Infections and infestations	1 (0.01%)
Viral pharyngitis	Infections and infestations	1 (0.01%)
Viral tonsillitis	Infections and infestations	1 (0.01%)
Viral upper respiratory tract infection	Infections and infestations	1 (0.01%)
Visual acuity reduced	Eye disorders	1 (0.01%)
Visual brightness	Eye disorders	1 (0.01%)
Vital functions abnormal	Investigations	1 (0.01%)
Vitreous floaters	Eye disorders	1 (0.01%)
Vocal cord disorder	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Vomiting psychogenic	Psychiatric disorders	1 (0.01%)
Vulval disorder	Reproductive system and breast disorders	1 (0.01%)
Vulvovaginal mycotic infection	Infections and infestations	1 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Vulvovaginal rash	Reproductive system and breast disorders	1 (0.01%)
Vulvovaginal swelling	Reproductive system and breast disorders	1 (0.01%)
Weight bearing difficulty	Musculoskeletal and connective tissue disorders	1 (0.01%)
Weight loss diet	Surgical and medical procedures	1 (0.01%)
White blood cell count decreased	Investigations	1 (0.01%)
Wound haemorrhage	Injury, poisoning and procedural complications	1 (0.01%)
Writer's cramp	Nervous system disorders	1 (0.01%)
Yawning	Respiratory, thoracic and mediastinal disorders	1 (0.01%)

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**APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

PF-07302048 - ALL

Reporting Period: Through 31-JAN-2021

Total Number of Cases: 18061 (100%) (ALL) / 18061 (OVERALL)

Total Number of Adverse Events (PT): 64007 (ALL)

**NON CT**

Total Number of Cases: 18061

Total Number of Adverse Events (PT): 64007

		Number of Cases	Percentage (%)
<b>Sex</b>			
	FEMALE	12461	69.0 %
	MALE	3762	20.8 %
	NO DATA	1838	10.2 %
<b>Age Range</b>			
Min = 0.01 Years	0 to 27 days	5	0.0 %
Max = 104.0 Years	28 days to 23 months	46	0.3 %
Mean = 48.2	2 to 11 years	24	0.1 %
Median = 46.0	12 to 17 years	16	0.1 %
Standard Deviation = 18.07	18 - 30 years	2243	12.4 %
n = 14024	31 - 50 years	6127	33.9 %
	51 - 64 years	3246	18.0 %
	65 - 74 years	799	4.4 %
	Greater than or equal to 75 years	1584	8.8 %
	Unknown	3971	22.0 %
<b>Country Where Event Occurred</b>			
	UNITED STATES	8819	48.8 %
	UNITED KINGDOM	5436	30.1 %
	GERMANY	727	4.0 %
	ITALY	657	3.6 %
	ISRAEL	373	2.1 %
	ROMANIA	244	1.4 %
	SPAIN	192	1.1 %
	PORTUGAL	169	0.9 %
	CANADA	152	0.8 %
	DENMARK	151	0.8 %
	POLAND	127	0.7 %
	SWEDEN	127	0.7 %
	GREECE	118	0.7 %
	MEXICO	117	0.6 %
	FRANCE	102	0.6 %
	HUNGARY	59	0.3 %
	NORWAY	55	0.3 %
	ICELAND	41	0.2 %
	PUERTO RICO	31	0.2 %
	SERBIA	30	0.2 %

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		Number of Cases	Percentage (%)
<b>Country Where Event Occured</b>			
	BELGIUM	27	0.1 %
	CHILE	26	0.1 %
	SLOVAKIA	23	0.1 %
	BULGARIA	22	0.1 %
	AUSTRIA	21	0.1 %
	FINLAND	20	0.1 %
	LATVIA	20	0.1 %
	CROATIA	19	0.1 %
	CZECH REPUBLIC	19	0.1 %
	COSTA RICA	14	0.1 %
	SWITZERLAND	14	0.1 %
	ESTONIA	13	0.1 %
	CYPRUS	11	0.1 %
	NETHERLANDS	11	0.1 %
	UNITED ARAB EMIRATES	11	0.1 %
	LITHUANIA	10	0.1 %
	IRELAND	8	0.0 %
	SAUDI ARABIA	8	0.0 %
	SINGAPORE	7	0.0 %
	SLOVENIA	7	0.0 %
	MALTA	6	0.0 %
	QATAR	3	0.0 %
	UNITED STATES MINOR OUTLYING ISLANDS	3	0.0 %
	NORTHERN MARIANA ISLANDS	2	0.0 %
	AFGHANISTAN	1	0.0 %
	ANDORRA	1	0.0 %
	BAHRAIN	1	0.0 %
	BERMUDA	1	0.0 %
	COLOMBIA	1	0.0 %
	INDIA	1	0.0 %
	KUWAIT	1	0.0 %
	LUXEMBOURG	1	0.0 %
	OMAN	1	0.0 %
<b>Source</b>			
	Clinical Study	13	0.1 %
	Literature - Study	14	0.1 %
	Solicited	1	0.0 %
	Spontaneous	18033	99.8 %
<b>Case Seriousness</b>			
	SERIOUS	6286	34.8 %
	NONSERIOUS	11775	65.2 %



		Number of Cases	Percentage (%)
<b>HP/Medically Confirmed</b>			
	Yes	11744	65.0 %
	No	6317	35.0 %
<b>Special Populations</b>	<b>Pregnant/Breastfeeding Women</b>		
	Yes	262	1.5 %
	<b>Pediatric Non EIU</b>		
	Yes	42	0.2 %
	<b>Elderly</b>		
	Yes	2383	13.2 %
	<b>Race/Ethnicity</b>		
	ASIAN - HISPANIC OR LATINO	11	0.1 %
	ASIAN - NO DATA	287	1.6 %
	ASIAN - NOT HISPANIC OR LATINO	270	1.5 %
	ASIAN - OTHER	1	0.0 %
	BLACK - HISPANIC OR LATINO	10	0.1 %
	BLACK - NO DATA	189	1.0 %
	BLACK - NOT HISPANIC OR LATINO	116	0.6 %
	BLACK - OTHER	1	0.0 %
	CAUCASIAN - HISPANIC OR LATINO	214	1.2 %
	CAUCASIAN - NO DATA	1939	10.7 %
	CAUCASIAN - NOT HISPANIC OR LATINO	2214	12.3 %
	CAUCASIAN - OTHER	3	0.0 %
	NATIVE AMERICAN - HISPANIC OR LATINO	6	0.0 %
	NATIVE AMERICAN - NO DATA	39	0.2 %
	NATIVE AMERICAN - NOT HISPANIC OR LATINO	15	0.1 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO	2	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA	5	0.0 %
	NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO	14	0.1 %
	NO DATA - HISPANIC OR LATINO	334	1.8 %
	NO DATA - NO DATA	12287	68.0 %
	NO DATA - NOT HISPANIC OR LATINO	72	0.4 %
	NO DATA - OTHER	32	0.2 %

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**APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

PF-07302048 - ALL

Reporting Period: Through 31-JAN-2021

Total Number of Cases: 18061 (100%) (ALL) / 18061 (OVERALL)

Total Number of Adverse Events (PT): 64007 (ALL)

**NON CT**

Total Number of Cases: 18061

Total Number of Adverse Events (PT): 64007

Preferred Term	System Organ Class (SOC)	Number of Cases
Headache	Nervous system disorders	4269 (23.64%)
Pyrexia	General disorders and administration site conditions	3281 (18.17%)
Fatigue	General disorders and administration site conditions	2984 (16.52%)
Vaccination site pain	General disorders and administration site conditions	2532 (14.02%)
Chills	General disorders and administration site conditions	2529 (14.00%)
Nausea	Gastrointestinal disorders	2140 (11.85%)
Myalgia	Musculoskeletal and connective tissue disorders	1949 (10.79%)
Pain in extremity	Musculoskeletal and connective tissue disorders	1817 (10.06%)
Pain	General disorders and administration site conditions	1797 (9.95%)
Dizziness	Nervous system disorders	1461 (8.09%)
Arthralgia	Musculoskeletal and connective tissue disorders	1382 (7.65%)
Drug ineffective	General disorders and administration site conditions	1233 (6.83%)
Malaise	General disorders and administration site conditions	1141 (6.32%)
Lymphadenopathy	Blood and lymphatic system disorders	832 (4.61%)
COVID-19	Infections and infestations	789 (4.37%)
Diarrhoea	Gastrointestinal disorders	711 (3.94%)
Asthenia	General disorders and administration site conditions	704 (3.90%)
Vomiting	Gastrointestinal disorders	633 (3.50%)
Dyspnoea	Respiratory, thoracic and mediastinal disorders	612 (3.39%)
Pruritus	Skin and subcutaneous tissue disorders	607 (3.36%)
Rash	Skin and subcutaneous tissue disorders	596 (3.30%)
Paraesthesia	Nervous system disorders	590 (3.27%)
Vaccination site erythema	General disorders and administration site conditions	448 (2.48%)
Cough	Respiratory, thoracic and mediastinal disorders	444 (2.46%)
Hypoaesthesia	Nervous system disorders	440 (2.44%)
Vaccination site swelling	General disorders and administration site conditions	430 (2.38%)
Urticaria	Skin and subcutaneous tissue disorders	403 (2.23%)
Influenza like illness	General disorders and administration site conditions	398 (2.20%)
Oropharyngeal pain	Respiratory, thoracic and mediastinal disorders	382 (2.12%)
Feeling abnormal	General disorders and administration site conditions	376 (2.08%)
Erythema	Skin and subcutaneous tissue disorders	371 (2.05%)
Tachycardia	Cardiac disorders	360 (1.99%)
Feeling hot	General disorders and administration site conditions	357 (1.98%)
Hyperhidrosis	Skin and subcutaneous tissue disorders	355 (1.97%)
Off label use	Injury, poisoning and procedural complications	355 (1.97%)
Heart rate increased	Investigations	340 (1.88%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Product use issue	Injury, poisoning and procedural complications	339 (1.88%)
SARS-CoV-2 test positive	Investigations	325 (1.80%)
Back pain	Musculoskeletal and connective tissue disorders	320 (1.77%)
Neck pain	Musculoskeletal and connective tissue disorders	320 (1.77%)
Inappropriate schedule of product administration	Injury, poisoning and procedural complications	304 (1.68%)
Palpitations	Cardiac disorders	294 (1.63%)
Tremor	Nervous system disorders	284 (1.57%)
Peripheral swelling	General disorders and administration site conditions	283 (1.57%)
Paraesthesia oral	Gastrointestinal disorders	280 (1.55%)
Poor quality product administered	Injury, poisoning and procedural complications	279 (1.54%)
Chest discomfort	General disorders and administration site conditions	267 (1.48%)
Migraine	Nervous system disorders	248 (1.37%)
Flushing	Vascular disorders	242 (1.34%)
Feeling cold	General disorders and administration site conditions	235 (1.30%)
Chest pain	General disorders and administration site conditions	234 (1.30%)
Lethargy	Nervous system disorders	227 (1.26%)
Dysgeusia	Nervous system disorders	226 (1.25%)
Decreased appetite	Metabolism and nutrition disorders	224 (1.24%)
Somnolence	Nervous system disorders	214 (1.18%)
Hypersensitivity	Immune system disorders	212 (1.17%)
Insomnia	Psychiatric disorders	204 (1.13%)
Swelling	General disorders and administration site conditions	204 (1.13%)
Anaphylactic reaction	Immune system disorders	199 (1.10%)
Vaccination site warmth	General disorders and administration site conditions	197 (1.09%)
Hypertension	Vascular disorders	184 (1.02%)
Lymph node pain	Blood and lymphatic system disorders	181 (1.00%)
Blood pressure increased	Investigations	177 (0.98%)
Abdominal pain	Gastrointestinal disorders	174 (0.96%)
Abdominal pain upper	Gastrointestinal disorders	173 (0.96%)
Limb discomfort	Musculoskeletal and connective tissue disorders	171 (0.95%)
Death	General disorders and administration site conditions	170 (0.94%)
Hypoaesthesia oral	Gastrointestinal disorders	168 (0.93%)
Syncope	Nervous system disorders	167 (0.92%)
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders	166 (0.92%)
Illness	General disorders and administration site conditions	165 (0.91%)
Vaccination site pruritus	General disorders and administration site conditions	164 (0.91%)
Musculoskeletal stiffness	Musculoskeletal and connective tissue disorders	160 (0.89%)
Swelling face	General disorders and administration site conditions	157 (0.87%)
Underdose	Injury, poisoning and procedural complications	156 (0.86%)
Nasal congestion	Respiratory, thoracic and mediastinal disorders	150 (0.83%)
Vertigo	Ear and labyrinth disorders	148 (0.82%)
Throat tightness	Respiratory, thoracic and mediastinal disorders	146 (0.81%)
Body temperature increased	Investigations	144 (0.80%)
Muscular weakness	Musculoskeletal and connective tissue disorders	141 (0.78%)
Axillary pain	General disorders and administration site conditions	139 (0.77%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Presyncope	Nervous system disorders	131 (0.73%)
Throat irritation	Respiratory, thoracic and mediastinal disorders	129 (0.71%)
Anxiety	Psychiatric disorders	128 (0.71%)
Facial paralysis	Nervous system disorders	128 (0.71%)
Rash erythematous	Skin and subcutaneous tissue disorders	127 (0.70%)
Suspected COVID-19	Infections and infestations	127 (0.70%)
Vision blurred	Eye disorders	127 (0.70%)
Hot flush	Vascular disorders	123 (0.68%)
Nasopharyngitis	Infections and infestations	119 (0.66%)
Muscle spasms	Musculoskeletal and connective tissue disorders	118 (0.65%)
Rash pruritic	Skin and subcutaneous tissue disorders	118 (0.65%)
Incorrect route of product administration	Injury, poisoning and procedural complications	116 (0.64%)
Lip swelling	Gastrointestinal disorders	115 (0.64%)
Product temperature excursion issue	Product issues	115 (0.64%)
Swollen tongue	Gastrointestinal disorders	115 (0.64%)
Product preparation error	Injury, poisoning and procedural complications	112 (0.62%)
Eye pain	Eye disorders	111 (0.61%)
Maternal exposure during pregnancy	Injury, poisoning and procedural complications	111 (0.61%)
Ageusia	Nervous system disorders	108 (0.60%)
Exposure via breast milk	Injury, poisoning and procedural complications	103 (0.57%)
Pharyngeal swelling	Respiratory, thoracic and mediastinal disorders	103 (0.57%)
Burning sensation	Nervous system disorders	102 (0.56%)
Dry mouth	Gastrointestinal disorders	102 (0.56%)
Product preparation issue	Injury, poisoning and procedural complications	102 (0.56%)
Cold sweat	Skin and subcutaneous tissue disorders	100 (0.55%)
Anosmia	Nervous system disorders	97 (0.54%)
Dysphagia	Gastrointestinal disorders	95 (0.53%)
Ear pain	Ear and labyrinth disorders	94 (0.52%)
Tinnitus	Ear and labyrinth disorders	93 (0.51%)
Hypotension	Vascular disorders	92 (0.51%)
Circumstance or information capable of leading to medication error	Injury, poisoning and procedural complications	87 (0.48%)
Confusional state	Psychiatric disorders	86 (0.48%)
Loss of consciousness	Nervous system disorders	86 (0.48%)
Night sweats	Skin and subcutaneous tissue disorders	86 (0.48%)
Rash macular	Skin and subcutaneous tissue disorders	85 (0.47%)
Discomfort	General disorders and administration site conditions	83 (0.46%)
Influenza	Infections and infestations	83 (0.46%)
Overdose	Injury, poisoning and procedural complications	83 (0.46%)
Abdominal discomfort	Gastrointestinal disorders	82 (0.45%)
Condition aggravated	General disorders and administration site conditions	82 (0.45%)
Gait disturbance	General disorders and administration site conditions	81 (0.45%)
Eye swelling	Eye disorders	79 (0.44%)
Bone pain	Musculoskeletal and connective tissue disorders	78 (0.43%)
Herpes zoster	Infections and infestations	74 (0.41%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Wrong technique in product usage process	Injury, poisoning and procedural complications	72 (0.40%)
Pallor	Vascular disorders	71 (0.39%)
Allergy to vaccine	Immune system disorders	70 (0.39%)
Peripheral coldness	Vascular disorders	70 (0.39%)
Vaccination site mass	General disorders and administration site conditions	66 (0.37%)
Vaccination site movement impairment	General disorders and administration site conditions	65 (0.36%)
Vaccination site rash	General disorders and administration site conditions	64 (0.35%)
Wheezing	Respiratory, thoracic and mediastinal disorders	63 (0.35%)
Feeling of body temperature change	General disorders and administration site conditions	62 (0.34%)
Mobility decreased	Musculoskeletal and connective tissue disorders	62 (0.34%)
Balance disorder	Nervous system disorders	59 (0.33%)
Sleep disorder	Psychiatric disorders	59 (0.33%)
Fall	Injury, poisoning and procedural complications	57 (0.32%)
Sneezing	Respiratory, thoracic and mediastinal disorders	57 (0.32%)
Vaccination site induration	General disorders and administration site conditions	55 (0.30%)
Dizziness postural	Nervous system disorders	54 (0.30%)
Pain in jaw	Musculoskeletal and connective tissue disorders	54 (0.30%)
Disturbance in attention	Nervous system disorders	53 (0.29%)
Angioedema	Skin and subcutaneous tissue disorders	51 (0.28%)
Joint swelling	Musculoskeletal and connective tissue disorders	51 (0.28%)
Oxygen saturation decreased	Investigations	51 (0.28%)
Dysphonia	Respiratory, thoracic and mediastinal disorders	50 (0.28%)
Head discomfort	Nervous system disorders	50 (0.28%)
Photophobia	Eye disorders	50 (0.28%)
Vaccination site bruising	General disorders and administration site conditions	50 (0.28%)
Epistaxis	Respiratory, thoracic and mediastinal disorders	49 (0.27%)
Cerebrovascular accident	Nervous system disorders	46 (0.25%)
Hypersomnia	Nervous system disorders	46 (0.25%)
Vaccination site discomfort	General disorders and administration site conditions	46 (0.25%)
Exposure to SARS-CoV-2	Injury, poisoning and procedural complications	45 (0.25%)
Facial pain	General disorders and administration site conditions	45 (0.25%)
Eye pruritus	Eye disorders	44 (0.24%)
Product administered at inappropriate site	Injury, poisoning and procedural complications	44 (0.24%)
Taste disorder	Nervous system disorders	44 (0.24%)
Cardiac arrest	Cardiac disorders	43 (0.24%)
Disease recurrence	General disorders and administration site conditions	43 (0.24%)
Joint range of motion decreased	Musculoskeletal and connective tissue disorders	43 (0.24%)
Seizure	Nervous system disorders	43 (0.24%)
Dehydration	Metabolism and nutrition disorders	42 (0.23%)
Nervousness	Psychiatric disorders	42 (0.23%)
Vaccination site reaction	General disorders and administration site conditions	42 (0.23%)
Visual impairment	Eye disorders	42 (0.23%)
Restlessness	Psychiatric disorders	41 (0.23%)
Accidental overdose	Injury, poisoning and procedural complications	40 (0.22%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Muscle tightness	Musculoskeletal and connective tissue disorders	40 (0.22%)
Sudden death	General disorders and administration site conditions	39 (0.22%)
Tenderness	General disorders and administration site conditions	39 (0.22%)
Dry throat	Respiratory, thoracic and mediastinal disorders	38 (0.21%)
Loss of personal independence in daily activities	Social circumstances	38 (0.21%)
Movement disorder	Nervous system disorders	38 (0.21%)
Poor quality sleep	Nervous system disorders	38 (0.21%)
Thirst	General disorders and administration site conditions	38 (0.21%)
Asthma	Respiratory, thoracic and mediastinal disorders	37 (0.20%)
Contusion	Injury, poisoning and procedural complications	37 (0.20%)
Neuralgia	Nervous system disorders	36 (0.20%)
Product colour issue	Product issues	36 (0.20%)
Vaccination site inflammation	General disorders and administration site conditions	36 (0.20%)
Blood pressure decreased	Investigations	35 (0.19%)
Dyspepsia	Gastrointestinal disorders	35 (0.19%)
Eye irritation	Eye disorders	35 (0.19%)
Anaphylactic shock	Immune system disorders	34 (0.19%)
Inflammation	General disorders and administration site conditions	34 (0.19%)
Vaccination site paraesthesia	General disorders and administration site conditions	34 (0.19%)
General physical health deterioration	General disorders and administration site conditions	33 (0.18%)
Rash papular	Skin and subcutaneous tissue disorders	33 (0.18%)
Sensation of foreign body	General disorders and administration site conditions	33 (0.18%)
Vaccination site urticaria	General disorders and administration site conditions	33 (0.18%)
Ocular hyperaemia	Eye disorders	32 (0.18%)
Pneumonia	Infections and infestations	32 (0.18%)
Tension headache	Nervous system disorders	32 (0.18%)
Hyperaesthesia	Nervous system disorders	31 (0.17%)
Injection site pain	General disorders and administration site conditions	31 (0.17%)
Muscle twitching	Musculoskeletal and connective tissue disorders	31 (0.17%)
Musculoskeletal pain	Musculoskeletal and connective tissue disorders	31 (0.17%)
Skin burning sensation	Skin and subcutaneous tissue disorders	31 (0.17%)
Swelling of eyelid	Eye disorders	31 (0.17%)
Atrial fibrillation	Cardiac disorders	30 (0.17%)
Ear discomfort	Ear and labyrinth disorders	30 (0.17%)
Lacrimation increased	Eye disorders	30 (0.17%)
Myocardial infarction	Cardiac disorders	30 (0.17%)
Arthritis	Musculoskeletal and connective tissue disorders	29 (0.16%)
Blister	Skin and subcutaneous tissue disorders	29 (0.16%)
Circulatory collapse	Vascular disorders	29 (0.16%)
Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	29 (0.16%)
Oral herpes	Infections and infestations	29 (0.16%)
Speech disorder	Nervous system disorders	29 (0.16%)
Dermatitis allergic	Skin and subcutaneous tissue disorders	28 (0.16%)
Musculoskeletal discomfort	Musculoskeletal and connective tissue disorders	28 (0.16%)
Pain of skin	Skin and subcutaneous tissue disorders	28 (0.16%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pharyngeal paraesthesia	Respiratory, thoracic and mediastinal disorders	28 (0.16%)
Exposure during pregnancy	Injury, poisoning and procedural complications	27 (0.15%)
Joint stiffness	Musculoskeletal and connective tissue disorders	27 (0.15%)
Skin discolouration	Skin and subcutaneous tissue disorders	27 (0.15%)
Blood glucose increased	Investigations	26 (0.14%)
Eye disorder	Eye disorders	26 (0.14%)
Retching	Gastrointestinal disorders	26 (0.14%)
Vaccination site hypoaesthesia	General disorders and administration site conditions	26 (0.14%)
Agitation	Psychiatric disorders	25 (0.14%)
Disorientation	Psychiatric disorders	25 (0.14%)
Oropharyngeal discomfort	Respiratory, thoracic and mediastinal disorders	25 (0.14%)
Productive cough	Respiratory, thoracic and mediastinal disorders	25 (0.14%)
Respiratory distress	Respiratory, thoracic and mediastinal disorders	25 (0.14%)
Body temperature abnormal	Investigations	24 (0.13%)
Breast pain	Reproductive system and breast disorders	24 (0.13%)
Lip oedema	Gastrointestinal disorders	24 (0.13%)
Liquid product physical issue	Product issues	24 (0.13%)
Middle insomnia	Psychiatric disorders	24 (0.13%)
Parosmia	Nervous system disorders	24 (0.13%)
Skin warm	Skin and subcutaneous tissue disorders	24 (0.13%)
Gait inability	General disorders and administration site conditions	23 (0.13%)
Gastrointestinal disorder	Gastrointestinal disorders	23 (0.13%)
Muscle fatigue	Musculoskeletal and connective tissue disorders	23 (0.13%)
Upper respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	23 (0.13%)
Abnormal dreams	Psychiatric disorders	22 (0.12%)
Cellulitis	Infections and infestations	22 (0.12%)
Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	22 (0.12%)
Hallucination	Psychiatric disorders	22 (0.12%)
Laryngeal oedema	Respiratory, thoracic and mediastinal disorders	22 (0.12%)
Sensory disturbance	Nervous system disorders	22 (0.12%)
Sinusitis	Infections and infestations	22 (0.12%)
Tachypnoea	Respiratory, thoracic and mediastinal disorders	22 (0.12%)
Abdominal distension	Gastrointestinal disorders	21 (0.12%)
Dysstasia	Nervous system disorders	21 (0.12%)
Incorrect dose administered	Injury, poisoning and procedural complications	21 (0.12%)
Spinal pain	Musculoskeletal and connective tissue disorders	21 (0.12%)
Toothache	Gastrointestinal disorders	21 (0.12%)
Unresponsive to stimuli	Nervous system disorders	21 (0.12%)
Vaccination site oedema	General disorders and administration site conditions	21 (0.12%)
Weight decreased	Investigations	21 (0.12%)
Acute myocardial infarction	Cardiac disorders	20 (0.11%)
Crying	General disorders and administration site conditions	20 (0.11%)
Delirium	Psychiatric disorders	20 (0.11%)
Dysarthria	Nervous system disorders	20 (0.11%)
Periorbital swelling	Eye disorders	20 (0.11%)
Product packaging quantity issue	Product issues	20 (0.11%)



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Preferred Term	System Organ Class (SOC)	Number of Cases
Renal pain	Renal and urinary disorders	20 (0.11%)
Sinus pain	Respiratory, thoracic and mediastinal disorders	20 (0.11%)
Vaccination site haemorrhage	General disorders and administration site conditions	20 (0.11%)
Axillary mass	Musculoskeletal and connective tissue disorders	19 (0.11%)
Deafness	Ear and labyrinth disorders	19 (0.11%)
Feeling drunk	General disorders and administration site conditions	19 (0.11%)
Hypoacusis	Ear and labyrinth disorders	19 (0.11%)
Memory impairment	Nervous system disorders	19 (0.11%)
Mouth ulceration	Gastrointestinal disorders	19 (0.11%)
Rash maculo-papular	Skin and subcutaneous tissue disorders	19 (0.11%)
Sinus congestion	Respiratory, thoracic and mediastinal disorders	19 (0.11%)
Depressed level of consciousness	Nervous system disorders	18 (0.10%)
Mental impairment	Nervous system disorders	18 (0.10%)
Oedema	General disorders and administration site conditions	18 (0.10%)
Respiratory rate increased	Investigations	18 (0.10%)
Sinus headache	Nervous system disorders	18 (0.10%)
Sinus tachycardia	Cardiac disorders	18 (0.10%)
Stomatitis	Gastrointestinal disorders	18 (0.10%)
Tongue discomfort	Gastrointestinal disorders	18 (0.10%)
Abdominal pain lower	Gastrointestinal disorders	17 (0.09%)
Bradycardia	Cardiac disorders	17 (0.09%)
Cardiac failure	Cardiac disorders	17 (0.09%)
Head injury	Injury, poisoning and procedural complications	17 (0.09%)
Urinary tract infection	Infections and infestations	17 (0.09%)
Vaccination site joint movement impairment	General disorders and administration site conditions	17 (0.09%)
Arrhythmia	Cardiac disorders	16 (0.09%)
Depressed mood	Psychiatric disorders	16 (0.09%)
Fear	Psychiatric disorders	16 (0.09%)
Glossodynia	Gastrointestinal disorders	16 (0.09%)
Hemiparesis	Nervous system disorders	16 (0.09%)
Local reaction	General disorders and administration site conditions	16 (0.09%)
Mouth swelling	Gastrointestinal disorders	16 (0.09%)
Petechiae	Skin and subcutaneous tissue disorders	16 (0.09%)
Product administered to patient of inappropriate age	Injury, poisoning and procedural complications	16 (0.09%)
Sensory loss	Nervous system disorders	16 (0.09%)
Skin disorder	Skin and subcutaneous tissue disorders	16 (0.09%)
Vaccination site nodule	General disorders and administration site conditions	16 (0.09%)
		16 (0.09%)
Accidental exposure to product	Injury, poisoning and procedural complications	15 (0.08%)
Asthenopia	Eye disorders	15 (0.08%)
Facial paresis	Nervous system disorders	15 (0.08%)
Feeding disorder	Metabolism and nutrition disorders	15 (0.08%)
Flatulence	Gastrointestinal disorders	15 (0.08%)
Hyperventilation	Respiratory, thoracic and mediastinal disorders	15 (0.08%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Hypoglycaemia	Metabolism and nutrition disorders	15 (0.08%)
Lymphadenitis	Blood and lymphatic system disorders	15 (0.08%)
Nightmare	Psychiatric disorders	15 (0.08%)
Odynophagia	Gastrointestinal disorders	15 (0.08%)
Oral discomfort	Gastrointestinal disorders	15 (0.08%)
Paralysis	Nervous system disorders	15 (0.08%)
Pharyngeal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	15 (0.08%)
Tongue pruritus	Gastrointestinal disorders	15 (0.08%)
Vaccination site discolouration	General disorders and administration site conditions	15 (0.08%)
Cyanosis	Vascular disorders	14 (0.08%)
Diplopia	Eye disorders	14 (0.08%)
Drug hypersensitivity	Immune system disorders	14 (0.08%)
Exposure via skin contact	Injury, poisoning and procedural complications	14 (0.08%)
Feeling jittery	General disorders and administration site conditions	14 (0.08%)
Gingival pain	Gastrointestinal disorders	14 (0.08%)
Heart rate decreased	Investigations	14 (0.08%)
Hypertensive crisis	Vascular disorders	14 (0.08%)
Infection	Infections and infestations	14 (0.08%)
Irritability	Psychiatric disorders	14 (0.08%)
Lymphoedema	Vascular disorders	14 (0.08%)
Neuropathy peripheral	Nervous system disorders	14 (0.08%)
Oedema peripheral	General disorders and administration site conditions	14 (0.08%)
SARS-CoV-2 antibody test positive	Investigations	14 (0.08%)
Sepsis	Infections and infestations	14 (0.08%)
Therapeutic response unexpected	General disorders and administration site conditions	14 (0.08%)
Tongue disorder	Gastrointestinal disorders	14 (0.08%)
Acute kidney injury	Renal and urinary disorders	13 (0.07%)
Body temperature decreased	Investigations	13 (0.07%)
Bronchospasm	Respiratory, thoracic and mediastinal disorders	13 (0.07%)
C-reactive protein increased	Investigations	13 (0.07%)
Dermatitis	Skin and subcutaneous tissue disorders	13 (0.07%)
Heart rate irregular	Investigations	13 (0.07%)
Hyperglycaemia	Metabolism and nutrition disorders	13 (0.07%)
Lip pruritus	Gastrointestinal disorders	13 (0.07%)
Lower respiratory tract infection	Infections and infestations	13 (0.07%)
Ocular discomfort	Eye disorders	13 (0.07%)
Oral pain	Gastrointestinal disorders	13 (0.07%)
Panic attack	Psychiatric disorders	13 (0.07%)
Pollakiuria	Renal and urinary disorders	13 (0.07%)
Product administration error	Injury, poisoning and procedural complications	13 (0.07%)
Rash vesicular	Skin and subcutaneous tissue disorders	13 (0.07%)
Rhinitis	Infections and infestations	13 (0.07%)
Sensitive skin	Skin and subcutaneous tissue disorders	13 (0.07%)
Upper-airway cough syndrome	Respiratory, thoracic and mediastinal disorders	13 (0.07%)
Anaphylactoid reaction	Immune system disorders	12 (0.07%)
Aphasia	Nervous system disorders	12 (0.07%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Blood pressure systolic increased	Investigations	12 (0.07%)
Cardiovascular disorder	Cardiac disorders	12 (0.07%)
COVID-19 pneumonia	Infections and infestations	12 (0.07%)
Deep vein thrombosis	Vascular disorders	12 (0.07%)
Face oedema	General disorders and administration site conditions	12 (0.07%)
Gastrointestinal pain	Gastrointestinal disorders	12 (0.07%)
Hangover	General disorders and administration site conditions	12 (0.07%)
Paranasal sinus discomfort	Respiratory, thoracic and mediastinal disorders	12 (0.07%)
Pulse abnormal	Investigations	12 (0.07%)
SARS-CoV-2 antibody test negative	Investigations	12 (0.07%)
Sinus disorder	Respiratory, thoracic and mediastinal disorders	12 (0.07%)
Skin irritation	Skin and subcutaneous tissue disorders	12 (0.07%)
Stress	Psychiatric disorders	12 (0.07%)
Tongue oedema	Gastrointestinal disorders	12 (0.07%)
Vaccination site cellulitis	Infections and infestations	12 (0.07%)
Vaccination site lymphadenopathy	General disorders and administration site conditions	12 (0.07%)
Vaccination site vesicles	General disorders and administration site conditions	12 (0.07%)
Vaginal haemorrhage	Reproductive system and breast disorders	12 (0.07%)
Cardiac disorder	Cardiac disorders	11 (0.06%)
Constipation	Gastrointestinal disorders	11 (0.06%)
Depression	Psychiatric disorders	11 (0.06%)
Drug interaction	General disorders and administration site conditions	11 (0.06%)
Dry skin	Skin and subcutaneous tissue disorders	11 (0.06%)
Eating disorder	Psychiatric disorders	11 (0.06%)
Formication	Nervous system disorders	11 (0.06%)
Groin pain	Musculoskeletal and connective tissue disorders	11 (0.06%)
Haemoptysis	Respiratory, thoracic and mediastinal disorders	11 (0.06%)
Incomplete course of vaccination	Injury, poisoning and procedural complications	11 (0.06%)
Ischaemic stroke	Nervous system disorders	11 (0.06%)
Respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	11 (0.06%)
Skin exfoliation	Skin and subcutaneous tissue disorders	11 (0.06%)
Supraventricular tachycardia	Cardiac disorders	11 (0.06%)
Sweating fever	Infections and infestations	11 (0.06%)
Thrombosis	Vascular disorders	11 (0.06%)
Transient ischaemic attack	Nervous system disorders	11 (0.06%)
Vaccination site joint pain	General disorders and administration site conditions	11 (0.06%)
Acute respiratory failure	Respiratory, thoracic and mediastinal disorders	10 (0.06%)
Bedridden	Social circumstances	10 (0.06%)
Cognitive disorder	Nervous system disorders	10 (0.06%)
Dry eye	Eye disorders	10 (0.06%)
Eczema	Skin and subcutaneous tissue disorders	10 (0.06%)
Epilepsy	Nervous system disorders	10 (0.06%)
Herpes virus infection	Infections and infestations	10 (0.06%)
Menstruation irregular	Reproductive system and breast disorders	10 (0.06%)
Musculoskeletal disorder	Musculoskeletal and connective tissue disorders	10 (0.06%)
Nasal discomfort	Respiratory, thoracic and mediastinal disorders	10 (0.06%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
No adverse event	General disorders and administration site conditions	10 (0.06%)
Product leakage	Product issues	10 (0.06%)
Pulmonary embolism	Respiratory, thoracic and mediastinal disorders	10 (0.06%)
Respiratory arrest	Respiratory, thoracic and mediastinal disorders	10 (0.06%)
Salivary hypersecretion	Gastrointestinal disorders	10 (0.06%)
Skin lesion	Skin and subcutaneous tissue disorders	10 (0.06%)
Thrombocytopenia	Blood and lymphatic system disorders	10 (0.06%)
Vaccination complication	Injury, poisoning and procedural complications	10 (0.06%)
Ventricular extrasystoles	Cardiac disorders	10 (0.06%)
Amnesia	Nervous system disorders	9 (0.05%)
Asymptomatic COVID-19	Infections and infestations	9 (0.05%)
Chromaturia	Renal and urinary disorders	9 (0.05%)
Dyskinesia	Nervous system disorders	9 (0.05%)
Ear pruritus	Ear and labyrinth disorders	9 (0.05%)
Frequent bowel movements	Gastrointestinal disorders	9 (0.05%)
Gastrooesophageal reflux disease	Gastrointestinal disorders	9 (0.05%)
Hypokinesia	Nervous system disorders	9 (0.05%)
Menstrual disorder	Reproductive system and breast disorders	9 (0.05%)
Muscle contractions involuntary	Nervous system disorders	9 (0.05%)
Nasal oedema	Respiratory, thoracic and mediastinal disorders	9 (0.05%)
Oral pruritus	Gastrointestinal disorders	9 (0.05%)
Painful respiration	Respiratory, thoracic and mediastinal disorders	9 (0.05%)
Pericarditis	Cardiac disorders	9 (0.05%)
Photosensitivity reaction	Skin and subcutaneous tissue disorders	9 (0.05%)
Rhinalgia	Respiratory, thoracic and mediastinal disorders	9 (0.05%)
Skin reaction	Skin and subcutaneous tissue disorders	9 (0.05%)
Skin tightness	Skin and subcutaneous tissue disorders	9 (0.05%)
Tonsillar hypertrophy	Respiratory, thoracic and mediastinal disorders	9 (0.05%)
Vaccination site infection	Infections and infestations	9 (0.05%)
Abortion spontaneous	Pregnancy, puerperium and perinatal conditions	8 (0.04%)
Angina pectoris	Cardiac disorders	8 (0.04%)
Aphthous ulcer	Gastrointestinal disorders	8 (0.04%)
Aura	Nervous system disorders	8 (0.04%)
Blood urine present	Investigations	8 (0.04%)
Cluster headache	Nervous system disorders	8 (0.04%)
Conjunctivitis	Infections and infestations	8 (0.04%)
Eructation	Gastrointestinal disorders	8 (0.04%)
Eye haemorrhage	Eye disorders	8 (0.04%)
Gastritis	Gastrointestinal disorders	8 (0.04%)
Gingival bleeding	Gastrointestinal disorders	8 (0.04%)
Haematemesis	Gastrointestinal disorders	8 (0.04%)
Haematochezia	Gastrointestinal disorders	8 (0.04%)
Hallucination, visual	Psychiatric disorders	8 (0.04%)
Hyperacusis	Ear and labyrinth disorders	8 (0.04%)
Hyposmia	Nervous system disorders	8 (0.04%)
Hypothermia	General disorders and administration site conditions	8 (0.04%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Impaired work ability	Social circumstances	8 (0.04%)
Increased upper airway secretion	Respiratory, thoracic and mediastinal disorders	8 (0.04%)
Injected limb mobility decreased	General disorders and administration site conditions	8 (0.04%)
International normalised ratio increased	Investigations	8 (0.04%)
Mental fatigue	Psychiatric disorders	8 (0.04%)
Migraine with aura	Nervous system disorders	8 (0.04%)
Neck mass	Musculoskeletal and connective tissue disorders	8 (0.04%)
Needle issue	Product issues	8 (0.04%)
Oral mucosal blistering	Gastrointestinal disorders	8 (0.04%)
Pharyngeal inflammation	Respiratory, thoracic and mediastinal disorders	8 (0.04%)
Piloerection	Skin and subcutaneous tissue disorders	8 (0.04%)
Thinking abnormal	Psychiatric disorders	8 (0.04%)
Urinary incontinence	Renal and urinary disorders	8 (0.04%)
Abnormal faeces	Gastrointestinal disorders	7 (0.04%)
Abnormal sensation in eye	Eye disorders	7 (0.04%)
Aphonia	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Appendicitis	Infections and infestations	7 (0.04%)
Arthropathy	Musculoskeletal and connective tissue disorders	7 (0.04%)
Blepharospasm	Eye disorders	7 (0.04%)
Blindness	Eye disorders	7 (0.04%)
Blood glucose decreased	Investigations	7 (0.04%)
Blood pressure fluctuation	Vascular disorders	7 (0.04%)
Body temperature fluctuation	Investigations	7 (0.04%)
Breast swelling	Reproductive system and breast disorders	7 (0.04%)
Bronchitis	Infections and infestations	7 (0.04%)
Cerebral haemorrhage	Nervous system disorders	7 (0.04%)
Dysmenorrhoea	Reproductive system and breast disorders	7 (0.04%)
Dysuria	Renal and urinary disorders	7 (0.04%)
Extrasystoles	Cardiac disorders	7 (0.04%)
Eye movement disorder	Eye disorders	7 (0.04%)
Generalised tonic-clonic seizure	Nervous system disorders	7 (0.04%)
Gingival swelling	Gastrointestinal disorders	7 (0.04%)
Gout	Metabolism and nutrition disorders	7 (0.04%)
Haemorrhage	Vascular disorders	7 (0.04%)
Hunger	General disorders and administration site conditions	7 (0.04%)
Hyperpyrexia	General disorders and administration site conditions	7 (0.04%)
Hypoxia	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Initial insomnia	Psychiatric disorders	7 (0.04%)
Leukocytosis	Blood and lymphatic system disorders	7 (0.04%)
Lip pain	Gastrointestinal disorders	7 (0.04%)
Mass	General disorders and administration site conditions	7 (0.04%)
Motion sickness	Ear and labyrinth disorders	7 (0.04%)
Muscle swelling	Musculoskeletal and connective tissue disorders	7 (0.04%)
Occupational exposure to SARS-CoV-2	Injury, poisoning and procedural complications	7 (0.04%)
Oral disorder	Gastrointestinal disorders	7 (0.04%)
Papule	Skin and subcutaneous tissue disorders	7 (0.04%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Peripheral vascular disorder	Vascular disorders	7 (0.04%)
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Pharyngeal oedema	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Pneumonia aspiration	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Pulmonary pain	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Respiratory disorder	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Respiratory failure	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Skin swelling	Skin and subcutaneous tissue disorders	7 (0.04%)
Sleep disorder due to a general medical condition	Psychiatric disorders	7 (0.04%)
Sluggishness	General disorders and administration site conditions	7 (0.04%)
Stridor	Respiratory, thoracic and mediastinal disorders	7 (0.04%)
Tongue ulceration	Gastrointestinal disorders	7 (0.04%)
Tonsillitis	Infections and infestations	7 (0.04%)
Urinary retention	Renal and urinary disorders	7 (0.04%)
Wrong product administered	Injury, poisoning and procedural complications	7 (0.04%)
Anger	Psychiatric disorders	6 (0.03%)
Blood pressure abnormal	Investigations	6 (0.03%)
Body height decreased	Investigations	6 (0.03%)
Bone swelling	Musculoskeletal and connective tissue disorders	6 (0.03%)
Cardiac flutter	Cardiac disorders	6 (0.03%)
Cardio-respiratory arrest	Cardiac disorders	6 (0.03%)
Choking	Respiratory, thoracic and mediastinal disorders	6 (0.03%)
Coronavirus infection	Infections and infestations	6 (0.03%)
Diabetes mellitus	Metabolism and nutrition disorders	6 (0.03%)
Ear swelling	Ear and labyrinth disorders	6 (0.03%)
Eye contusion	Injury, poisoning and procedural complications	6 (0.03%)
Eye inflammation	Eye disorders	6 (0.03%)
Eyelid ptosis	Eye disorders	6 (0.03%)
Eyelids pruritus	Eye disorders	6 (0.03%)
Flank pain	Musculoskeletal and connective tissue disorders	6 (0.03%)
Haematoma	Vascular disorders	6 (0.03%)
Heart rate abnormal	Investigations	6 (0.03%)
Hordeolum	Infections and infestations	6 (0.03%)
Hypophagia	Metabolism and nutrition disorders	6 (0.03%)
Limb injury	Injury, poisoning and procedural complications	6 (0.03%)
Lip disorder	Gastrointestinal disorders	6 (0.03%)
Livedo reticularis	Skin and subcutaneous tissue disorders	6 (0.03%)
Menorrhagia	Reproductive system and breast disorders	6 (0.03%)
Metrorrhagia	Reproductive system and breast disorders	6 (0.03%)
Muscle discomfort	Musculoskeletal and connective tissue disorders	6 (0.03%)
Nerve compression	Nervous system disorders	6 (0.03%)
Nipple pain	Reproductive system and breast disorders	6 (0.03%)
Oral mucosal eruption	Gastrointestinal disorders	6 (0.03%)
Pleuritic pain	Respiratory, thoracic and mediastinal disorders	6 (0.03%)
Pulmonary oedema	Respiratory, thoracic and mediastinal disorders	6 (0.03%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Renal failure	Renal and urinary disorders	6 (0.03%)
Restless legs syndrome	Nervous system disorders	6 (0.03%)
Rheumatoid arthritis	Musculoskeletal and connective tissue disorders	6 (0.03%)
Sleep disorder due to general medical condition, insomnia type	Psychiatric disorders	6 (0.03%)
Tongue dry	Gastrointestinal disorders	6 (0.03%)
Type IV hypersensitivity reaction	Immune system disorders	6 (0.03%)
Vaccination site haematoma	General disorders and administration site conditions	6 (0.03%)
Vaccination site hyperaesthesia	General disorders and administration site conditions	6 (0.03%)
Ventricular fibrillation	Cardiac disorders	6 (0.03%)
Vertigo positional	Ear and labyrinth disorders	6 (0.03%)
Acne	Skin and subcutaneous tissue disorders	5 (0.03%)
Alanine aminotransferase increased	Investigations	5 (0.03%)
Alopecia	Skin and subcutaneous tissue disorders	5 (0.03%)
Apathy	Psychiatric disorders	5 (0.03%)
Blood pressure diastolic increased	Investigations	5 (0.03%)
Conjunctival haemorrhage	Eye disorders	5 (0.03%)
Deafness neurosensory	Ear and labyrinth disorders	5 (0.03%)
Dysaesthesia	Nervous system disorders	5 (0.03%)
Ear disorder	Ear and labyrinth disorders	5 (0.03%)
Ear infection	Infections and infestations	5 (0.03%)
Emotional disorder	Psychiatric disorders	5 (0.03%)
Enlarged uvula	Gastrointestinal disorders	5 (0.03%)
Erythema of eyelid	Eye disorders	5 (0.03%)
Eyelid oedema	Eye disorders	5 (0.03%)
Eye oedema	Eye disorders	5 (0.03%)
Facial discomfort	General disorders and administration site conditions	5 (0.03%)
Fibromyalgia	Musculoskeletal and connective tissue disorders	5 (0.03%)
Gastric disorder	Gastrointestinal disorders	5 (0.03%)
Glossitis	Gastrointestinal disorders	5 (0.03%)
Grip strength decreased	Investigations	5 (0.03%)
Hypogeusia	Nervous system disorders	5 (0.03%)
Hypopnoea	Respiratory, thoracic and mediastinal disorders	5 (0.03%)
Hypotonia	Nervous system disorders	5 (0.03%)
Impaired driving ability	Social circumstances	5 (0.03%)
Induration	General disorders and administration site conditions	5 (0.03%)
Injection site erythema	General disorders and administration site conditions	5 (0.03%)
Irritable bowel syndrome	Gastrointestinal disorders	5 (0.03%)
Labyrinthitis	Infections and infestations	5 (0.03%)
Lip blister	Gastrointestinal disorders	5 (0.03%)
Localised oedema	General disorders and administration site conditions	5 (0.03%)
Maternal exposure timing unspecified	Injury, poisoning and procedural complications	5 (0.03%)
Mental disorder	Psychiatric disorders	5 (0.03%)
Miliaria	Skin and subcutaneous tissue disorders	5 (0.03%)
Multiple organ dysfunction syndrome	General disorders and administration site conditions	5 (0.03%)
Multiple sclerosis relapse	Nervous system disorders	5 (0.03%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Muscle rigidity	Musculoskeletal and connective tissue disorders	5 (0.03%)
Muscle strain	Injury, poisoning and procedural complications	5 (0.03%)
Myocarditis	Cardiac disorders	5 (0.03%)
Neuritis	Nervous system disorders	5 (0.03%)
Nodule	General disorders and administration site conditions	5 (0.03%)
Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	5 (0.03%)
Occupational exposure to product	Injury, poisoning and procedural complications	5 (0.03%)
Palatal swelling	Gastrointestinal disorders	5 (0.03%)
Panic reaction	Psychiatric disorders	5 (0.03%)
Pelvic pain	Reproductive system and breast disorders	5 (0.03%)
Periarthritis	Musculoskeletal and connective tissue disorders	5 (0.03%)
Pharyngitis	Infections and infestations	5 (0.03%)
Photopsia	Eye disorders	5 (0.03%)
Platelet count increased	Investigations	5 (0.03%)
Polyuria	Renal and urinary disorders	5 (0.03%)
Product label confusion	Injury, poisoning and procedural complications	5 (0.03%)
Product prescribing error	Injury, poisoning and procedural complications	5 (0.03%)
Rales	Respiratory, thoracic and mediastinal disorders	5 (0.03%)
Respiration abnormal	Respiratory, thoracic and mediastinal disorders	5 (0.03%)
SARS-CoV-2 test false positive	Investigations	5 (0.03%)
Sciatica	Nervous system disorders	5 (0.03%)
Scratch	Injury, poisoning and procedural complications	5 (0.03%)
Tunnel vision	Nervous system disorders	5 (0.03%)
Vaccination site macule	General disorders and administration site conditions	5 (0.03%)
Vomiting projectile	Gastrointestinal disorders	5 (0.03%)
White blood cell count increased	Investigations	5 (0.03%)
Abdominal tenderness	Gastrointestinal disorders	4 (0.02%)
Acute coronary syndrome	Cardiac disorders	4 (0.02%)
Anaesthesia	Nervous system disorders	4 (0.02%)
Arthropod bite	Injury, poisoning and procedural complications	4 (0.02%)
Autoimmune disorder	Immune system disorders	4 (0.02%)
Blood lactic acid increased	Investigations	4 (0.02%)
Blood pressure diastolic decreased	Investigations	4 (0.02%)
Breast discomfort	Reproductive system and breast disorders	4 (0.02%)
Coma scale abnormal	Investigations	4 (0.02%)
Coordination abnormal	Nervous system disorders	4 (0.02%)
Deafness unilateral	Ear and labyrinth disorders	4 (0.02%)
Defaecation urgency	Gastrointestinal disorders	4 (0.02%)
Dermatitis contact	Skin and subcutaneous tissue disorders	4 (0.02%)
Dissociation	Psychiatric disorders	4 (0.02%)
Drug eruption	Skin and subcutaneous tissue disorders	4 (0.02%)
Episcleritis	Eye disorders	4 (0.02%)
Euphoric mood	Psychiatric disorders	4 (0.02%)
Face injury	Injury, poisoning and procedural complications	4 (0.02%)
Facial spasm	Nervous system disorders	4 (0.02%)
Faeces discoloured	Gastrointestinal disorders	4 (0.02%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Fibrin D dimer increased	Investigations	4 (0.02%)
Fine motor skill dysfunction	Nervous system disorders	4 (0.02%)
Fluid intake reduced	Metabolism and nutrition disorders	4 (0.02%)
Gastroenteritis viral	Infections and infestations	4 (0.02%)
Guillain-Barre syndrome	Nervous system disorders	4 (0.02%)
Haemoglobin decreased	Investigations	4 (0.02%)
Haemorrhage intracranial	Nervous system disorders	4 (0.02%)
Haemorrhagic stroke	Nervous system disorders	4 (0.02%)
Huntington's disease	Congenital, familial and genetic disorders	4 (0.02%)
Hypertensive emergency	Vascular disorders	4 (0.02%)
Hyperthermia	General disorders and administration site conditions	4 (0.02%)
Hypoaesthesia eye	Eye disorders	4 (0.02%)
Immune thrombocytopenia	Blood and lymphatic system disorders	4 (0.02%)
Incontinence	Renal and urinary disorders	4 (0.02%)
Jaundice	Hepatobiliary disorders	4 (0.02%)
Joint effusion	Musculoskeletal and connective tissue disorders	4 (0.02%)
Laryngospasm	Respiratory, thoracic and mediastinal disorders	4 (0.02%)
Lip dry	Gastrointestinal disorders	4 (0.02%)
Localised infection	Infections and infestations	4 (0.02%)
Lung disorder	Respiratory, thoracic and mediastinal disorders	4 (0.02%)
Mastitis	Infections and infestations	4 (0.02%)
Mechanical urticaria	Skin and subcutaneous tissue disorders	4 (0.02%)
Monoplegia	Nervous system disorders	4 (0.02%)
Motor dysfunction	Nervous system disorders	4 (0.02%)
Nasal dryness	Respiratory, thoracic and mediastinal disorders	4 (0.02%)
Neurogenic shock	Vascular disorders	4 (0.02%)
Nipple swelling	Reproductive system and breast disorders	4 (0.02%)
Nuchal rigidity	Musculoskeletal and connective tissue disorders	4 (0.02%)
Nystagmus	Nervous system disorders	4 (0.02%)
Oedema mouth	Gastrointestinal disorders	4 (0.02%)
Oral candidiasis	Infections and infestations	4 (0.02%)
Orthostatic hypotension	Vascular disorders	4 (0.02%)
Palmar erythema	Skin and subcutaneous tissue disorders	4 (0.02%)
Pancreatitis	Gastrointestinal disorders	4 (0.02%)
Paresis	Nervous system disorders	4 (0.02%)
Parotitis	Infections and infestations	4 (0.02%)
Periorbital oedema	Eye disorders	4 (0.02%)
Pharyngeal disorder	Respiratory, thoracic and mediastinal disorders	4 (0.02%)
Pleural effusion	Respiratory, thoracic and mediastinal disorders	4 (0.02%)
Pulmonary congestion	Respiratory, thoracic and mediastinal disorders	4 (0.02%)
Purpura	Skin and subcutaneous tissue disorders	4 (0.02%)
Pustule	Infections and infestations	4 (0.02%)
Reaction to excipient	Immune system disorders	4 (0.02%)
Rectal haemorrhage	Gastrointestinal disorders	4 (0.02%)
Red blood cell sedimentation rate increased	Investigations	4 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Respiratory tract infection	Infections and infestations	4 (0.02%)
Seasonal allergy	Immune system disorders	4 (0.02%)
Skin laceration	Injury, poisoning and procedural complications	4 (0.02%)
Skin mass	Skin and subcutaneous tissue disorders	4 (0.02%)
Sudden hearing loss	Ear and labyrinth disorders	4 (0.02%)
Suppressed lactation	Reproductive system and breast disorders	4 (0.02%)
Tachyarrhythmia	Cardiac disorders	4 (0.02%)
Tachyphrenia	Psychiatric disorders	4 (0.02%)
Temperature regulation disorder	General disorders and administration site conditions	4 (0.02%)
Tendonitis	Musculoskeletal and connective tissue disorders	4 (0.02%)
Throat clearing	Respiratory, thoracic and mediastinal disorders	4 (0.02%)
Tongue erythema	Gastrointestinal disorders	4 (0.02%)
Trismus	Musculoskeletal and connective tissue disorders	4 (0.02%)
Vaccination site extravasation	General disorders and administration site conditions	4 (0.02%)
Vaccination site hypersensitivity	General disorders and administration site conditions	4 (0.02%)
Vaccination site irritation	General disorders and administration site conditions	4 (0.02%)
Viral rash	Infections and infestations	4 (0.02%)
Visual field defect	Nervous system disorders	4 (0.02%)
Weight increased	Investigations	4 (0.02%)
Adverse event	General disorders and administration site conditions	3 (0.02%)
Aggression	Psychiatric disorders	3 (0.02%)
Allodynia	Nervous system disorders	3 (0.02%)
Anal incontinence	Gastrointestinal disorders	3 (0.02%)
Arrhythmia supraventricular	Cardiac disorders	3 (0.02%)
Arthritis reactive	Musculoskeletal and connective tissue disorders	3 (0.02%)
Aspiration	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Bladder discomfort	Renal and urinary disorders	3 (0.02%)
Blood potassium decreased	Investigations	3 (0.02%)
Body temperature	Investigations	3 (0.02%)
Breast tenderness	Reproductive system and breast disorders	3 (0.02%)
Breath odour	Gastrointestinal disorders	3 (0.02%)
Cerebral infarction	Nervous system disorders	3 (0.02%)
Chapped lips	Gastrointestinal disorders	3 (0.02%)
Chronic obstructive pulmonary disease	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Coma	Nervous system disorders	3 (0.02%)
Contraindicated product administered	Injury, poisoning and procedural complications	3 (0.02%)
Coronavirus test positive	Investigations	3 (0.02%)
Costochondritis	Musculoskeletal and connective tissue disorders	3 (0.02%)
Cystitis	Infections and infestations	3 (0.02%)
Dementia	Nervous system disorders	3 (0.02%)
Depersonalisation/derealisation disorder	Psychiatric disorders	3 (0.02%)
Derealisation	Psychiatric disorders	3 (0.02%)
Diabetic ketoacidosis	Metabolism and nutrition disorders	3 (0.02%)
Diet refusal	Metabolism and nutrition disorders	3 (0.02%)
Dizziness exertional	Nervous system disorders	3 (0.02%)
Ear congestion	Ear and labyrinth disorders	3 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Electrocardiogram abnormal	Investigations	3 (0.02%)
Emotional distress	Psychiatric disorders	3 (0.02%)
Energy increased	General disorders and administration site conditions	3 (0.02%)
Enuresis	Psychiatric disorders	3 (0.02%)
Expired product administered	Injury, poisoning and procedural complications	3 (0.02%)
Eye allergy	Eye disorders	3 (0.02%)
Eye discharge	Eye disorders	3 (0.02%)
Eye infection	Infections and infestations	3 (0.02%)
Eyelid irritation	Eye disorders	3 (0.02%)
Eyelid pain	Eye disorders	3 (0.02%)
Frustration tolerance decreased	Psychiatric disorders	3 (0.02%)
Fungal infection	Infections and infestations	3 (0.02%)
Gastroenteritis	Infections and infestations	3 (0.02%)
Gastrointestinal sounds abnormal	Gastrointestinal disorders	3 (0.02%)
Glassy eyes	General disorders and administration site conditions	3 (0.02%)
Haematuria	Renal and urinary disorders	3 (0.02%)
Hepatic enzyme increased	Investigations	3 (0.02%)
Herpes simplex	Infections and infestations	3 (0.02%)
Hiccups	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Hyperaesthesia teeth	Gastrointestinal disorders	3 (0.02%)
Hypertonia	Nervous system disorders	3 (0.02%)
Hypokalaemia	Metabolism and nutrition disorders	3 (0.02%)
Hypothyroidism	Endocrine disorders	3 (0.02%)
Immune system disorder	Immune system disorders	3 (0.02%)
Infantile vomiting	Gastrointestinal disorders	3 (0.02%)
Infant irritability	Nervous system disorders	3 (0.02%)
Inflammatory marker increased	Investigations	3 (0.02%)
Injection site rash	General disorders and administration site conditions	3 (0.02%)
Injection site swelling	General disorders and administration site conditions	3 (0.02%)
Intestinal ischaemia	Gastrointestinal disorders	3 (0.02%)
Intranasal paraesthesia	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Intraocular pressure increased	Investigations	3 (0.02%)
Limb mass	Musculoskeletal and connective tissue disorders	3 (0.02%)
Lip erythema	Gastrointestinal disorders	3 (0.02%)
Lung infiltration	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Lymphopenia	Blood and lymphatic system disorders	3 (0.02%)
Mean cell haemoglobin decreased	Investigations	3 (0.02%)
Medication error	Injury, poisoning and procedural complications	3 (0.02%)
Mononeuropathy	Nervous system disorders	3 (0.02%)
Monoparesis	Nervous system disorders	3 (0.02%)
Mood altered	Psychiatric disorders	3 (0.02%)
Multiple sclerosis	Nervous system disorders	3 (0.02%)
Nasal obstruction	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Neuralgic amyotrophy	Nervous system disorders	3 (0.02%)
Oral mucosal erythema	Gastrointestinal disorders	3 (0.02%)
Oropharyngeal blistering	Respiratory, thoracic and mediastinal disorders	3 (0.02%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Paranoia	Psychiatric disorders	3 (0.02%)
Parotid gland enlargement	Gastrointestinal disorders	3 (0.02%)
Peroneal nerve palsy	Nervous system disorders	3 (0.02%)
Petit mal epilepsy	Nervous system disorders	3 (0.02%)
Pharyngitis streptococcal	Infections and infestations	3 (0.02%)
Platelet count decreased	Investigations	3 (0.02%)
Pleurisy	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Pneumonitis	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Polydipsia	Metabolism and nutrition disorders	3 (0.02%)
Poor peripheral circulation	Vascular disorders	3 (0.02%)
Post viral fatigue syndrome	Infections and infestations	3 (0.02%)
Pre-existing condition improved	General disorders and administration site conditions	3 (0.02%)
Procedural pain	Injury, poisoning and procedural complications	3 (0.02%)
Psoriasis	Skin and subcutaneous tissue disorders	3 (0.02%)
Psychomotor hyperactivity	Nervous system disorders	3 (0.02%)
Radiculopathy	Nervous system disorders	3 (0.02%)
Rash pustular	Infections and infestations	3 (0.02%)
Raynaud's phenomenon	Vascular disorders	3 (0.02%)
Renal disorder	Renal and urinary disorders	3 (0.02%)
Respiratory rate decreased	Investigations	3 (0.02%)
Rhabdomyolysis	Musculoskeletal and connective tissue disorders	3 (0.02%)
Sedation	Nervous system disorders	3 (0.02%)
Slow response to stimuli	Nervous system disorders	3 (0.02%)
Snoring	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Sputum discoloured	Respiratory, thoracic and mediastinal disorders	3 (0.02%)
Systemic inflammatory response syndrome	General disorders and administration site conditions	3 (0.02%)
Terminal insomnia	Psychiatric disorders	3 (0.02%)
Tongue discoloration	Gastrointestinal disorders	3 (0.02%)
Tongue eruption	Gastrointestinal disorders	3 (0.02%)
Tongue haematoma	Gastrointestinal disorders	3 (0.02%)
Trigeminal neuralgia	Nervous system disorders	3 (0.02%)
Troponin increased	Investigations	3 (0.02%)
Upper respiratory tract infection	Infections and infestations	3 (0.02%)
Urosepsis	Infections and infestations	3 (0.02%)
Vaccination site coldness	General disorders and administration site conditions	3 (0.02%)
Vaccination site discharge	General disorders and administration site conditions	3 (0.02%)
Vaccination site scab	General disorders and administration site conditions	3 (0.02%)
Vasodilatation	Vascular disorders	3 (0.02%)
Abdominal rigidity	Gastrointestinal disorders	2 (0.01%)
Abnormal behaviour	Psychiatric disorders	2 (0.01%)
Abscess	Infections and infestations	2 (0.01%)
Accidental underdose	Injury, poisoning and procedural complications	2 (0.01%)
Acidosis	Metabolism and nutrition disorders	2 (0.01%)
Acute disseminated encephalomyelitis	Nervous system disorders	2 (0.01%)
Acute respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Administration site pain	General disorders and administration site conditions	2 (0.01%)
Adverse drug reaction	General disorders and administration site conditions	2 (0.01%)
Allergic cough	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Allergic oedema	Immune system disorders	2 (0.01%)
Anal haemorrhage	Gastrointestinal disorders	2 (0.01%)
Aortic dissection	Vascular disorders	2 (0.01%)
Arteriosclerosis	Vascular disorders	2 (0.01%)
Aspartate aminotransferase increased	Investigations	2 (0.01%)
Asphyxia	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Auricular swelling	Ear and labyrinth disorders	2 (0.01%)
Basal ganglia haemorrhage	Nervous system disorders	2 (0.01%)
Bladder pain	Renal and urinary disorders	2 (0.01%)
Blood alkaline phosphatase increased	Investigations	2 (0.01%)
Blood chloride increased	Investigations	2 (0.01%)
Blood creatine phosphokinase increased	Investigations	2 (0.01%)
Blood glucose abnormal	Investigations	2 (0.01%)
Blood glucose fluctuation	Investigations	2 (0.01%)
Blood sodium decreased	Investigations	2 (0.01%)
Blood test abnormal	Investigations	2 (0.01%)
Blood thyroid stimulating hormone increased	Investigations	2 (0.01%)
Booster dose missed	Injury, poisoning and procedural complications	2 (0.01%)
Bowel movement irregularity	Gastrointestinal disorders	2 (0.01%)
Brain injury	Nervous system disorders	2 (0.01%)
Brain oedema	Nervous system disorders	2 (0.01%)
Breast mass	Reproductive system and breast disorders	2 (0.01%)
Cardiac failure congestive	Cardiac disorders	2 (0.01%)
Cerebellar haemorrhage	Nervous system disorders	2 (0.01%)
Cerebellar infarction	Nervous system disorders	2 (0.01%)
Cheilitis	Gastrointestinal disorders	2 (0.01%)
Chillblains	Injury, poisoning and procedural complications	2 (0.01%)
Choking sensation	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Circumoral swelling	Skin and subcutaneous tissue disorders	2 (0.01%)
Colitis ulcerative	Gastrointestinal disorders	2 (0.01%)
Communication disorder	Psychiatric disorders	2 (0.01%)
Conjunctivitis allergic	Eye disorders	2 (0.01%)
Contraindication to vaccination	Social circumstances	2 (0.01%)
Coronary artery disease	Cardiac disorders	2 (0.01%)
Costovertebral angle tenderness	Renal and urinary disorders	2 (0.01%)
Cranial nerve disorder	Nervous system disorders	2 (0.01%)
Crepitations	General disorders and administration site conditions	2 (0.01%)
Cyst	General disorders and administration site conditions	2 (0.01%)
Decreased interest	Psychiatric disorders	2 (0.01%)
Delusional perception	Psychiatric disorders	2 (0.01%)
Demyelination	Nervous system disorders	2 (0.01%)
Dental paraesthesia	Gastrointestinal disorders	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Dental restoration failure	Injury, poisoning and procedural complications	2 (0.01%)
Diabetes mellitus inadequate control	Metabolism and nutrition disorders	2 (0.01%)
Diarrhoea haemorrhagic	Gastrointestinal disorders	2 (0.01%)
Discoloured vomit	Gastrointestinal disorders	2 (0.01%)
Disease progression	General disorders and administration site conditions	2 (0.01%)
Drooling	Nervous system disorders	2 (0.01%)
Dystonia	Nervous system disorders	2 (0.01%)
Eosinophil count increased	Investigations	2 (0.01%)
Eosinophilia	Blood and lymphatic system disorders	2 (0.01%)
Epicondylitis	Injury, poisoning and procedural complications	2 (0.01%)
Erectile dysfunction	Reproductive system and breast disorders	2 (0.01%)
Erythema multiforme	Skin and subcutaneous tissue disorders	2 (0.01%)
Exposure via eye contact	Injury, poisoning and procedural complications	2 (0.01%)
Extremity contracture	Musculoskeletal and connective tissue disorders	2 (0.01%)
Eyelid disorder	Eye disorders	2 (0.01%)
Eyelid function disorder	Eye disorders	2 (0.01%)
Eyelid rash	Eye disorders	2 (0.01%)
Eye paraesthesia	Eye disorders	2 (0.01%)
Facial asymmetry	Musculoskeletal and connective tissue disorders	2 (0.01%)
Facial nerve disorder	Nervous system disorders	2 (0.01%)
Faeces pale	Gastrointestinal disorders	2 (0.01%)
Febrile infection	Infections and infestations	2 (0.01%)
Fluid retention	Metabolism and nutrition disorders	2 (0.01%)
Folliculitis	Infections and infestations	2 (0.01%)
Food refusal	Metabolism and nutrition disorders	2 (0.01%)
Foreign body sensation in eyes	Eye disorders	2 (0.01%)
Fracture	Injury, poisoning and procedural complications	2 (0.01%)
Furuncle	Infections and infestations	2 (0.01%)
Gallbladder disorder	Hepatobiliary disorders	2 (0.01%)
Genital herpes	Infections and infestations	2 (0.01%)
Gingival blister	Gastrointestinal disorders	2 (0.01%)
Gingival erythema	Gastrointestinal disorders	2 (0.01%)
Glaucoma	Eye disorders	2 (0.01%)
Haemolytic anaemia	Blood and lymphatic system disorders	2 (0.01%)
Hallucination, auditory	Psychiatric disorders	2 (0.01%)
Hand-eye coordination impaired	Nervous system disorders	2 (0.01%)
Hepatic pain	Hepatobiliary disorders	2 (0.01%)
Hepatitis	Hepatobiliary disorders	2 (0.01%)
Hidradenitis	Skin and subcutaneous tissue disorders	2 (0.01%)
Hypocalcaemia	Metabolism and nutrition disorders	2 (0.01%)
Hyponatraemia	Metabolism and nutrition disorders	2 (0.01%)
Hyporeflexia	Nervous system disorders	2 (0.01%)
Immunisation anxiety related reaction	Psychiatric disorders	2 (0.01%)
Immunodeficiency	Immune system disorders	2 (0.01%)
Incoherent	Nervous system disorders	2 (0.01%)
Increased appetite	Metabolism and nutrition disorders	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Increased bronchial secretion	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Increased viscosity of upper respiratory secretion	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Injection related reaction	Injury, poisoning and procedural complications	2 (0.01%)
Injection site extravasation	General disorders and administration site conditions	2 (0.01%)
Injury	Injury, poisoning and procedural complications	2 (0.01%)
Intranasal hypoaesthesia	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Iridocyclitis	Eye disorders	2 (0.01%)
Irritability postvaccinal	General disorders and administration site conditions	2 (0.01%)
Jaw clicking	Musculoskeletal and connective tissue disorders	2 (0.01%)
Joint dislocation	Injury, poisoning and procedural complications	2 (0.01%)
Joint instability	Musculoskeletal and connective tissue disorders	2 (0.01%)
Joint noise	Musculoskeletal and connective tissue disorders	2 (0.01%)
Lacunar infarction	Nervous system disorders	2 (0.01%)
Laryngeal pain	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Laryngitis	Infections and infestations	2 (0.01%)
Laziness	Psychiatric disorders	2 (0.01%)
Ligament injury	Injury, poisoning and procedural complications	2 (0.01%)
Ligament sprain	Injury, poisoning and procedural complications	2 (0.01%)
Lip injury	Injury, poisoning and procedural complications	2 (0.01%)
Liver function test abnormal	Investigations	2 (0.01%)
Liver function test increased	Investigations	2 (0.01%)
Liver injury	Hepatobiliary disorders	2 (0.01%)
Lymph node palpable	Investigations	2 (0.01%)
Malnutrition	Metabolism and nutrition disorders	2 (0.01%)
Mastication disorder	Musculoskeletal and connective tissue disorders	2 (0.01%)
Menopausal symptoms	Reproductive system and breast disorders	2 (0.01%)
Metamorphopsia	Eye disorders	2 (0.01%)
Micturition urgency	Renal and urinary disorders	2 (0.01%)
Monocyte count increased	Investigations	2 (0.01%)
Mucosal disorder	General disorders and administration site conditions	2 (0.01%)
Mucosal dryness	General disorders and administration site conditions	2 (0.01%)
Muscle contracture	Musculoskeletal and connective tissue disorders	2 (0.01%)
Muscle disorder	Musculoskeletal and connective tissue disorders	2 (0.01%)
Mydriasis	Eye disorders	2 (0.01%)
Myelitis transverse	Nervous system disorders	2 (0.01%)
Myocardial ischaemia	Cardiac disorders	2 (0.01%)
Myocardial necrosis marker increased	Investigations	2 (0.01%)
Myoclonus	Nervous system disorders	2 (0.01%)
Myositis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Nail discolouration	Skin and subcutaneous tissue disorders	2 (0.01%)
Nasal injury	Injury, poisoning and procedural complications	2 (0.01%)
Nervous system disorder	Nervous system disorders	2 (0.01%)
Neutrophil count increased	Investigations	2 (0.01%)
Nocturia	Renal and urinary disorders	2 (0.01%)
Oesophageal pain	Gastrointestinal disorders	2 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Optic neuritis	Nervous system disorders	2 (0.01%)
Oral dysaesthesia	Gastrointestinal disorders	2 (0.01%)
Oral mucosa erosion	Gastrointestinal disorders	2 (0.01%)
Oropharyngeal oedema	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Oropharyngeal swelling	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Orthopnoea	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Otitis media	Infections and infestations	2 (0.01%)
Palatal oedema	Gastrointestinal disorders	2 (0.01%)
Pancytopenia	Blood and lymphatic system disorders	2 (0.01%)
Paraesthesia ear	Ear and labyrinth disorders	2 (0.01%)
Paranasal sinus hypersecretion	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Peripheral circulatory failure	Vascular disorders	2 (0.01%)
Peripheral ischaemia	Vascular disorders	2 (0.01%)
Personality change	Psychiatric disorders	2 (0.01%)
Phlebitis	Vascular disorders	2 (0.01%)
PO2 decreased	Investigations	2 (0.01%)
Polymenorrhoea	Reproductive system and breast disorders	2 (0.01%)
Polymyalgia rheumatica	Musculoskeletal and connective tissue disorders	2 (0.01%)
Polyneuropathy	Nervous system disorders	2 (0.01%)
Post-traumatic stress disorder	Psychiatric disorders	2 (0.01%)
Primary cough headache	Nervous system disorders	2 (0.01%)
Product complaint	Product issues	2 (0.01%)
Product dose omission issue	Injury, poisoning and procedural complications	2 (0.01%)
Product quality issue	Product issues	2 (0.01%)
Psoriatic arthropathy	Musculoskeletal and connective tissue disorders	2 (0.01%)
Pulmonary thrombosis	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Pupil fixed	Eye disorders	2 (0.01%)
Pupils unequal	Eye disorders	2 (0.01%)
Q fever	Infections and infestations	2 (0.01%)
Reduced facial expression	Nervous system disorders	2 (0.01%)
Respiratory symptom	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Rhonchi	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Rosacea	Skin and subcutaneous tissue disorders	2 (0.01%)
Sacroiliitis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Salivary gland pain	Gastrointestinal disorders	2 (0.01%)
Scar	Injury, poisoning and procedural complications	2 (0.01%)
Screaming	General disorders and administration site conditions	2 (0.01%)
Scrotal pain	Reproductive system and breast disorders	2 (0.01%)
Secretion discharge	General disorders and administration site conditions	2 (0.01%)
Septic shock	Infections and infestations	2 (0.01%)
Serotonin syndrome	Nervous system disorders	2 (0.01%)
Severe acute respiratory syndrome	Infections and infestations	2 (0.01%)
Shock symptom	Vascular disorders	2 (0.01%)
Skin erosion	Skin and subcutaneous tissue disorders	2 (0.01%)
Skin injury	Injury, poisoning and procedural complications	2 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Skin sensitisation	Skin and subcutaneous tissue disorders	2 (0.01%)
Skin ulcer	Skin and subcutaneous tissue disorders	2 (0.01%)
Sleep attacks	Psychiatric disorders	2 (0.01%)
Sleep talking	Psychiatric disorders	2 (0.01%)
Small intestinal obstruction	Gastrointestinal disorders	2 (0.01%)
Somatic symptom disorder	Psychiatric disorders	2 (0.01%)
Staring	Psychiatric disorders	2 (0.01%)
Stevens-Johnson syndrome	Skin and subcutaneous tissue disorders	2 (0.01%)
Stiff tongue	Gastrointestinal disorders	2 (0.01%)
Stupor	Nervous system disorders	2 (0.01%)
Subarachnoid haemorrhage	Nervous system disorders	2 (0.01%)
Sudden cardiac death	General disorders and administration site conditions	2 (0.01%)
Suffocation feeling	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Sunburn	Injury, poisoning and procedural complications	2 (0.01%)
Superficial vein prominence	Vascular disorders	2 (0.01%)
Syringe issue	Product issues	2 (0.01%)
Systemic lupus erythematosus	Musculoskeletal and connective tissue disorders	2 (0.01%)
Systolic hypertension	Vascular disorders	2 (0.01%)
Tachycardia paroxysmal	Cardiac disorders	2 (0.01%)
Tearfulness	Psychiatric disorders	2 (0.01%)
Temporomandibular joint syndrome	Musculoskeletal and connective tissue disorders	2 (0.01%)
Tendon pain	Musculoskeletal and connective tissue disorders	2 (0.01%)
Tenosynovitis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Tension	Psychiatric disorders	2 (0.01%)
Tetany	Metabolism and nutrition disorders	2 (0.01%)
Thyroid disorder	Endocrine disorders	2 (0.01%)
Tongue movement disturbance	Gastrointestinal disorders	2 (0.01%)
Tonsillar erythema	Respiratory, thoracic and mediastinal disorders	2 (0.01%)
Torticollis	Musculoskeletal and connective tissue disorders	2 (0.01%)
Tuberculosis	Infections and infestations	2 (0.01%)
Upper gastrointestinal haemorrhage	Gastrointestinal disorders	2 (0.01%)
Vaccination site ulcer	General disorders and administration site conditions	2 (0.01%)
Vaginal discharge	Reproductive system and breast disorders	2 (0.01%)
Vaginal infection	Infections and infestations	2 (0.01%)
Varicella	Infections and infestations	2 (0.01%)
Varicose vein	Vascular disorders	2 (0.01%)
Vasculitis	Vascular disorders	2 (0.01%)
Ventricular tachycardia	Cardiac disorders	2 (0.01%)
Vestibular neuronitis	Infections and infestations	2 (0.01%)
Viral infection	Infections and infestations	2 (0.01%)
Vitreous floaters	Eye disorders	2 (0.01%)
Vulvovaginal candidiasis	Infections and infestations	2 (0.01%)
Vulvovaginal pruritus	Reproductive system and breast disorders	2 (0.01%)
Wound	Injury, poisoning and procedural complications	2 (0.01%)
Abdominal adhesions	Gastrointestinal disorders	1 (0.01%)
Acarodermatitis	Infections and infestations	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Acoustic neuritis	Nervous system disorders	1 (0.01%)
Acute cardiac event	Cardiac disorders	1 (0.01%)
Acute pulmonary oedema	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Administration site reaction	General disorders and administration site conditions	1 (0.01%)
Adnexa uteri pain	Reproductive system and breast disorders	1 (0.01%)
Adverse reaction	General disorders and administration site conditions	1 (0.01%)
Aerophagia	Gastrointestinal disorders	1 (0.01%)
Affect lability	Psychiatric disorders	1 (0.01%)
African trypanosomiasis	Infections and infestations	1 (0.01%)
Age-related macular degeneration	Eye disorders	1 (0.01%)
Akathisia	Nervous system disorders	1 (0.01%)
Alcohol interaction	General disorders and administration site conditions	1 (0.01%)
Allergic respiratory symptom	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Allergy to chemicals	Immune system disorders	1 (0.01%)
Altered state of consciousness	Nervous system disorders	1 (0.01%)
Amblyopia	Eye disorders	1 (0.01%)
Anaesthesia oral	Gastrointestinal disorders	1 (0.01%)
Aneurysm	Vascular disorders	1 (0.01%)
Angle closure glaucoma	Eye disorders	1 (0.01%)
Angular cheilitis	Gastrointestinal disorders	1 (0.01%)
Animal bite	Injury, poisoning and procedural complications	1 (0.01%)
Ankylosing spondylitis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Antibody test positive	Investigations	1 (0.01%)
Anticholinergic syndrome	Nervous system disorders	1 (0.01%)
Anticoagulation drug level increased	Investigations	1 (0.01%)
Aortic aneurysm	Vascular disorders	1 (0.01%)
Aortic aneurysm rupture	Vascular disorders	1 (0.01%)
Appetite disorder	Metabolism and nutrition disorders	1 (0.01%)
Aptyalism	Gastrointestinal disorders	1 (0.01%)
Arteriospasm coronary	Cardiac disorders	1 (0.01%)
Asthma prophylaxis	Surgical and medical procedures	1 (0.01%)
Ataxia	Nervous system disorders	1 (0.01%)
Atrioventricular block complete	Cardiac disorders	1 (0.01%)
Atypical pneumonia	Infections and infestations	1 (0.01%)
Auscultation	Investigations	1 (0.01%)
Autoimmune thyroiditis	Endocrine disorders	1 (0.01%)
Autonomic nervous system imbalance	Nervous system disorders	1 (0.01%)
Axonal neuropathy	Nervous system disorders	1 (0.01%)
Bacteraemia	Infections and infestations	1 (0.01%)
Band sensation	Nervous system disorders	1 (0.01%)
Bile duct stone	Hepatobiliary disorders	1 (0.01%)
Biliary sepsis	Infections and infestations	1 (0.01%)
Bilirubin urine present	Investigations	1 (0.01%)
Bite	Injury, poisoning and procedural complications	1 (0.01%)
Blepharitis	Eye disorders	1 (0.01%)
Blepharochalasis	Eye disorders	1 (0.01%)



Preferred Term	System Organ Class (SOC)	Number of Cases
Blindness transient	Eye disorders	1 (0.01%)
Blood count abnormal	Investigations	1 (0.01%)
Blood creatinine increased	Investigations	1 (0.01%)
Blood disorder	Blood and lymphatic system disorders	1 (0.01%)
Blood electrolytes increased	Investigations	1 (0.01%)
Blood iron decreased	Investigations	1 (0.01%)
Blood ketone body present	Investigations	1 (0.01%)
Blood pH increased	Investigations	1 (0.01%)
Blood potassium abnormal	Investigations	1 (0.01%)
Blood pressure inadequately controlled	Vascular disorders	1 (0.01%)
Blood pressure orthostatic abnormal	Investigations	1 (0.01%)
Blood pressure orthostatic decreased	Investigations	1 (0.01%)
Blood pressure systolic decreased	Investigations	1 (0.01%)
Blood testosterone decreased	Investigations	1 (0.01%)
Blood urea increased	Investigations	1 (0.01%)
Blood uric acid increased	Investigations	1 (0.01%)
Bone disorder	Musculoskeletal and connective tissue disorders	1 (0.01%)
Brachial plexopathy	Nervous system disorders	1 (0.01%)
Bradykinesia	Nervous system disorders	1 (0.01%)
Bradyphrenia	Psychiatric disorders	1 (0.01%)
Breast abscess	Infections and infestations	1 (0.01%)
Breast milk discoloration	Reproductive system and breast disorders	1 (0.01%)
Bronchial disorder	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Bronchial obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Bruxism	Psychiatric disorders	1 (0.01%)
Bundle branch block right	Cardiac disorders	1 (0.01%)
Burning sensation mucosal	Nervous system disorders	1 (0.01%)
Burn oral cavity	Injury, poisoning and procedural complications	1 (0.01%)
Buttock injury	Injury, poisoning and procedural complications	1 (0.01%)
Candida infection	Infections and infestations	1 (0.01%)
Capillary nail refill test abnormal	Investigations	1 (0.01%)
Cardiac discomfort	Cardiac disorders	1 (0.01%)
Cardiac fibrillation	Cardiac disorders	1 (0.01%)
Cardiac valve disease	Cardiac disorders	1 (0.01%)
Cardiac valve sclerosis	Cardiac disorders	1 (0.01%)
Cardiogenic shock	Cardiac disorders	1 (0.01%)
Cardiopulmonary failure	Cardiac disorders	1 (0.01%)
Cardio-respiratory distress	Cardiac disorders	1 (0.01%)
Cardiovascular insufficiency	Cardiac disorders	1 (0.01%)
Cataplexy	Nervous system disorders	1 (0.01%)
Catarrh	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Central nervous system lesion	Nervous system disorders	1 (0.01%)
Central vision loss	Eye disorders	1 (0.01%)
Cerebellar stroke	Nervous system disorders	1 (0.01%)
Cerebral disorder	Nervous system disorders	1 (0.01%)
Cerebral ischaemia	Nervous system disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Cerebral venous sinus thrombosis	Nervous system disorders	1 (0.01%)
Cervix oedema	Reproductive system and breast disorders	1 (0.01%)
Chalazion	Eye disorders	1 (0.01%)
Cholecystitis	Hepatobiliary disorders	1 (0.01%)
Cholecystitis infective	Infections and infestations	1 (0.01%)
Chronic fatigue syndrome	General disorders and administration site conditions	1 (0.01%)
Chronic kidney disease	Renal and urinary disorders	1 (0.01%)
Circumoral oedema	Skin and subcutaneous tissue disorders	1 (0.01%)
Circumstance or information capable of leading to device use error	Injury, poisoning and procedural complications	1 (0.01%)
Clinical death	General disorders and administration site conditions	1 (0.01%)
Clostridium difficile colitis	Infections and infestations	1 (0.01%)
Clumsiness	Nervous system disorders	1 (0.01%)
Coagulation time prolonged	Investigations	1 (0.01%)
Coagulopathy	Blood and lymphatic system disorders	1 (0.01%)
Concomitant disease aggravated	General disorders and administration site conditions	1 (0.01%)
Conjunctival hyperaemia	Eye disorders	1 (0.01%)
Conjunctival irritation	Eye disorders	1 (0.01%)
Conjunctival oedema	Eye disorders	1 (0.01%)
Conjunctivitis viral	Infections and infestations	1 (0.01%)
Consciousness fluctuating	Nervous system disorders	1 (0.01%)
Contrast media allergy	Immune system disorders	1 (0.01%)
Corneal bleeding	Eye disorders	1 (0.01%)
Corneal oedema	Eye disorders	1 (0.01%)
Cortisol decreased	Investigations	1 (0.01%)
Crystal urine	Investigations	1 (0.01%)
Culture negative	Investigations	1 (0.01%)
Deafness bilateral	Ear and labyrinth disorders	1 (0.01%)
Decreased activity	General disorders and administration site conditions	1 (0.01%)
Delusion	Psychiatric disorders	1 (0.01%)
Dementia of the Alzheimer's type, with delirium	Nervous system disorders	1 (0.01%)
Demyelinating polyneuropathy	Nervous system disorders	1 (0.01%)
Dermatitis bullous	Skin and subcutaneous tissue disorders	1 (0.01%)
Dermatitis exfoliative	Skin and subcutaneous tissue disorders	1 (0.01%)
Dermatitis exfoliative generalised	Skin and subcutaneous tissue disorders	1 (0.01%)
Device breakage	Product issues	1 (0.01%)
Diabetic complication	Metabolism and nutrition disorders	1 (0.01%)
Diastolic hypertension	Vascular disorders	1 (0.01%)
Diastolic hypotension	Vascular disorders	1 (0.01%)
Dilatation ventricular	Cardiac disorders	1 (0.01%)
Disorganised speech	Psychiatric disorders	1 (0.01%)
Distractibility	Psychiatric disorders	1 (0.01%)
Drug administered in wrong device	Injury, poisoning and procedural complications	1 (0.01%)
Dyschromatopsia	Eye disorders	1 (0.01%)
Dyslexia	Nervous system disorders	1 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Dysphemia	Psychiatric disorders	1 (0.01%)
Dysphoria	Psychiatric disorders	1 (0.01%)
Dyspnoea at rest	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Ear neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Ecchymosis	Skin and subcutaneous tissue disorders	1 (0.01%)
Ejection fraction abnormal	Investigations	1 (0.01%)
Electrocardiogram QT prolonged	Investigations	1 (0.01%)
Electrocardiogram ST segment abnormal	Investigations	1 (0.01%)
Electrocardiogram ST segment elevation	Investigations	1 (0.01%)
Embolism	Vascular disorders	1 (0.01%)
Enanthema	General disorders and administration site conditions	1 (0.01%)
Encephalitis post immunisation	Nervous system disorders	1 (0.01%)
Encephalopathy	Nervous system disorders	1 (0.01%)
Enteritis	Gastrointestinal disorders	1 (0.01%)
Eosinophilic oesophagitis	Gastrointestinal disorders	1 (0.01%)
Epigastric discomfort	Gastrointestinal disorders	1 (0.01%)
Epiglottic oedema	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Epinephrine increased	Investigations	1 (0.01%)
Erysipelas	Infections and infestations	1 (0.01%)
Erythema nodosum	Skin and subcutaneous tissue disorders	1 (0.01%)
Escherichia infection	Infections and infestations	1 (0.01%)
Escherichia sepsis	Infections and infestations	1 (0.01%)
Exercise lack of	Social circumstances	1 (0.01%)
Exercise tolerance decreased	General disorders and administration site conditions	1 (0.01%)
Exertional headache	Nervous system disorders	1 (0.01%)
Exophthalmos	Eye disorders	1 (0.01%)
Extensive swelling of vaccinated limb	General disorders and administration site conditions	1 (0.01%)
Eye injury	Injury, poisoning and procedural complications	1 (0.01%)
Eyelid exfoliation	Eye disorders	1 (0.01%)
Eyelid sensory disorder	Eye disorders	1 (0.01%)
Face crushing	Injury, poisoning and procedural complications	1 (0.01%)
Facet joint syndrome	Musculoskeletal and connective tissue disorders	1 (0.01%)
Facial neuralgia	Nervous system disorders	1 (0.01%)
Faeces soft	Gastrointestinal disorders	1 (0.01%)
Fear of death	Psychiatric disorders	1 (0.01%)
Fear of injection	Psychiatric disorders	1 (0.01%)
Febrile convulsion	Nervous system disorders	1 (0.01%)
Febrile neutropenia	Blood and lymphatic system disorders	1 (0.01%)
Femoral neck fracture	Injury, poisoning and procedural complications	1 (0.01%)
Fixed eruption	Skin and subcutaneous tissue disorders	1 (0.01%)
Fluid imbalance	Metabolism and nutrition disorders	1 (0.01%)
Foaming at mouth	General disorders and administration site conditions	1 (0.01%)
Food allergy	Immune system disorders	1 (0.01%)
Food aversion	Metabolism and nutrition disorders	1 (0.01%)
Food craving	Metabolism and nutrition disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Food poisoning	Gastrointestinal disorders	1 (0.01%)
Foreign body aspiration	Injury, poisoning and procedural complications	1 (0.01%)
Freezing phenomenon	Nervous system disorders	1 (0.01%)
Frostbite	Injury, poisoning and procedural complications	1 (0.01%)
Functional gastrointestinal disorder	Gastrointestinal disorders	1 (0.01%)
Gamma-glutamyltransferase increased	Investigations	1 (0.01%)
Gastric pH decreased	Investigations	1 (0.01%)
Gastrointestinal haemorrhage	Gastrointestinal disorders	1 (0.01%)
Gastrointestinal hypermotility	Gastrointestinal disorders	1 (0.01%)
Gastrointestinal motility disorder	Gastrointestinal disorders	1 (0.01%)
Gastrointestinal stoma complication	Injury, poisoning and procedural complications	1 (0.01%)
Gastrointestinal viral infection	Infections and infestations	1 (0.01%)
Gastrooesophageal sphincter insufficiency	Gastrointestinal disorders	1 (0.01%)
General physical condition abnormal	Investigations	1 (0.01%)
Genital blister	Reproductive system and breast disorders	1 (0.01%)
Giant cell arteritis	Vascular disorders	1 (0.01%)
Gingival discolouration	Gastrointestinal disorders	1 (0.01%)
Gingival discomfort	Gastrointestinal disorders	1 (0.01%)
Gingival disorder	Gastrointestinal disorders	1 (0.01%)
Gingivitis	Infections and infestations	1 (0.01%)
Gingivitis ulcerative	Gastrointestinal disorders	1 (0.01%)
Glare	Eye disorders	1 (0.01%)
Glomerular filtration rate decreased	Investigations	1 (0.01%)
Glycosylated haemoglobin increased	Investigations	1 (0.01%)
Grunting	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Haematocrit decreased	Investigations	1 (0.01%)
Haematoma muscle	Musculoskeletal and connective tissue disorders	1 (0.01%)
Haemoglobin increased	Investigations	1 (0.01%)
Haemorrhage subcutaneous	Skin and subcutaneous tissue disorders	1 (0.01%)
Haemorrhage urinary tract	Renal and urinary disorders	1 (0.01%)
Haemorrhoids	Gastrointestinal disorders	1 (0.01%)
Hair colour changes	Skin and subcutaneous tissue disorders	1 (0.01%)
Hallucination, olfactory	Psychiatric disorders	1 (0.01%)
Hallucination, tactile	Psychiatric disorders	1 (0.01%)
Head titubation	Nervous system disorders	1 (0.01%)
Heat illness	Injury, poisoning and procedural complications	1 (0.01%)
Heat oedema	Injury, poisoning and procedural complications	1 (0.01%)
Heat stroke	Injury, poisoning and procedural complications	1 (0.01%)
Helplessness	Psychiatric disorders	1 (0.01%)
Hemiparaesthesia	Nervous system disorders	1 (0.01%)
Hemiplegia	Nervous system disorders	1 (0.01%)
Hepatic artery embolism	Hepatobiliary disorders	1 (0.01%)
Herpes zoster oticus	Infections and infestations	1 (0.01%)
Herpes zoster reactivation	Infections and infestations	1 (0.01%)
Hip fracture	Injury, poisoning and procedural complications	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Horner's syndrome	Nervous system disorders	1 (0.01%)
Hydrophobia	Psychiatric disorders	1 (0.01%)
Hyperaemia	Vascular disorders	1 (0.01%)
Hypercalcaemia	Metabolism and nutrition disorders	1 (0.01%)
Hyperchlorhydria	Gastrointestinal disorders	1 (0.01%)
Hyperleukocytosis	Blood and lymphatic system disorders	1 (0.01%)
Hypersensitivity pneumonitis	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Hypertonic bladder	Renal and urinary disorders	1 (0.01%)
Hypervigilance	Psychiatric disorders	1 (0.01%)
Hypoaesthesia teeth	Gastrointestinal disorders	1 (0.01%)
Hypomagnesaemia	Metabolism and nutrition disorders	1 (0.01%)
Hyporesponsive to stimuli	Nervous system disorders	1 (0.01%)
Hypoventilation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Hypovolaemic shock	Vascular disorders	1 (0.01%)
Idiopathic intracranial hypertension	Nervous system disorders	1 (0.01%)
Ill-defined disorder	General disorders and administration site conditions	1 (0.01%)
Illness anxiety disorder	Psychiatric disorders	1 (0.01%)
Immobile	Social circumstances	1 (0.01%)
Immune-mediated adverse reaction	Immune system disorders	1 (0.01%)
Immune-mediated arthritis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Immunisation reaction	Immune system disorders	1 (0.01%)
Impaired quality of life	Social circumstances	1 (0.01%)
Impulsive behaviour	Psychiatric disorders	1 (0.01%)
Incision site haemorrhage	Injury, poisoning and procedural complications	1 (0.01%)
Incision site pain	Injury, poisoning and procedural complications	1 (0.01%)
Indifference	Psychiatric disorders	1 (0.01%)
Infarction	Vascular disorders	1 (0.01%)
Infection parasitic	Infections and infestations	1 (0.01%)
Infective exacerbation of chronic obstructive airways disease	Infections and infestations	1 (0.01%)
Infertility	Reproductive system and breast disorders	1 (0.01%)
Inflammatory pain	General disorders and administration site conditions	1 (0.01%)
Influenza B virus test positive	Investigations	1 (0.01%)
Infrequent bowel movements	Gastrointestinal disorders	1 (0.01%)
Inguinal mass	Musculoskeletal and connective tissue disorders	1 (0.01%)
Inhibitory drug interaction	General disorders and administration site conditions	1 (0.01%)
Injection site discomfort	General disorders and administration site conditions	1 (0.01%)
Injection site hypoaesthesia	General disorders and administration site conditions	1 (0.01%)
Injection site joint movement impairment	General disorders and administration site conditions	1 (0.01%)
Injection site muscle weakness	General disorders and administration site conditions	1 (0.01%)
Injection site pruritus	General disorders and administration site conditions	1 (0.01%)
Injection site urticaria	General disorders and administration site conditions	1 (0.01%)
Injection site warmth	General disorders and administration site conditions	1 (0.01%)
Injury associated with device	General disorders and administration site conditions	1 (0.01%)
Injury corneal	Injury, poisoning and procedural complications	1 (0.01%)
Inspiratory capacity abnormal	Investigations	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Insulin resistance	Metabolism and nutrition disorders	1 (0.01%)
Intentional product misuse	Injury, poisoning and procedural complications	1 (0.01%)
Intentional self-injury	Psychiatric disorders	1 (0.01%)
Intercepted medication error	Injury, poisoning and procedural complications	1 (0.01%)
Intercepted product preparation error	Injury, poisoning and procedural complications	1 (0.01%)
Intercostal neuralgia	Nervous system disorders	1 (0.01%)
International normalised ratio abnormal	Investigations	1 (0.01%)
International normalised ratio decreased	Investigations	1 (0.01%)
Intervertebral disc protrusion	Musculoskeletal and connective tissue disorders	1 (0.01%)
Intestinal dilatation	Gastrointestinal disorders	1 (0.01%)
Intestinal obstruction	Gastrointestinal disorders	1 (0.01%)
Intracardiac thrombus	Cardiac disorders	1 (0.01%)
Intrusive thoughts	Psychiatric disorders	1 (0.01%)
Iritis	Eye disorders	1 (0.01%)
Irregular breathing	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Irregular sleep wake rhythm disorder	Nervous system disorders	1 (0.01%)
Itching scar	Skin and subcutaneous tissue disorders	1 (0.01%)
IVth nerve paralysis	Nervous system disorders	1 (0.01%)
Jaw disorder	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint ankylosis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint contracture	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint lock	Musculoskeletal and connective tissue disorders	1 (0.01%)
Joint warmth	Musculoskeletal and connective tissue disorders	1 (0.01%)
Kidney infection	Infections and infestations	1 (0.01%)
Labile hypertension	Vascular disorders	1 (0.01%)
Lacunar stroke	Nervous system disorders	1 (0.01%)
Language disorder	Nervous system disorders	1 (0.01%)
Leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Leukopenia	Blood and lymphatic system disorders	1 (0.01%)
Leukoplakia	Skin and subcutaneous tissue disorders	1 (0.01%)
Limb immobilisation	Surgical and medical procedures	1 (0.01%)
Lip discolouration	Gastrointestinal disorders	1 (0.01%)
Lip exfoliation	Gastrointestinal disorders	1 (0.01%)
Lipids increased	Investigations	1 (0.01%)
Locked-in syndrome	Nervous system disorders	1 (0.01%)
Loss of proprioception	Nervous system disorders	1 (0.01%)
Lower limb fracture	Injury, poisoning and procedural complications	1 (0.01%)
Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Lung consolidation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Lung neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Lung opacity	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Lymphangitis	Infections and infestations	1 (0.01%)
Lymphatic disorder	Blood and lymphatic system disorders	1 (0.01%)
Lymph gland infection	Infections and infestations	1 (0.01%)



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Preferred Term	System Organ Class (SOC)	Number of Cases
Lymphocyte count increased	Investigations	1 (0.01%)
Lymphocytosis	Blood and lymphatic system disorders	1 (0.01%)
Macule	Skin and subcutaneous tissue disorders	1 (0.01%)
Maculopathy	Eye disorders	1 (0.01%)
Malignant hypertension	Vascular disorders	1 (0.01%)
Mania	Psychiatric disorders	1 (0.01%)
Mast cell activation syndrome	Blood and lymphatic system disorders	1 (0.01%)
Masticatory pain	Musculoskeletal and connective tissue disorders	1 (0.01%)
Maternal exposure during breast feeding	Injury, poisoning and procedural complications	1 (0.01%)
Mean cell haemoglobin concentration decreased	Investigations	1 (0.01%)
Mean cell volume decreased	Investigations	1 (0.01%)
Mean platelet volume increased	Investigations	1 (0.01%)
Medication overuse headache	Nervous system disorders	1 (0.01%)
Melaena	Gastrointestinal disorders	1 (0.01%)
Meningism	Nervous system disorders	1 (0.01%)
Meningitis	Infections and infestations	1 (0.01%)
Meningitis viral	Infections and infestations	1 (0.01%)
Mesenteric vein thrombosis	Gastrointestinal disorders	1 (0.01%)
Metabolic acidosis	Metabolism and nutrition disorders	1 (0.01%)
Microembolism	Vascular disorders	1 (0.01%)
Micturition disorder	Renal and urinary disorders	1 (0.01%)
Middle ear inflammation	Ear and labyrinth disorders	1 (0.01%)
Mixed connective tissue disease	Musculoskeletal and connective tissue disorders	1 (0.01%)
Morning sickness	Pregnancy, puerperium and perinatal conditions	1 (0.01%)
Mouth cyst	Gastrointestinal disorders	1 (0.01%)
Mucous stools	Gastrointestinal disorders	1 (0.01%)
Multimorbidity	General disorders and administration site conditions	1 (0.01%)
Multi-organ disorder	General disorders and administration site conditions	1 (0.01%)
Muscle atrophy	Musculoskeletal and connective tissue disorders	1 (0.01%)
Muscle spasticity	Nervous system disorders	1 (0.01%)
Muscle tone disorder	Nervous system disorders	1 (0.01%)
Mutism	Psychiatric disorders	1 (0.01%)
Myelitis	Infections and infestations	1 (0.01%)
Myofascial pain syndrome	Musculoskeletal and connective tissue disorders	1 (0.01%)
Myopathy	Musculoskeletal and connective tissue disorders	1 (0.01%)
Myopia	Eye disorders	1 (0.01%)
Narcolepsy	Nervous system disorders	1 (0.01%)
Nasal discharge discolouration	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Nasal disorder	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Nasal odour	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Nasal pruritus	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Neck injury	Injury, poisoning and procedural complications	1 (0.01%)
Negative thoughts	Psychiatric disorders	1 (0.01%)
Neoplasm skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Nephrolithiasis	Renal and urinary disorders	1 (0.01%)
Nephrotic syndrome	Renal and urinary disorders	1 (0.01%)
Nerve degeneration	Nervous system disorders	1 (0.01%)
Nerve injury	Injury, poisoning and procedural complications	1 (0.01%)
Neurological symptom	Nervous system disorders	1 (0.01%)
Neutropenia	Blood and lymphatic system disorders	1 (0.01%)
Nodal rhythm	Cardiac disorders	1 (0.01%)
Noninfective encephalitis	Nervous system disorders	1 (0.01%)
Noninfective gingivitis	Gastrointestinal disorders	1 (0.01%)
Obsessive-compulsive symptom	Psychiatric disorders	1 (0.01%)
Occipital neuralgia	Nervous system disorders	1 (0.01%)
Oligodipsia	Metabolism and nutrition disorders	1 (0.01%)
Oral blood blister	Gastrointestinal disorders	1 (0.01%)
Oral papule	Gastrointestinal disorders	1 (0.01%)
Oral viral infection	Infections and infestations	1 (0.01%)
Orchitis	Infections and infestations	1 (0.01%)
Organising pneumonia	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Oropharyngeal spasm	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Orthostatic heart rate response increased	Investigations	1 (0.01%)
Orthostatic intolerance	Nervous system disorders	1 (0.01%)
Oscillopsia	Eye disorders	1 (0.01%)
Osteoarthritis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Osteochondritis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Otitis externa	Infections and infestations	1 (0.01%)
Overweight	Metabolism and nutrition disorders	1 (0.01%)
Oxygen consumption	Investigations	1 (0.01%)
Palatal disorder	Gastrointestinal disorders	1 (0.01%)
Palmar-plantar erythrodysesthesia syndrome	Skin and subcutaneous tissue disorders	1 (0.01%)
Pancreatitis acute	Gastrointestinal disorders	1 (0.01%)
Panic disorder	Psychiatric disorders	1 (0.01%)
Paraesthesia mucosal	Nervous system disorders	1 (0.01%)
Paranasal sinus inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Paraparesis	Nervous system disorders	1 (0.01%)
Paraplegia	Nervous system disorders	1 (0.01%)
Paresis cranial nerve	Nervous system disorders	1 (0.01%)
Partial seizures	Nervous system disorders	1 (0.01%)
Pathogen resistance	Infections and infestations	1 (0.01%)
Patient elopement	Nervous system disorders	1 (0.01%)
Peau d'orange	Skin and subcutaneous tissue disorders	1 (0.01%)
Pelvic fracture	Injury, poisoning and procedural complications	1 (0.01%)
Penile haemorrhage	Reproductive system and breast disorders	1 (0.01%)
Penile swelling	Reproductive system and breast disorders	1 (0.01%)
Performance status decreased	General disorders and administration site conditions	1 (0.01%)
Pericardial effusion	Cardiac disorders	1 (0.01%)



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Preferred Term	System Organ Class (SOC)	Number of Cases
Periorbital discomfort	Eye disorders	1 (0.01%)
Peripheral embolism	Vascular disorders	1 (0.01%)
Peripheral motor neuropathy	Nervous system disorders	1 (0.01%)
Peripheral sensory neuropathy	Nervous system disorders	1 (0.01%)
Peroneal nerve injury	Injury, poisoning and procedural complications	1 (0.01%)
Pertussis	Infections and infestations	1 (0.01%)
Pharyngeal ulceration	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Phonophobia	Psychiatric disorders	1 (0.01%)
Pityriasis rosea	Skin and subcutaneous tissue disorders	1 (0.01%)
Plantar erythema	Skin and subcutaneous tissue disorders	1 (0.01%)
Plicated tongue	Gastrointestinal disorders	1 (0.01%)
Pneumonia bacterial	Infections and infestations	1 (0.01%)
Poisoning	Injury, poisoning and procedural complications	1 (0.01%)
Poor feeding infant	Metabolism and nutrition disorders	1 (0.01%)
Posterior reversible encephalopathy syndrome	Nervous system disorders	1 (0.01%)
Postictal state	Nervous system disorders	1 (0.01%)
Post lumbar puncture syndrome	Injury, poisoning and procedural complications	1 (0.01%)
Postoperative ileus	Injury, poisoning and procedural complications	1 (0.01%)
Post procedural haemorrhage	Injury, poisoning and procedural complications	1 (0.01%)
Postural orthostatic tachycardia syndrome	Cardiac disorders	1 (0.01%)
Posture abnormal	Musculoskeletal and connective tissue disorders	1 (0.01%)
Premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	1 (0.01%)
Pressure of speech	Psychiatric disorders	1 (0.01%)
Primary headache associated with sexual activity	Nervous system disorders	1 (0.01%)
Procedural nausea	Injury, poisoning and procedural complications	1 (0.01%)
Proctitis ulcerative	Gastrointestinal disorders	1 (0.01%)
Product confusion	Injury, poisoning and procedural complications	1 (0.01%)
Product deposit	Product issues	1 (0.01%)
Product formulation issue	Product issues	1 (0.01%)
Prolonged expiration	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Prostatomegaly	Reproductive system and breast disorders	1 (0.01%)
Protein urine present	Investigations	1 (0.01%)
Pruritus allergic	Skin and subcutaneous tissue disorders	1 (0.01%)
Pruritus genital	Reproductive system and breast disorders	1 (0.01%)
Pseudolymphoma	Blood and lymphatic system disorders	1 (0.01%)
Psychiatric symptom	Psychiatric disorders	1 (0.01%)
Psychological factor affecting medical condition	Psychiatric disorders	1 (0.01%)
Psychotic behaviour	Psychiatric disorders	1 (0.01%)
Pulmonary sepsis	Infections and infestations	1 (0.01%)
Pulpitis dental	Infections and infestations	1 (0.01%)
Pulseless electrical activity	Cardiac disorders	1 (0.01%)
Pupillary disorder	Eye disorders	1 (0.01%)
Pupillary reflex impaired	Eye disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Pyelonephritis	Infections and infestations	1 (0.01%)
Rash morbilliform	Skin and subcutaneous tissue disorders	1 (0.01%)
Reaction to preservatives	Immune system disorders	1 (0.01%)
Red blood cell count decreased	Investigations	1 (0.01%)
Red blood cell count increased	Investigations	1 (0.01%)
Red blood cells urine positive	Investigations	1 (0.01%)
Regurgitation	Gastrointestinal disorders	1 (0.01%)
Renal impairment	Renal and urinary disorders	1 (0.01%)
Respiratory depression	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Respiratory tract oedema	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Retinal migraine	Nervous system disorders	1 (0.01%)
Rhinovirus infection	Infections and infestations	1 (0.01%)
Rib fracture	Injury, poisoning and procedural complications	1 (0.01%)
Right ventricular dysfunction	Cardiac disorders	1 (0.01%)
Right ventricular enlargement	Cardiac disorders	1 (0.01%)
Rubber sensitivity	Immune system disorders	1 (0.01%)
SARS-CoV-1 test positive	Investigations	1 (0.01%)
SARS-CoV-2 test negative	Investigations	1 (0.01%)
Scab	Skin and subcutaneous tissue disorders	1 (0.01%)
Scar pain	Skin and subcutaneous tissue disorders	1 (0.01%)
Sciatic nerve neuropathy	Nervous system disorders	1 (0.01%)
Scleritis	Eye disorders	1 (0.01%)
Scrotal erythema	Reproductive system and breast disorders	1 (0.01%)
Scrotal exfoliation	Reproductive system and breast disorders	1 (0.01%)
Scrotal swelling	Reproductive system and breast disorders	1 (0.01%)
Sense of oppression	General disorders and administration site conditions	1 (0.01%)
Sensitisation	Immune system disorders	1 (0.01%)
Serositis	General disorders and administration site conditions	1 (0.01%)
Serum sickness	Immune system disorders	1 (0.01%)
Sinonasal obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Sinus arrhythmia	Cardiac disorders	1 (0.01%)
Sinus bradycardia	Cardiac disorders	1 (0.01%)
Sinus tarsi syndrome	Musculoskeletal and connective tissue disorders	1 (0.01%)
Sitophobia	Psychiatric disorders	1 (0.01%)
Sjogren's syndrome	Musculoskeletal and connective tissue disorders	1 (0.01%)
Skin abrasion	Injury, poisoning and procedural complications	1 (0.01%)
Skin cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.01%)
Skin indentation	Skin and subcutaneous tissue disorders	1 (0.01%)
Skin induration	Skin and subcutaneous tissue disorders	1 (0.01%)
Skin odour abnormal	Skin and subcutaneous tissue disorders	1 (0.01%)
Skin weeping	Skin and subcutaneous tissue disorders	1 (0.01%)
Sleep deficit	Nervous system disorders	1 (0.01%)
Sleep paralysis	Nervous system disorders	1 (0.01%)
Sleep terror	Psychiatric disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Soft tissue swelling	Musculoskeletal and connective tissue disorders	1 (0.01%)
Spinal disorder	Musculoskeletal and connective tissue disorders	1 (0.01%)
Spinal fusion surgery	Surgical and medical procedures	1 (0.01%)
Splenomegaly	Blood and lymphatic system disorders	1 (0.01%)
Sputum purulent	Infections and infestations	1 (0.01%)
Staphylococcal infection	Infections and infestations	1 (0.01%)
Staphylococcal sepsis	Infections and infestations	1 (0.01%)
Staphylococcal skin infection	Infections and infestations	1 (0.01%)
Status asthmaticus	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Status epilepticus	Nervous system disorders	1 (0.01%)
Stiff leg syndrome	Nervous system disorders	1 (0.01%)
Stoma site discharge	Injury, poisoning and procedural complications	1 (0.01%)
Stoma site extravasation	Injury, poisoning and procedural complications	1 (0.01%)
Stoma site haemorrhage	Injury, poisoning and procedural complications	1 (0.01%)
Strawberry tongue	Gastrointestinal disorders	1 (0.01%)
Streptococcal infection	Infections and infestations	1 (0.01%)
Streptococcus test positive	Investigations	1 (0.01%)
Submaxillary gland enlargement	Gastrointestinal disorders	1 (0.01%)
Substance abuse	Psychiatric disorders	1 (0.01%)
Superficial injury of eye	Injury, poisoning and procedural complications	1 (0.01%)
Supraventricular extrasystoles	Cardiac disorders	1 (0.01%)
Suspected counterfeit product	Product issues	1 (0.01%)
Suture related complication	Injury, poisoning and procedural complications	1 (0.01%)
Symphysisolysis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Symptom recurrence	General disorders and administration site conditions	1 (0.01%)
Synovial cyst	Musculoskeletal and connective tissue disorders	1 (0.01%)
Synovial rupture	Injury, poisoning and procedural complications	1 (0.01%)
Synovitis	Musculoskeletal and connective tissue disorders	1 (0.01%)
Systemic scleroderma	Musculoskeletal and connective tissue disorders	1 (0.01%)
Temperature intolerance	General disorders and administration site conditions	1 (0.01%)
Tendon injury	Injury, poisoning and procedural complications	1 (0.01%)
Thrombocytosis	Blood and lymphatic system disorders	1 (0.01%)
Thrombotic thrombocytopenic purpura	Blood and lymphatic system disorders	1 (0.01%)
Thunderclap headache	Nervous system disorders	1 (0.01%)
Thyroid function test abnormal	Investigations	1 (0.01%)
Tic	Psychiatric disorders	1 (0.01%)
Tongue blistering	Gastrointestinal disorders	1 (0.01%)
Tongue coated	Gastrointestinal disorders	1 (0.01%)
Tongue haemorrhage	Gastrointestinal disorders	1 (0.01%)
Tongue injury	Injury, poisoning and procedural complications	1 (0.01%)
Tonic clonic movements	Nervous system disorders	1 (0.01%)
Tonsillar inflammation	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Tonsillitis bacterial	Infections and infestations	1 (0.01%)
Tonsillolith	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Tooth infection	Infections and infestations	1 (0.01%)
Toxic epidermal necrolysis	Skin and subcutaneous tissue disorders	1 (0.01%)

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Preferred Term	System Organ Class (SOC)	Number of Cases
Toxic skin eruption	Skin and subcutaneous tissue disorders	1 (0.01%)
Tracheomalacia	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Transaminases increased	Investigations	1 (0.01%)
Transient global amnesia	Nervous system disorders	1 (0.01%)
Trigeminal nerve disorder	Nervous system disorders	1 (0.01%)
Trigeminal neuritis	Nervous system disorders	1 (0.01%)
Tri-iodothyronine decreased	Investigations	1 (0.01%)
Troponin T increased	Investigations	1 (0.01%)
Tryptase increased	Investigations	1 (0.01%)
Type I hypersensitivity	Immune system disorders	1 (0.01%)
Ulcer	General disorders and administration site conditions	1 (0.01%)
Undifferentiated connective tissue disease	Musculoskeletal and connective tissue disorders	1 (0.01%)
Upper airway obstruction	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Upper limb fracture	Injury, poisoning and procedural complications	1 (0.01%)
Urethral pain	Renal and urinary disorders	1 (0.01%)
Urge incontinence	Renal and urinary disorders	1 (0.01%)
Urinary tract disorder	Renal and urinary disorders	1 (0.01%)
Urinary tract infection bacterial	Infections and infestations	1 (0.01%)
Urine analysis abnormal	Investigations	1 (0.01%)
Urine output decreased	Investigations	1 (0.01%)
Urine output increased	Investigations	1 (0.01%)
Urticaria cholinergic	Skin and subcutaneous tissue disorders	1 (0.01%)
Urticaria papular	Skin and subcutaneous tissue disorders	1 (0.01%)
Uterine contractions during pregnancy	Pregnancy, puerperium and perinatal conditions	1 (0.01%)
Uterine haemorrhage	Reproductive system and breast disorders	1 (0.01%)
Uvulitis	Gastrointestinal disorders	1 (0.01%)
Vaccination site abscess	Infections and infestations	1 (0.01%)
Vaccination site dermatitis	General disorders and administration site conditions	1 (0.01%)
Vaccination site injury	General disorders and administration site conditions	1 (0.01%)
Vaccination site joint erythema	General disorders and administration site conditions	1 (0.01%)
Vaccination site joint swelling	General disorders and administration site conditions	1 (0.01%)
Vaccination site joint warmth	General disorders and administration site conditions	1 (0.01%)
Vaccination site pallor	General disorders and administration site conditions	1 (0.01%)
Vaccination site papule	General disorders and administration site conditions	1 (0.01%)
Vaccination site plaque	General disorders and administration site conditions	1 (0.01%)
Varicella zoster virus infection	Infections and infestations	1 (0.01%)
Vascular pain	Vascular disorders	1 (0.01%)
Vasculitic rash	Skin and subcutaneous tissue disorders	1 (0.01%)
Vasoconstriction	Vascular disorders	1 (0.01%)
Vasomotor rhinitis	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Vein discolouration	Vascular disorders	1 (0.01%)
Vein disorder	Vascular disorders	1 (0.01%)
Vein rupture	Vascular disorders	1 (0.01%)
Vena cava thrombosis	Vascular disorders	1 (0.01%)
Vessel puncture site haemorrhage	General disorders and administration site conditions	1 (0.01%)

Preferred Term	System Organ Class (SOC)	Number of Cases
Vessel puncture site injury	General disorders and administration site conditions	1 (0.01%)
Vestibular disorder	Ear and labyrinth disorders	1 (0.01%)
Vestibular migraine	Nervous system disorders	1 (0.01%)
Viral labyrinthitis	Infections and infestations	1 (0.01%)
Viral pharyngitis	Infections and infestations	1 (0.01%)
Viral tonsillitis	Infections and infestations	1 (0.01%)
Viral upper respiratory tract infection	Infections and infestations	1 (0.01%)
Visual acuity reduced	Eye disorders	1 (0.01%)
Visual brightness	Eye disorders	1 (0.01%)
Vital functions abnormal	Investigations	1 (0.01%)
Vocal cord disorder	Respiratory, thoracic and mediastinal disorders	1 (0.01%)
Vomiting psychogenic	Psychiatric disorders	1 (0.01%)
Von Willebrand's disease	Congenital, familial and genetic disorders	1 (0.01%)
Vulval disorder	Reproductive system and breast disorders	1 (0.01%)
Vulvovaginal mycotic infection	Infections and infestations	1 (0.01%)
Vulvovaginal rash	Reproductive system and breast disorders	1 (0.01%)
Vulvovaginal swelling	Reproductive system and breast disorders	1 (0.01%)
Weight bearing difficulty	Musculoskeletal and connective tissue disorders	1 (0.01%)
Weight loss diet	Surgical and medical procedures	1 (0.01%)
White blood cell count decreased	Investigations	1 (0.01%)
Wound haemorrhage	Injury, poisoning and procedural complications	1 (0.01%)
Writer's cramp	Nervous system disorders	1 (0.01%)
Yawning	Respiratory, thoracic and mediastinal disorders	1 (0.01%)

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**Appendix 2.2 Interval Summary Tabulation of Case Reports with DME Events from Post-Marketing Data Sources**

PF-07302048 - ALL

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval)

Total Number of Cases with DME 351 (Interval)

Total Number of Adverse Events (PT) (DME only) 396 (Interval)

MedDRA Version: v.23.1J

SOC and PT	Number of Events	Percentage (%)
<b>Eye disorders</b>	1	
Angle closure glaucoma	1	0.0 %
<b>Gastrointestinal disorders</b>	16	
Pancreatitis	3	0.0 %
Pancreatitis acute	1	0.0 %
Tongue oedema	12	0.1 %
<b>General disorders and administration site conditions</b>	10	
Face oedema	10	0.1 %
<b>Immune system disorders</b>	200	
Anaphylactic reaction	162	1.1 %
Anaphylactic shock	30	0.2 %
Anaphylactoid reaction	7	0.0 %
Type I hypersensitivity	1	0.0 %
<b>Injury, poisoning and procedural complications</b>	3	
Contraindicated product administered	3	0.0 %

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Multiple adverse event coding to the same Preferred Term (DME) may have been reported in some cases. Counts are provided for the number of unique Preferred Terms Reported.

<b>Musculoskeletal and connective tissue disorders</b>	6	
Myopathy	1	0.0 %
Myositis	2	0.0 %
Rhabdomyolysis	3	0.0 %
<b>Psychiatric disorders</b>	1	
Intentional self-injury	1	0.0 %
<b>Respiratory, thoracic and mediastinal disorders</b>	100	
Hypersensitivity pneumonitis	1	0.0 %
Laryngeal oedema	21	0.1 %
Oropharyngeal oedema	2	0.0 %
Pharyngeal swelling	76	0.5 %
<b>Skin and subcutaneous tissue disorders</b>	59	
Angioedema	39	0.3 %
Circumoral swelling	2	0.0 %
Dermatitis exfoliative	1	0.0 %
Dermatitis exfoliative generalised	1	0.0 %
Erythema multiforme	2	0.0 %
Skin exfoliation	11	0.1 %
Stevens-Johnson syndrome	2	0.0 %
Toxic epidermal necrolysis	1	0.0 %

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Multiple adverse event coding to the same Preferred Term (DME) may have been reported in some cases. Counts are provided for the number of unique Preferred Terms Reported.

**APPENDIX 2.3: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Case Reports From Post-Marketing Data Sources by Medically Confirmed and Non Medically Confirmed, Region and Country**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval) / 18,061 (Cumulative)

MedDRA Version: v.23.1J

**Medically Confirmed**

**Region : European Countries (27 EU)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
AUSTRIA	19	19			10	10	7	7	2	2
BELGIUM	19	19			5	5	7	7	7	7
BULGARIA	18	20			14	15			4	5
CROATIA	11	14			7	10			4	4
CYPRUS	8	9			5	5		1	3	3
CZECH REPUBLIC	15	15			8	8			7	7
DENMARK	128	128			82	82	12	12	34	34
ESTONIA	11	11			10	10			1	1
FINLAND	15	15			8	8	2	2	5	5
FRANCE	97	97			57	57	17	17	23	23
GERMANY	308	321	1	1	103	110	73	73	132	138
GREECE	109	111			78	79	4	4	27	28
HUNGARY	51	53			45	46			6	7
IRELAND	8	8			2	2	2	2	4	4
ITALY	632	635	1	1	537	540	11	11	84	84
LATVIA	15	15			8	8			7	7
LITHUANIA	4	4			4	4				
LUXEMBOURG	1	1			1	1				
MALTA	4	5			1	1			3	4
NETHERLANDS	7	7			5	5			2	2
POLAND	87	89			69	71			18	18
PORTUGAL	130	133			63	65	3	3	64	65
ROMANIA	215	232			178	195			37	37
SLOVAKIA	16	16			9	9			7	7
SLOVENIA	6	6			4	4	2	2		

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\* I=Interval, C=Cumulative



**Medically Confirmed**

**Region : European Countries (27 EU)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
SPAIN	163	166			130	132	11	11	22	23
SWEDEN	99	100			64	64	22	23	13	13
	2,196	2,249	2	2	1507	1546	173	175	516	528

**Region : European Economic Area (3 EEA)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
ICELAND	39	39	31	31	7	7	1	1
NORWAY	53	53	15	15	30	30	8	8
	92	92	46	46	37	37	9	9

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
AFGHANISTAN		1								1
BERMUDA	1	1			1	1				
CANADA	110	121			90	99			20	22
CHILE	14	22			11	18			3	4
COLOMBIA	1	1			1	1				
COSTA RICA	13	13			12	12			1	1
ISRAEL	110	155	1	1	74	113	5	8	31	34
KUWAIT	1	1			1	1				
MEXICO	44	49			25	29			19	20
PUERTO RICO	15	26			13	24			2	2
QATAR		2				1				1
SAUDI ARABIA	6	6			5	5			1	1
SERBIA	26	26			19	19			7	7
SINGAPORE	7	7			2	2			5	5
SWITZERLAND	10	10			7	7	2	2	1	1
UNITED ARAB EMIRATES	2	2							2	2
UNITED KINGDOM	2,563	3,183	11	11	1032	1478	105	107	1426	1598

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\* I=Interval, C=Cumulative

**Medically Confirmed**

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Non Interventional Study		Spontaneous					
			Serious Non Fatal		Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C	I	C
UNITED STATES	3,966	5,760			3088	4535	20	21	858	1204
UNITED STATES MINOR OUTLYING ISLANDS	2	3			2	3				
	6,891	9,389	12	12	4383	6348	132	138	2376	2903

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\* I=Interval, C=Cumulative

**Non Medically Confirmed**

**Region : European Countries (27 EU)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
AUSTRIA	2	2	2	2				
BELGIUM	8	8	6	6	2	2		
BULGARIA	2	2	2	2				
CROATIA	4	5	4	5				
CYPRUS	2	2	1	1			1	1
CZECH REPUBLIC	4	4	3	3			1	1
DENMARK	23	23	22	22			1	1
ESTONIA	2	2	2	2				
FINLAND	5	5	5	5				
FRANCE	5	5	2	2	1	1	2	2
GERMANY	404	405	343	343	10	10	51	52
GREECE	7	7	5	5	1	1	1	1
HUNGARY	6	6	6	6				
ITALY	21	21	19	19			2	2
LATVIA	5	5	3	3			2	2
LITHUANIA	6	6	6	6				
MALTA	1	1	1	1				
NETHERLANDS	4	4	3	3			1	1
POLAND	38	38	33	33			5	5
PORTUGAL	36	36	23	23			13	13
ROMANIA	12	12	11	11			1	1
SLOVAKIA	7	7	6	6			1	1
SLOVENIA	1	1					1	1
SPAIN	26	26	21	21	1	1	4	4
SWEDEN	27	27	21	21	2	2	4	4
	658	660	550	551	17	17	91	92

**Region : European Economic Area (3 EEA)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous	
			Nonserious	
			I	C
ICELAND	2	2	2	2
NORWAY	2	2	2	2

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\* I=Interval, C=Cumulative

**Non Medically Confirmed**

**Region : European Economic Area (3 EEA)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous	
			Nonserious	
			I	C
	4	4	4	4

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous					
			Nonserious		Serious Fatal		Serious Non Fatal	
			I	C	I	C	I	C
ANDORRA	1	1	1	1				
BAHRAIN	1	1	1	1				
CANADA	29	31	27	29	1	1	1	1
CHILE	4	4	4	4				
COSTA RICA	1	1	1	1				
INDIA		1		1				
ISRAEL	181	217	134	166	10	10	37	41
MEXICO	67	68	52	53			15	15
NORTHERN MARIANA ISLANDS	2	2	2	2				
OMAN		1		1				
PUERTO RICO	2	5	2	5				
QATAR	1	1	1	1				
SAUDI ARABIA	2	2	2	2				
SERBIA	4	4	3	3			1	1
SWITZERLAND	4	4	1	1	3	3		
UNITED ARAB EMIRATES	8	9	6	7			2	2
UNITED KINGDOM	1,977	2,242	316	452	12	12	1649	1778
UNITED STATES	2,386	3,059	1976	2550	27	28	383	481
	4,670	5,653	2529	3280	53	54	2088	2319

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\* I=Interval, C=Cumulative

**Unknown**

**Region : European Countries (27 EU)**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous							
			Nonserious		Serious Fatal		Serious Non Fatal			
			I	C	I	C	I	C		
CYPRUS										
MALTA										
ROMANIA										
SPAIN										

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases
------------------------------	---------------------------------------	---

**Region : Non-European Countries**

Country where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous			
			Nonserious		Serious Non Fatal	
			I	C	I	C
AFGHANISTAN						
CHILE						
INDIA						
ISRAEL						
MEXICO						
OMAN						
QATAR						
UNITED KINGDOM						
UNITED STATES						

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\* I=Interval, C=Cumulative

**Appendix 2.4: Cumulative and Interval Summary Tabulation of Fatal Case Reports From Post-Marketing Data Sources by Country**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 412 (Interval) / 421 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred	Interval Total # Spontaneous Cases	Cumulative Total # Spontaneous Cases	Spontaneous	
			Serious Fatal	
			I	C
AUSTRIA	7	7	7	7
BELGIUM	9	9	9	9
CANADA	1	1	1	1
CYPRUS		1		1
DENMARK	12	12	12	12
FINLAND	2	2	2	2
FRANCE	18	18	18	18
GERMANY	83	83	83	83
GREECE	5	5	5	5
ICELAND	7	7	7	7
IRELAND	2	2	2	2
ISRAEL	15	18	15	18
ITALY	11	11	11	11
NORWAY	30	30	30	30
PORTUGAL	3	3	3	3
SLOVENIA	2	2	2	2
SPAIN	12	12	12	12
SWEDEN	24	25	24	25
SWITZERLAND	5	5	5	5
UNITED KINGDOM	117	119	117	119
UNITED STATES	47	49	47	49
	412	421	412	421

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\* I=Interval, C=Cumulative

**APPENDIX 2.5: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by Preferred Term**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval) / 18,061 (Cumulative)

Total Number of Adverse Events (PT): 51,740 (Interval) / 63,975 (Cumulative)

MedDRA Version: v.23.1J

*System Organ Class*

**Blood and lymphatic system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood disorder	1	1	1	1		
Coagulopathy	1	1			1	1
Eosinophilia	2	2	2	2		
Febrile neutropenia	1	1			1	1
Haemolytic anaemia	2	2			2	2
Hyperleukocytosis	1	1			1	1
Immune thrombocytopenia	3	4			3	4
Leukocytosis	7	7	3	3	4	4
Leukopenia		1				1
Lymphadenitis	13	15	11	13	2	2
Lymphadenopathy	711	832	530	627	181	205
Lymphatic disorder	1	1	1	1		
Lymph node pain	151	181	116	141	35	40
Lymphocytosis	1	1	1	1		
Lymphopenia	3	3	1	1	2	2
Mast cell activation syndrome	1	1			1	1
Neutropenia	1	1			1	1
Pancytopenia	2	2			2	2
Pseudolymphoma	1	1			1	1
Splenomegaly	1	1			1	1
Thrombocytopenia	10	10			10	10
Thrombocytosis	1	1			1	1
Thrombotic thrombocytopenic purpura		1				1

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\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	915	1,071	666	790	249	281

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute cardiac event	1	1			1	1
Acute coronary syndrome	4	4			4	4
Acute myocardial infarction	18	20			18	20
Angina pectoris	8	8			8	8
Arrhythmia	14	16	1	1	13	15
Arrhythmia supraventricular	3	3	1	1	2	2
Arteriospasm coronary	1	1			1	1
Atrial fibrillation	27	30	1	1	26	29
Atrioventricular block complete	1	1			1	1
Bradycardia	16	17			16	17
Bundle branch block right	1	1	1	1		
Cardiac arrest	38	43			38	43
Cardiac discomfort		1		1		
Cardiac disorder	8	11	2	5	6	6
Cardiac failure	15	16			15	16
Cardiac failure congestive	2	2			2	2
Cardiac fibrillation	1	1			1	1
Cardiac flutter	5	6			5	6
Cardiac valve disease	1	1			1	1
Cardiac valve sclerosis	1	1			1	1
Cardiogenic shock	1	1			1	1
Cardiopulmonary failure	1	1			1	1
Cardio-respiratory arrest	6	6			6	6
Cardio-respiratory distress	1	1			1	1

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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular disorder	11	11	6	6	5	5
Cardiovascular insufficiency	1	1			1	1
Coronary artery disease	2	2			2	2
Dilatation ventricular	1	1			1	1
Extrasystoles	5	7	4	5	1	2
Intracardiac thrombus	1	1			1	1
Myocardial infarction	25	30			25	30
Myocardial ischaemia	2	2			2	2
Myocarditis	5	5			5	5
Nodal rhythm	1	1	1	1		
Palpitations	219	294	136	189	83	105
Pericardial effusion	1	1			1	1
Pericarditis	7	9			7	9
Postural orthostatic tachycardia syndrome	1	1	1	1		
Pulseless electrical activity	1	1			1	1
Right ventricular dysfunction	1	1			1	1
Right ventricular enlargement	1	1	1	1		
Sinus arrhythmia	1	1			1	1
Sinus bradycardia		1				1
Sinus tachycardia	14	18	6	8	8	10
Supraventricular extrasystoles	1	1			1	1
Supraventricular tachycardia	7	11	3	3	4	8
Tachyarrhythmia	4	4			4	4
Tachycardia	272	360	145	205	127	155
Tachycardia paroxysmal	2	2	1	1	1	1
Ventricular extrasystoles	5	10	3	6	2	4
Ventricular fibrillation	5	6			5	6
Ventricular tachycardia	1	2			1	2
	771	978	313	436	458	542

System Organ Class

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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Huntington's disease	4	4	4	4
Von Willebrand's disease		1		1
	4	5	4	5

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling	2	2	1	1	1	1
Deafness	16	19			16	19
Deafness bilateral	1	1			1	1
Deafness neurosensory	3	5			3	5
Deafness unilateral	2	4			2	4
Ear congestion	3	3	2	2	1	1
Ear discomfort	23	30	21	27	2	3
Ear disorder	5	5	4	4	1	1
Ear pain	76	94	59	73	17	21
Ear pruritus	9	9	8	8	1	1
Ear swelling	2	6	2	5		1
Hyperacusis	5	8	3	5	2	3
Hypoacusis	15	19	14	17	1	2
Middle ear inflammation	1	1			1	1
Motion sickness	5	7	5	7		
Paraesthesia ear	1	2	1	2		
Sudden hearing loss	4	4			4	4
Tinnitus	67	93	48	66	19	27
Vertigo	126	148	85	101	41	47
Vertigo positional	5	6	1	2	4	4
Vestibular disorder	1	1	1	1		
	372	467	255	321	117	146

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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune thyroiditis	1	1			1	1
Hypothyroidism	3	3			3	3
Thyroid disorder	2	2	2	2		
	6	6	2	2	4	4

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	6	7	5	6	1	1
Age-related macular degeneration	1	1			1	1
Amblyopia	1	1	1	1		
Angle closure glaucoma	1	1			1	1
Asthenopia	12	15	9	12	3	3
Blepharitis	1	1	1	1		
Blepharochalasis	1	1	1	1		
Blepharospasm	6	7	4	5	2	2
Blindness	6	7			6	7
Blindness transient		1				1
Central vision loss	1	1			1	1
Chalazion	1	1	1	1		
Conjunctival haemorrhage	4	5			4	5
Conjunctival hyperaemia	1	1	1	1		
Conjunctival irritation	1	1	1	1		
Conjunctival oedema	1	1	1	1		
Conjunctivitis allergic	2	2	2	2		
Corneal bleeding	1	1			1	1
Corneal oedema	1	1	1	1		
Diplopia	12	14	7	9	5	5
Dry eye	9	10	7	8	2	2

\* I=Interval, C=Cumulative  
\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyschromatopsia	1	1
Episcleritis	4	4
Erythema of eyelid	4	5
Exophthalmos	1	1
Eye allergy	3	3
Eye discharge	1	3
Eye disorder	21	26
Eye haemorrhage	6	8
Eye inflammation	5	6
Eye irritation	30	35
Eyelid disorder	1	2
Eyelid exfoliation	1	1
Eyelid function disorder	1	2
Eyelid irritation	3	3
Eyelid oedema	5	5
Eyelid pain	3	3
Eyelid ptosis	4	6
Eyelid rash	2	2
Eyelid sensory disorder	1	1
Eyelids pruritus	4	6
Eye movement disorder	6	7
Eye oedema	5	5
Eye pain	94	111
Eye paraesthesia	2	2
Eye pruritus	35	44
Eye swelling	61	79
Foreign body sensation in eyes	2	2
Glare	1	1
Glaucoma	2	2
Hypoaesthesia eye	4	4
Iridocyclitis	2	2
Iritis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
4	4		
4	5		
1	1		
2	2	1	1
1	3		
12	16	9	10
		6	8
3	4	2	2
23	26	7	9
1	2		
		1	1
	1	1	1
3	3		
3	3	2	2
2	2	1	1
2	3	2	3
		2	2
1	1		
2	4	2	2
1	1	5	6
4	4	1	1
54	69	40	42
		2	2
19	26	16	18
36	52	25	27
		2	2
1	1		
		2	2
2	2	2	2
		2	2
1	1		

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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation increased	28	30	15	17	13	13
Maculopathy		1				1
Metamorphopsia	1	2			1	2
Mydriasis	2	2	1	1	1	1
Myopia	1	1	1	1		
Ocular discomfort	11	13	8	10	3	3
Ocular hyperaemia	25	32	16	22	9	10
Oscillopsia	1	1	1	1		
Periorbital discomfort		1		1		
Periorbital oedema	3	4	1	2	2	2
Periorbital swelling	11	20	10	17	1	3
Photophobia	37	50	19	27	18	23
Photopsia	4	5	3	4	1	1
Pupil fixed	2	2			2	2
Pupillary disorder	1	1	1	1		
Pupillary reflex impaired	1	1			1	1
Pupils unequal	2	2			2	2
Scleritis	1	1			1	1
Swelling of eyelid	21	31	17	26	4	5
Vision blurred	106	127	67	81	39	46
Visual acuity reduced	1	1	1	1		
Visual brightness	1	1	1	1		
Visual impairment	35	42	19	24	16	18
Vitreous floaters	1	2	1	2		
	681	836	406	525	275	311

System Organ Class

Gastrointestinal disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal adhesions	1	1
Abdominal discomfort	65	82
Abdominal distension	15	21
Abdominal pain	142	174
Abdominal pain lower	12	17
Abdominal pain upper	146	172
Abdominal rigidity	1	2
Abdominal tenderness	3	4
Abnormal faeces	6	7
Aerophagia	1	1
Anaesthesia oral		1
Anal haemorrhage	1	2
Anal incontinence	3	3
Angular cheilitis	1	1
Aphthous ulcer	8	8
Aptyalism		1
Bowel movement irregularity	2	2
Breath odour	3	3
Chapped lips	3	3
Cheilitis	1	2
Colitis ulcerative	2	2
Constipation	10	11
Defaecation urgency	2	4
Dental paraesthesia		2
Diarrhoea	573	710
Diarrhoea haemorrhagic		2
Discoloured vomit	2	2
Dry mouth	71	102
Dyspepsia	30	35
Dysphagia	84	95
Enlarged uvula	4	5
Enteritis		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		49	66	16	16
		10	15	5	6
		102	129	40	45
		9	12	3	5
		100	121	46	51
		1	1		1
		1	2	2	2
		6	7		
				1	1
			1		
		1	1		1
		2	2	1	1
		1	1		
		6	6	2	2
			1		
		2	2		
		3	3		
		3	3		
			1	1	1
				2	2
		7	8	3	3
			1	2	3
			2		
		410	524	163	186
					2
		2	2		
		46	70	25	32
		27	32	3	3
		34	42	50	53
		2	2	2	3
			1		

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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eosinophilic oesophagitis	1	1
Epigastric discomfort	1	1
Eructation	8	8
Faeces discoloured	3	4
Faeces pale	1	2
Faeces soft	1	1
Flatulence	12	15
Food poisoning		1
Frequent bowel movements	5	8
Functional gastrointestinal disorder	1	1
Gastric disorder	4	5
Gastritis	5	8
Gastrointestinal disorder	17	22
Gastrointestinal haemorrhage	1	1
Gastrointestinal hypermotility		1
Gastrointestinal motility disorder	1	1
Gastrointestinal pain	10	12
Gastrointestinal sounds abnormal	3	3
Gastrooesophageal reflux disease	9	9
Gastrooesophageal sphincter insufficiency	1	1
Gingival bleeding	6	8
Gingival blister	2	2
Gingival discolouration		1
Gingival discomfort		1
Gingival disorder	1	1
Gingival erythema	2	2
Gingival pain	11	14
Gingival swelling	7	7
Gingivitis ulcerative	1	1
Glossitis	4	5
Glossodynia	12	16
Haematemesis	7	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		3	3	5	5
		2	3	1	1
			1	1	1
		1	1		
		10	12	2	3
			1		
		3	5	2	3
				1	1
		3	4	1	1
		3	6	2	2
		15	20	2	2
				1	1
					1
		1	1		
		7	8	3	4
		3	3		
		6	6	3	3
				1	1
		4	6	2	2
		2	2		
					1
					1
		1	1		
		2	2		
		7	8	4	6
		7	7		
				1	1
		3	4	1	1
		9	12	3	4
				7	8

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematochezia	7	8
Haemorrhoids	1	1
Hyperaesthesia teeth	3	3
Hyperchlorhydria	1	1
Hypoaesthesia oral	129	168
Hypoaesthesia teeth	1	1
Infantile vomiting	2	3
Infrequent bowel movements	1	1
Intestinal dilatation	1	1
Intestinal ischaemia	3	3
Intestinal obstruction		1
Irritable bowel syndrome	5	5
Lip blister	3	5
Lip discolouration	1	1
Lip disorder	3	6
Lip dry	3	4
Lip erythema	1	3
Lip exfoliation	1	1
Lip oedema	22	24
Lip pain	4	7
Lip pruritus	10	13
Lip swelling	83	115
Melaena	1	1
Mesenteric vein thrombosis	1	1
Mouth cyst	1	1
Mouth swelling	10	16
Mouth ulceration	14	19
Mucous stools		1
Nausea	1,718	2,136
Noninfective gingivitis	1	1
Odynophagia	12	15
Oedema mouth	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	8
		1	1		
		3	3		
		1	1		
		90	122	39	46
		1	1		
		2	3		
		1	1		
				1	1
				3	3
					1
		2	2	3	3
		2	3	1	2
				1	1
		2	5	1	1
		2	3	1	1
		1	3		
		1	1		
		13	14	9	10
		2	4	2	3
		9	11	1	2
		44	62	39	53
				1	1
				1	1
		1	1		
		5	9	5	7
		7	12	7	7
			1		
3	3	1140	1497	578	639
		1	1		
		8	10	4	5
		2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oesophageal pain	2	2
Oral blood blister	1	1
Oral discomfort	9	15
Oral disorder	4	7
Oral dysaesthesia	2	2
Oral mucosa erosion	1	2
Oral mucosal blistering	6	8
Oral mucosal eruption	3	6
Oral mucosal erythema	2	3
Oral pain	8	13
Oral papule	1	1
Oral pruritus	6	9
Palatal disorder	1	1
Palatal oedema	2	2
Palatal swelling	4	5
Pancreatitis	3	4
Pancreatitis acute	1	1
Paraesthesia oral	197	280
Parotid gland enlargement	3	3
Plicated tongue	1	1
Proctitis ulcerative	1	1
Rectal haemorrhage	4	4
Regurgitation	1	1
Retching	23	26
Salivary gland pain	2	2
Salivary hypersecretion	7	10
Small intestinal obstruction	1	2
Stiff tongue	1	2
Stomatitis	17	18
Strawberry tongue		1
Submaxillary gland enlargement	1	1
Swollen tongue	89	115

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
				1	1
		6	10	3	5
		3	6	1	1
		1	1	1	1
		1	2		
		5	7	1	1
		3	6		
		1	2	1	1
		6	9	2	4
				1	1
		5	8	1	1
		1	1		
				2	2
		4	4		1
				3	4
				1	1
		132	198	65	82
		3	3		
				1	1
				1	1
				4	4
				1	1
		15	18	8	8
		1	1	1	1
		4	7	3	3
				1	2
				1	2
		15	16	2	2
			1		
		1	1		
		32	45	57	70

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tongue blistering	1	1
Tongue coated		1
Tongue discolouration	2	3
Tongue discomfort	12	18
Tongue disorder	9	14
Tongue dry	4	6
Tongue eruption	3	3
Tongue erythema	4	4
Tongue haematoma	2	3
Tongue haemorrhage	1	1
Tongue movement disturbance	2	2
Tongue oedema	12	12
Tongue pruritus	12	15
Tongue ulceration	7	7
Toothache	14	21
Upper gastrointestinal haemorrhage	2	2
Uvulitis	1	1
Vomiting	509	633
Vomiting projectile	4	5
	4,381	5,520

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
		2	3		
		10	16	2	2
		5	10	4	4
		1	3	3	3
		1	1	2	2
		4	4		
		2	3		
		1	1		
				2	2
		3	3	9	9
		8	10	4	5
		5	5	2	2
		11	18	3	3
				2	2
		1	1		
1	1	323	429	186	204
		1	2	3	3
4	4	2879	3808	1502	1712

System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Administration site pain	2	2
Administration site reaction	1	1
Adverse drug reaction	2	2
Adverse event	3	3
Adverse reaction	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
				1	1
				2	2
		3	3		
		1	1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Alcohol interaction		1
Asthenia	597	704
Axillary pain	116	139
Chest discomfort	203	267
Chest pain	193	234
Chills	2,085	2,527
Chronic fatigue syndrome		1
Clinical death	1	1
Concomitant disease aggravated	1	1
Condition aggravated	64	80
Crepitations	2	2
Crying	17	20
Cyst	2	2
Death	165	168
Decreased activity	1	1
Discomfort	71	83
Disease progression	2	2
Disease recurrence	36	43
Drug ineffective	1,044	1,231
Drug interaction	11	11
Enanthema		1
Energy increased	3	3
Exercise tolerance decreased	1	1
Extensive swelling of vaccinated limb		1
Face oedema	10	12
Facial discomfort	2	5
Facial pain	39	45
Fatigue	2,394	2,976
Feeling abnormal	294	375
Feeling cold	200	234
Feeling drunk	16	19
Feeling hot	262	357

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
		484	577	113	127
		80	99	36	40
		106	152	97	115
		93	122	100	112
2	2	1549	1955	536	572
			1		
				1	1
				1	1
		38	49	26	31
		1	1	1	1
		14	16	3	4
		2	2		
				165	168
		1	1		
		58	69	13	14
		1	1	1	1
		23	29	13	14
1	1	6	6	1038	1225
		9	9	2	2
			1		
		3	3		
				1	1
			1		
		3	4	7	8
			2	2	3
		26	30	13	15
7	7	1690	2208	704	768
1	1	234	303	60	72
1	1	135	164	65	70
		11	11	5	8
		191	269	71	88

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling jittery	9	14
Feeling of body temperature change	47	62
Foaming at mouth	1	1
Gait disturbance	67	81
Gait inability	21	23
General physical health deterioration	32	33
Glassy eyes	2	3
Hangover	11	12
Hunger	5	7
Hyperpyrexia	6	7
Hyperthermia	4	4
Hypothermia	8	8
Ill-defined disorder	1	1
Illness	135	164
Induration	4	5
Inflammation	27	34
Inflammatory pain	1	1
Influenza like illness	344	398
Inhibitory drug interaction	1	1
Injected limb mobility decreased	8	8
Injection site discomfort	1	1
Injection site erythema	5	5
Injection site extravasation	1	2
Injection site hypoaesthesia		1
Injection site joint movement impairment	1	1
Injection site muscle weakness	1	1
Injection site pain	23	31
Injection site pruritus	1	1
Injection site rash	2	3
Injection site swelling	3	3
Injection site urticaria		1
Injection site warmth	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	11	1	3
		27	41	20	21
		1	1		
		46	58	21	23
		13	14	8	9
		2	3	30	30
		1	2	1	1
		8	9	3	3
		5	7		
				6	7
		3	3	1	1
				8	8
				1	1
		92	117	43	47
		2	3	2	2
		17	23	10	11
		1	1		
		230	277	114	121
		1	1		
		6	6	2	2
		1	1		
		5	5		
		1	2		
			1		
				1	1
		1	1		
		19	26	4	5
		1	1		
		2	3		
		3	3		
			1		
		1	1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injury associated with device		1
Irritability postvaccinal	2	2
Localised oedema	4	5
Local reaction	14	16
Malaise	923	1,140
Mass	7	7
Mucosal disorder	2	2
Mucosal dryness	1	2
Multimorbidity	1	1
Multi-organ disorder	1	1
Multiple organ dysfunction syndrome	5	5
No adverse event	10	10
Nodule	3	5
Oedema	17	18
Oedema peripheral	13	14
Pain	1,453	1,795
Performance status decreased		1
Peripheral swelling	234	283
Pre-existing condition improved	2	3
Pyrexia	2,768	3,275
Screaming	2	2
Secretion discharge	1	2
Sensation of foreign body	24	33
Sense of oppression	1	1
Serositis	1	1
Sluggishness	6	7
Sudden cardiac death	2	2
Sudden death	39	39
Swelling	172	204
Swelling face	119	157
Symptom recurrence	1	1
Systemic inflammatory response syndrome	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		2	2		
		4	5		
		9	11	5	5
1	1	593	776	330	364
		6	6	1	1
		2	2		
		1	1		1
				1	1
				1	1
				5	5
		10	10		
		3	5		
		13	14	4	4
		7	8	6	6
		1160	1474	293	321
			1		
		157	200	77	83
		2	3		
5	5	1933	2366	835	909
		1	1	1	1
			1	1	1
		12	17	12	16
		1	1		
				1	1
		6	7		
				2	2
				39	39
		125	152	47	52
		65	93	54	64
		1	1		
				3	3

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temperature intolerance	1	1
Temperature regulation disorder	4	4
Tenderness	31	39
Therapeutic response unexpected	13	14
Thirst	33	38
Ulcer	1	1
Vaccination site bruising	42	49
Vaccination site coldness	1	3
Vaccination site dermatitis	1	1
Vaccination site discharge	3	3
Vaccination site discolouration	14	15
Vaccination site discomfort	33	46
Vaccination site erythema	364	448
Vaccination site extravasation	4	4
Vaccination site haematoma	6	6
Vaccination site haemorrhage	11	20
Vaccination site hyperaesthesia	5	6
Vaccination site hypersensitivity	3	4
Vaccination site hypoaesthesia	19	26
Vaccination site induration	41	55
Vaccination site inflammation	31	36
Vaccination site injury	1	1
Vaccination site irritation	4	4
Vaccination site joint erythema	1	1
Vaccination site joint movement impairment	16	17
Vaccination site joint pain	9	11
Vaccination site joint swelling	1	1
Vaccination site joint warmth	1	1
Vaccination site lymphadenopathy	12	12
Vaccination site macule	4	5
Vaccination site mass	58	66
Vaccination site movement impairment	47	65

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	2	2	2
		24	32	7	7
		12	13	1	1
		24	28	9	10
		1	1		
1	1	29	35	13	14
		1	3		
		1	1		
		3	3		
		10	11	4	4
		26	39	7	7
		305	379	59	69
		4	4		
		4	4	2	2
		8	17	3	3
		5	6		
		3	4		
		14	21	5	5
		37	51	4	4
		23	26	8	10
		1	1		
		3	3	1	1
		1	1		
		11	11	5	6
		4	5	5	6
		1	1		
		1	1		
		9	9	3	3
		4	5		
		42	49	16	17
		38	54	9	11

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site nodule	14	16
Vaccination site oedema	19	21
Vaccination site pain	2,014	2,528
Vaccination site pallor	1	1
Vaccination site papule	1	1
Vaccination site paraesthesia	23	34
Vaccination site plaque	1	1
Vaccination site pruritus	136	164
Vaccination site rash	47	64
Vaccination site reaction	37	42
Vaccination site scab	3	3
Vaccination site swelling	350	430
Vaccination site ulcer	2	2
Vaccination site urticaria	24	33
Vaccination site vesicles	10	12
Vaccination site warmth	164	197
Vessel puncture site haemorrhage		1
Vessel puncture site injury		1
	18,106	22,066

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		14	16		
		13	15	6	6
4	4	1676	2157	338	371
		1	1		
		1	1		
		17	26	6	8
		1	1		
		119	144	17	20
		34	50	13	14
		29	34	8	8
		3	3		
		278	347	72	83
		1	1	1	1
		21	30	3	3
		7	9	3	3
		125	155	39	42
			1		
			1		
23	23	12366	15684	5740	6382

System Organ Class

**Hepatobiliary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Bile duct stone	1	1
Cholecystitis	1	1
Gallbladder disorder	1	2
Hepatic artery embolism	1	1
Hepatic pain	1	2
Hepatitis	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
	1	1	1
		1	1
	1	1	1
		2	2

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System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Jaundice	4	4	3	3	1	1
Liver injury	2	2			2	2
	13	15	3	5	10	10

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	2	2	1	1	1	1
Allergy to chemicals	1	1	1	1		
Allergy to vaccine	44	70	22	41	22	29
Anaphylactic reaction	162	199	1	1	161	198
Anaphylactic shock	30	34			30	34
Anaphylactoid reaction	7	12			7	12
Autoimmune disorder	1	4			1	4
Contrast media allergy	1	1	1	1		
Drug hypersensitivity	12	14	10	11	2	3
Food allergy		1		1		
Hypersensitivity	161	212	88	117	73	95
Immune-mediated adverse reaction		1		1		
Immune system disorder	1	3			1	3
Immunisation reaction	1	1	1	1		
Immunodeficiency	1	2			1	2
Reaction to excipient	4	4	3	3	1	1
Reaction to preservatives	1	1			1	1
Rubber sensitivity	1	1	1	1		
Seasonal allergy	4	4	4	4		
Sensitisation	1	1	1	1		
Serum sickness		1				1
Type I hypersensitivity	1	1			1	1

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Type IV hypersensitivity reaction	5	6	4	4	1	2
	441	576	138	189	303	387

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abscess	2	2					2	2
Acarodermatitis	1	1			1	1		
African trypanosomiasis	1	1					1	1
Appendicitis	5	7					5	7
Asymptomatic COVID-19	5	9					5	9
Atypical pneumonia	1	1					1	1
Bacteraemia	1	1					1	1
Biliary sepsis	1	1					1	1
Breast abscess	1	1					1	1
Bronchitis	5	7			3	4	2	3
Candida infection	1	1			1	1		
Cellulitis	19	22					19	22
Cholecystitis infective	1	1					1	1
Clostridium difficile colitis	1	1					1	1
Conjunctivitis	7	8			4	5	3	3
Conjunctivitis viral	1	1			1	1		
Coronavirus infection	3	6			2	2	1	4
COVID-19	687	788	1	1	3	4	684	784
COVID-19 pneumonia	12	12					12	12
Cystitis	3	3			1	1	2	2
Ear infection	4	5			2	3	2	2
Erysipelas	1	1					1	1
Escherichia infection	1	1					1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Escherichia sepsis	1	1
Eye infection	1	3
Febrile infection	2	2
Folliculitis	1	2
Fungal infection	3	3
Furuncle	2	2
Gastroenteritis	2	3
Gastroenteritis viral	3	4
Gastrointestinal viral infection	1	1
Genital herpes	2	2
Gingivitis	1	1
Herpes simplex	2	3
Herpes virus infection	8	10
Herpes zoster	64	74
Herpes zoster oticus	1	1
Herpes zoster reactivation	1	1
Hordeolum	3	6
Infection	13	14
Infection parasitic	1	1
Infective exacerbation of chronic obstructive airways disease	1	1
Influenza	68	83
Kidney infection	1	1
Labyrinthitis	3	5
Laryngitis	1	2
Localised infection	4	4
Lower respiratory tract infection	13	13
Lymphangitis	1	1
Lymph gland infection	1	1
Mastitis	3	4
Meningitis		1
Meningitis viral	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2	1	1
				2	2
			1	1	1
		3	3		
		2	2		
		1	2	1	1
		2	2	1	2
		1	1		
		1	1	1	1
		1	1		
		2	3		
		8	9		1
		50	60	14	14
				1	1
				1	1
		2	5	1	1
		3	4	10	10
		1	1		
				1	1
		38	52	30	31
				1	1
		1	1	2	4
		1	2		
		2	2	2	2
				13	13
				1	1
		1	1		
				3	4
					1
				1	1

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myelitis	1	1
Nasopharyngitis	94	116
Oral candidiasis	3	4
Oral herpes	21	29
Oral viral infection		1
Orchitis		1
Otitis externa	1	1
Otitis media	2	2
Parotitis	4	4
Pathogen resistance	1	1
Pertussis		1
Pharyngitis	4	5
Pharyngitis streptococcal	2	3
Pneumonia	29	32
Pneumonia bacterial	1	1
Post viral fatigue syndrome	3	3
Pulmonary sepsis	1	1
Pulpitis dental		1
Pustule	3	4
Pyelonephritis	1	1
Q fever	2	2
Rash pustular	2	3
Respiratory tract infection	4	4
Rhinitis	10	13
Rhinovirus infection	1	1
Sepsis	14	14
Septic shock	2	2
Severe acute respiratory syndrome	2	2
Sinusitis	13	21
Sputum purulent		1
Staphylococcal infection	1	1
Staphylococcal sepsis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		73	94	21	22
		2	3	1	1
		18	24	3	5
			1		
			1		
		1	1		
		2	2		
		2	2	2	2
				1	1
					1
		3	4	1	1
			1	2	2
		1	1	28	31
				1	1
		1	1	2	2
				1	1
			1		
		2	2	1	2
				1	1
				2	2
		1	2	1	1
				4	4
		8	11	2	2
		1	1		
				14	14
				2	2
				2	2
		11	19	2	2
					1
				1	1
				1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Staphylococcal skin infection		1
Streptococcal infection		1
Suspected COVID-19	115	127
Sweating fever	10	11
Tonsillitis	6	7
Tonsillitis bacterial	1	1
Tooth infection	1	1
Tuberculosis	2	2
Upper respiratory tract infection	3	3
Urinary tract infection	15	17
Urinary tract infection bacterial	1	1
Urosepsis	3	3
Vaccination site abscess	1	1
Vaccination site cellulitis	9	12
Vaccination site infection	8	9
Vaginal infection	1	2
Varicella	1	2
Varicella zoster virus infection		1
Vestibular neuronitis	1	2
Viral infection	2	2
Viral labyrinthitis	1	1
Viral pharyngitis	1	1
Viral rash	3	4
Viral tonsillitis	1	1
Viral upper respiratory tract infection	1	1
Vulvovaginal candidiasis	2	2
Vulvovaginal mycotic infection	1	1
	1,386	1,626

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
					1
		5	7	110	120
				10	11
		2	2	4	5
				1	1
		1	1		
				2	2
		2	2	1	1
		8	10	7	7
				1	1
				3	3
				1	1
		3	4	6	8
		5	6	3	3
		1	2		
		1	2		
			1		
				1	2
		2	2		
		1	1		
				1	1
		1	2	2	2
				1	1
		1	1	1	1
		1	1		
1	1	298	392	1088	1234

System Organ Class

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Accidental exposure to product	10	15
Accidental overdose	15	40
Accidental underdose	1	2
Animal bite	1	1
Arthropod bite	4	4
Bite	1	1
Booster dose missed	2	2
Burn oral cavity	1	1
Buttock injury	1	1
Chillblains	2	2
Circumstance or information capable of leading to device use error	1	1
Circumstance or information capable of leading to medication error	75	87
Contraindicated product administered	3	3
Contusion	30	37
Dental restoration failure	2	2
Drug administered in wrong device	1	1
Epicondylitis	2	2
Expired product administered	2	3
Exposure during pregnancy	23	27
Exposure to SARS-CoV-2	37	44
Exposure via breast milk	70	103
Exposure via eye contact	1	2
Exposure via skin contact	11	14
Eye contusion	6	6
Eye injury	1	1
Face crushing	1	1
Face injury	3	4
Fall	51	57
Femoral neck fracture	1	1
Foreign body aspiration		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	14	1	1
		14	37	1	3
		1	2		
		1	1		
		4	4		
				1	1
		2	2		
				1	1
		1	1		
		1	1	1	1
		1	1		
		75	87		
		2	2	1	1
		19	25	11	12
		2	2		
		1	1		
		2	2		
		2	3		
		22	26	1	1
1	1	25	32	12	12
		70	103		
		1	2		
		10	13	1	1
		5	5	1	1
				1	1
		3	3		1
		18	22	33	35
				1	1
					1

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fracture	1	2
Frostbite	1	1
Gastrointestinal stoma complication	1	1
Head injury	16	17
Heat illness	1	1
Heat oedema	1	1
Heat stroke	1	1
Hip fracture	1	1
Inappropriate schedule of product administration	297	304
Incision site haemorrhage	1	1
Incision site pain		1
Incomplete course of vaccination	11	11
Incorrect dose administered	18	21
Incorrect route of product administration	85	116
Injection related reaction	2	2
Injury	2	2
Injury corneal	1	1
Intentional product misuse	1	1
Intercepted medication error	1	1
Intercepted product preparation error	1	1
Joint dislocation	1	2
Ligament injury	2	2
Ligament sprain	2	2
Limb injury	5	6
Lip injury	2	2
Lower limb fracture	1	1
Maternal exposure during breast feeding	1	1
Maternal exposure during pregnancy	87	111
Maternal exposure timing unspecified	5	5
Medication error	3	3
Muscle strain	3	5
Nasal injury	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	1		
				1	1
		8	9	8	8
				1	1
		1	1		
		1	1		
				1	1
		297	303		1
				1	1
					1
		11	11		
		17	20	1	1
		82	113	3	3
		1	1	1	1
		2	2		
				1	1
		1	1		
		1	1		
				1	2
		2	2		
		1	1	1	1
		4	5	1	1
		1	1	1	1
				1	1
		1	1		
		84	108	3	3
		5	5		
		3	3		
		1	3	2	2
		2	2		

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neck injury		1
Nerve injury		1
Occupational exposure to product	4	5
Occupational exposure to SARS-CoV-2	6	7
Off label use	288	355
Overdose	62	83
Pelvic fracture	1	1
Peroneal nerve injury	1	1
Poisoning	1	1
Poor quality product administered	145	279
Post lumbar puncture syndrome	1	1
Postoperative ileus	1	1
Post procedural haemorrhage	1	1
Procedural nausea	1	1
Procedural pain	2	3
Product administered at inappropriate site	32	44
Product administered to patient of inappropriate age	13	16
Product administration error	13	13
Product confusion	1	1
Product dose omission issue	2	2
Product label confusion	3	5
Product preparation error	81	112
Product preparation issue	85	102
Product prescribing error	2	5
Product use issue	264	339
Rib fracture	1	1
Scar	2	2
Scratch	4	5
Skin abrasion	1	1
Skin injury	1	2
Skin laceration	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
			1		
		4	5		
		5	6	1	1
		283	350	5	5
		62	83		
				1	1
				1	1
				1	1
		145	279		
				1	1
				1	1
				1	1
		1	2	1	1
		29	41	3	3
		12	15	1	1
		13	13		
		1	1		
		2	2		
		3	5		
		81	111		1
		85	101		1
		2	5		
		258	333	6	6
				1	1
		2	2		
		2	3	2	2
				1	1
		1	2		
		2	3	1	1

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage		1
Sunburn	2	2
Superficial injury of eye	1	1
Suture related complication	1	1
Synovial rupture	1	1
Tendon injury	1	1
Tongue injury	1	1
Underdose	113	156
Upper limb fracture	1	1
Vaccination complication	9	10
Wound	2	2
Wound haemorrhage	1	1
Wrong product administered	6	7
Wrong technique in product usage process	47	72
	2,124	2,749

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
			1		
					1
		2	2		
				1	1
				1	1
		1	1		
		1	1		
		1	1		
		113	156		
				1	1
		6	7	3	3
		2	2		
				1	1
		6	7		
		46	71	1	1
1	1	1989	2599	135	150

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Alanine aminotransferase increased	5	5
Antibody test positive	1	1
Anticoagulation drug level increased	1	1
Aspartate aminotransferase increased	2	2
Auscultation	1	1
Bilirubin urine present	1	1
Blood alkaline phosphatase increased	2	2
Blood chloride increased	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	4	4
		1	1		
				1	1
		1	1	1	1
		1	1		
		1	1		
		1	1	1	1
		1	1	1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood count abnormal		1
Blood creatine phosphokinase increased	2	2
Blood creatinine increased	1	1
Blood electrolytes increased	1	1
Blood glucose abnormal	2	2
Blood glucose decreased	6	7
Blood glucose fluctuation	2	2
Blood glucose increased	24	26
Blood iron decreased	1	1
Blood ketone body present	1	1
Blood lactic acid increased	4	4
Blood pH increased	1	1
Blood potassium abnormal	1	1
Blood potassium decreased	3	3
Blood pressure abnormal	4	6
Blood pressure decreased	27	35
Blood pressure diastolic decreased	4	4
Blood pressure diastolic increased	3	5
Blood pressure increased	124	177
Blood pressure orthostatic abnormal	1	1
Blood pressure orthostatic decreased		1
Blood pressure systolic decreased	1	1
Blood pressure systolic increased	10	12
Blood sodium decreased	2	2
Blood test abnormal	1	2
Blood testosterone decreased	1	1
Blood thyroid stimulating hormone increased	2	2
Blood urea increased	1	1
Blood uric acid increased	1	1
Blood urine present	7	8
Body height decreased	5	6
Body temperature	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1	1	1
		1	1		
		1	1		
		2	2		
		2	3	4	4
		2	2		
		13	15	11	11
		1	1		
				1	1
		1	1	3	3
		1	1		
				1	1
		2	2	1	1
		2	4	2	2
		13	18	14	17
		4	4		
		3	4		1
		69	103	55	74
				1	1
					1
				1	1
		4	5	6	7
		2	2		
				1	2
		1	1		
		2	2		
		1	1		
		1	1		
		6	7	1	1
		5	6		
				3	3

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature abnormal	21	24
Body temperature decreased	12	13
Body temperature fluctuation	5	7
Body temperature increased	119	143
Capillary nail refill test abnormal		1
Coagulation time prolonged	1	1
Coma scale abnormal	3	4
Coronavirus test positive	3	3
Cortisol decreased	1	1
C-reactive protein increased	13	13
Crystal urine	1	1
Culture negative	1	1
Ejection fraction abnormal		1
Electrocardiogram abnormal	3	3
Electrocardiogram QT prolonged		1
Electrocardiogram ST segment abnormal	1	1
Electrocardiogram ST segment elevation	1	1
Eosinophil count increased	2	2
Epinephrine increased		1
Fibrin D dimer increased	3	4
Gamma-glutamyltransferase increased	1	1
Gastric pH decreased	1	1
General physical condition abnormal	1	1
Glomerular filtration rate decreased	1	1
Glycosylated haemoglobin increased	1	1
Grip strength decreased	4	5
Haematocrit decreased	1	1
Haemoglobin decreased	4	4
Haemoglobin increased	1	1
Heart rate abnormal	5	6
Heart rate decreased	9	14
Heart rate increased	236	340

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	12	12	12
		10	10	2	3
		2	4	3	3
1	1	84	105	35	38
			1		
				1	1
				3	4
		1	1	2	2
				1	1
		8	8	5	5
		1	1		
				1	1
			1		
		3	3		
					1
				1	1
				1	1
			1		
		1	2	2	2
				1	1
		1	1		
				1	1
				1	1
		1	1		
		4	5		
		1	1		
		2	2	2	2
		1	1		
		3	4	2	2
		4	7	5	7
		155	239	81	101

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heart rate irregular	10	13
Hepatic enzyme increased	3	3
Inflammatory marker increased	2	3
Influenza B virus test positive	1	1
Inspiratory capacity abnormal	1	1
International normalised ratio abnormal	1	1
International normalised ratio decreased	1	1
International normalised ratio increased	8	8
Intraocular pressure increased	3	3
Lipids increased		1
Liver function test abnormal	2	2
Liver function test increased	2	2
Lymph node palpable	2	2
Lymphocyte count increased	1	1
Mean cell haemoglobin concentration decreased	1	1
Mean cell haemoglobin decreased	3	3
Mean cell volume decreased	1	1
Mean platelet volume increased	1	1
Monocyte count increased	2	2
Myocardial necrosis marker increased	1	2
Neutrophil count increased	2	2
Orthostatic heart rate response increased	1	1
Oxygen consumption	1	1
Oxygen saturation decreased	45	51
Platelet count decreased	2	3
Platelet count increased	5	5
PO2 decreased	2	2
Protein urine present	1	1
Pulse abnormal	10	12
Red blood cell count decreased	1	1
Red blood cell count increased	1	1
Red blood cell sedimentation rate increased	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		7	9	3	4
		2	2	1	1
		1	1	1	2
		1	1		
		1	1		
				1	1
		1	1		
		2	2	6	6
		1	1	2	2
			1		
				2	2
		1	1	1	1
		2	2		
		1	1		
		1	1		
		2	2	1	1
		1	1		
		1	1		
		2	2		
				1	2
				2	2
		1	1		
		1	1		
		12	14	33	37
			1	2	2
		3	3	2	2
		1	1	1	1
		1	1		
		5	7	5	5
		1	1		
		1	1		
		3	3	1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Red blood cells urine positive	1	1			1	1		
Respiratory rate decreased	2	3			1	1	1	2
Respiratory rate increased	14	18			1	4	13	14
SARS-CoV-1 test positive	1	1					1	1
SARS-CoV-2 ant body test negative	12	12			12	12		
SARS-CoV-2 ant body test positive	10	14			7	10	3	4
SARS-CoV-2 test false positive	5	5			5	5		
SARS-CoV-2 test negative	1	1			1	1		
SARS-CoV-2 test positive	251	324			10	11	241	313
Streptococcus test positive		1				1		
Thyroid function test abnormal	1	1			1	1		
Transaminases increased	1	1			1	1		
Tri-iodothyronine decreased	1	1					1	1
Troponin increased	3	3					3	3
Troponin T increased	1	1					1	1
Tryptase increased	1	1			1	1		
Urine analysis abnormal	1	1					1	1
Urine output decreased	1	1					1	1
Urine output increased	1	1			1	1		
Vital functions abnormal	1	1					1	1
Weight decreased	18	21			13	16	5	5
Weight increased	2	4			2	4		
White blood cell count decreased	1	1					1	1
White blood cell count increased	4	5			1	1	3	4
	1,171	1,497	1	1	552	741	619	756

System Organ Class

Metabolism and nutrition disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C

Spontaneous			
Nonserious		Serious	
I	C	I	C

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis	2	2	1	1	1	1
Appetite disorder	1	1			1	1
Decreased appetite	192	224	108	131	84	93
Dehydration	33	41	20	27	13	14
Diabetes mellitus	4	6			4	6
Diabetes mellitus inadequate control	1	2			1	2
Diabetic complication	1	1			1	1
Diabetic ketoacidosis	2	3			2	3
Diet refusal	3	3			3	3
Feeding disorder	13	15	11	13	2	2
Fluid imbalance	1	1			1	1
Fluid intake reduced	4	4	2	2	2	2
Fluid retention		2		2		
Food aversion	1	1	1	1		
Food craving	1	1	1	1		
Food refusal	2	2			2	2
Gout	7	7	5	5	2	2
Hypercalcaemia	1	1			1	1
Hyperglycaemia	11	13	2	3	9	10
Hypocalcaemia	2	2			2	2
Hypoglycaemia	12	15	6	8	6	7
Hypokalaemia	3	3			3	3
Hypomagnesaemia	1	1			1	1
Hyponatraemia	2	2			2	2
Hypophagia	6	6	3	3	3	3
Increased appetite	2	2	2	2		
Insulin resistance	1	1	1	1		
Malnutrition	1	2		1	1	1
Metabolic acidosis	1	1			1	1
Oligodipsia	1	1			1	1
Overweight	1	1	1	1		
Polydipsia	3	3	3	3		

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Poor feeding infant		1		1		
Tetany	1	2			1	2
	317	373	167	206	150	167

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ankylosing spondylitis	1	1					1	1
Arthralgia	1,172	1,381	1	1	794	975	378	406
Arthritis	26	29			17	20	9	9
Arthritis reactive	2	3					2	3
Arthropathy	5	7			4	6	1	1
Axillary mass	13	19			10	15	3	4
Back pain	270	320			193	239	77	81
Bone disorder	1	1			1	1		
Bone pain	65	78			49	61	16	17
Bone swelling	3	6			2	5	1	1
Costochondritis	3	3					3	3
Extremity contracture	2	2			2	2		
Facet joint syndrome	1	1			1	1		
Facial asymmetry	1	2			1	2		
Fibromyalgia	5	5			1	1	4	4
Flank pain	5	6			4	5	1	1
Groin pain	11	11			8	8	3	3
Haematoma muscle	1	1					1	1
Immune-mediated arthritis		1						1
Inguinal mass	1	1					1	1
Intervertebral disc protrusion	1	1			1	1		
Jaw clicking	2	2					2	2

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Jaw disorder	1	1
Joint ankylosis	1	1
Joint contracture	1	1
Joint effusion	4	4
Joint instability	1	2
Joint lock	1	1
Joint noise	2	2
Joint range of motion decreased	32	43
Joint stiffness	23	27
Joint swelling	38	51
Joint warmth		1
Limb discomfort	126	171
Limb mass	3	3
Mastication disorder	2	2
Masticatory pain	1	1
Mixed connective tissue disease	1	1
Mobility decreased	49	62
Muscle atrophy	1	1
Muscle contracture	2	2
Muscle discomfort	5	6
Muscle disorder	2	2
Muscle fatigue	16	23
Muscle rigidity	5	5
Muscle spasms	98	117
Muscle swelling	7	7
Muscle tightness	30	40
Muscle twitching	28	31
Muscular weakness	118	141
Musculoskeletal chest pain	21	29
Musculoskeletal discomfort	24	28
Musculoskeletal disorder	9	10
Musculoskeletal pain	28	31

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		1	1		
		1	1	3	3
				1	2
				1	1
		1	1	1	1
		19	29	13	14
		13	15	10	12
		20	32	18	19
			1		
		87	122	39	49
		2	2	1	1
				2	2
		1	1		
				1	1
		31	41	18	21
		1	1		
		2	2		
		5	6		
		2	2		
		7	11	9	12
				5	5
		73	89	25	28
		5	5	2	2
		29	37	1	3
		22	25	6	6
		68	87	50	54
		14	22	7	7
		21	25	3	3
		4	5	5	5
		20	22	8	9

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal stiffness	138	160
Myalgia	1,625	1,946
Myofascial pain syndrome		1
Myopathy	1	1
Myositis	2	2
Neck mass	8	8
Neck pain	267	320
Nuchal rigidity	3	4
Osteoarthritis	1	1
Osteochondritis	1	1
Pain in extremity	1,468	1,813
Pain in jaw	43	54
Periarthritis	5	5
Polymyalgia rheumatica	2	2
Posture abnormal	1	1
Psoriatic arthropathy	2	2
Rhabdomyolysis	3	3
Rheumatoid arthritis	5	6
Sacroiliitis	2	2
Sinus tarsi syndrome	1	1
Sjogren's syndrome		1
Soft tissue swelling		1
Spinal disorder	1	1
Spinal pain	18	21
Symphysiolysis	1	1
Synovial cyst	1	1
Synovitis	1	1
Systemic lupus erythematosus	2	2
Systemic scleroderma		1
Temporomandibular joint syndrome	2	2
Tendonitis	3	4
Tendon pain	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		92	108	46	52
4	4	1098	1376	527	570
			1		
		1	1		
				2	2
		6	6	2	2
		195	240	72	80
		2	3	1	1
		1	1		
		1	1		
3	3	1134	1445	334	368
		31	42	12	12
		2	2	3	3
				2	2
				1	1
				2	2
				3	3
				5	6
				2	2
		1	1		
					1
			1		
		1	1		
		15	18	3	3
				1	1
		1	1		
				1	1
				2	2
					1
		2	2		
		1	2	2	2
		2	2		

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tenosynovitis	1	2			1	2		
Torticollis	2	2			1	1	1	1
Trismus	4	4			3	3	1	1
Undifferentiated connective tissue disease		1						1
Weight bearing difficulty	1	1					1	1
	5,888	7,109	8	8	4129	5188	1759	1921

System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear neoplasm	1	1	1	1		
Leukaemia	1	1			1	1
Lung neoplasm malignant	1	1			1	1
Neoplasm skin	1	1	1	1		
Skin cancer	1	1			1	1
	5	5	2	2	3	3

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Acoustic neuritis		1						1
Acute disseminated encephalomyelitis	1	1					1	1
Ageusia	79	108			56	81	23	27
Akathisia	1	1			1	1		
Allodynia	3	3			2	2	1	1
Altered state of consciousness	1	1					1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Amnesia	8	9
Anaesthesia	2	4
Anosmia	70	97
Anticholinergic syndrome	1	1
Aphasia	9	12
Ataxia		1
Aura	7	8
Autonomic nervous system imbalance	1	1
Axonal neuropathy	1	1
Balance disorder	44	58
Band sensation	1	1
Basal ganglia haemorrhage	1	2
Brachial plexopathy	1	1
Bradykinesia		1
Brain injury	2	2
Brain oedema	2	2
Burning sensation	83	102
Burning sensation mucosal	1	1
Cataplexy		1
Central nervous system lesion	1	1
Cerebellar haemorrhage	2	2
Cerebellar infarction	1	2
Cerebellar stroke	1	1
Cerebral disorder		1
Cerebral haemorrhage	7	7
Cerebral infarction	2	3
Cerebral ischaemia	1	1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	41	46
Clumsiness	1	1
Cluster headache	8	8
Cognitive disorder	7	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	6	3	3
		1	3	1	1
		55	78	15	19
				1	1
		2	5	7	7
					1
		4	5	3	3
				1	1
				1	1
1	1	26	34	18	24
		1	1		
				1	2
				1	1
			1		
				2	2
				2	2
		53	67	30	35
		1	1		
					1
		1	1		
				2	2
				1	2
				1	1
			1		
				7	7
				2	3
				1	1
				1	1
				41	46
				1	1
		2	2	6	6
		2	4	5	6

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coma	3	3
Consciousness fluctuating	1	1
Coordination abnormal	4	4
Cranial nerve disorder	2	2
Dementia	3	3
Dementia of the Alzheimer's type, with delirium	1	1
Demyelinating polyneuropathy	1	1
Demyelination	2	2
Depressed level of consciousness	17	18
Disturbance in attention	41	53
Dizziness	1,106	1,460
Dizziness exertional	3	3
Dizziness postural	45	54
Droling	2	2
Dysaesthesia	4	5
Dysarthria	16	20
Dysgeusia	166	226
Dyskinesia	7	9
Dyslexia		1
Dysstasia	20	21
Dystonia	2	2
Encephalitis post immunisation		1
Encephalopathy	1	1
Epilepsy	8	10
Exertional headache	1	1
Facial nerve disorder	2	2
Facial neuralgia	1	1
Facial paralysis	105	128
Facial paresis	13	15
Facial spasm	3	4
Febrile convulsion	1	1
Fine motor skill dysfunction	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
				1	1
		2	2	2	2
		1	1	1	1
				3	3
				1	1
				1	1
				2	2
		1	1	16	17
		27	35	14	18
1	1	762	1047	344	413
		3	3		
		15	21	30	33
		1	1	1	1
		3	4	1	1
		4	8	12	12
		138	192	28	34
		3	4	4	5
			1		
		12	12	8	9
				2	2
					1
				1	1
				8	10
		1	1		
		2	2		
		1	1		
		2	3	103	125
		3	5	10	10
		2	3	1	1
				1	1
		3	4		

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Formication	10	11
Freezing phenomenon		1
Generalised tonic-clonic seizure	5	7
Guillain-Barre syndrome	3	4
Haemorrhage intracranial	4	4
Haemorrhagic stroke	4	4
Hand-eye coordination impaired	2	2
Headache	3,505	4,261
Head discomfort	40	50
Head titubation	1	1
Hemiparaesthesia	1	1
Hemiparesis	13	16
Hemiplegia	1	1
Horner's syndrome	1	1
Hyperaesthesia	26	31
Hypersomnia	35	46
Hypertonia	2	3
Hypoaesthesia	332	440
Hypogeusia	3	5
Hypokinesia	8	9
Hyporeflexia	2	2
Hyporesponsive to stimuli	1	1
Hyposmia	5	8
Hypotonia	5	5
Idiopathic intracranial hypertension	1	1
Incoherent	2	2
Infant irritability	1	3
Intercostal neuralgia	1	1
Irregular sleep wake rhythm disorder		1
Ischaemic stroke	9	11
IVth nerve paralysis	1	1
Lacunar infarction	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	8	2	3
			1		
				5	7
				3	4
				4	4
				4	4
				2	2
7	7	2494	3153	1011	1108
		30	39	10	11
		1	1		
				1	1
				13	16
				1	1
				1	1
		19	24	7	7
		24	35	11	11
			1	2	2
		240	333	92	107
		3	5		
		6	7	2	2
				2	2
				1	1
		3	6	2	2
		3	3	2	2
				1	1
				2	2
		1	3		
		1	1		
			1		
				9	11
				1	1
				2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lacunar stroke	1	1
Language disorder	1	1
Lethargy	195	227
Locked-in syndrome	1	1
Loss of consciousness	75	86
Loss of proprioception	1	1
Medication overuse headache	1	1
Memory impairment	15	19
Meningism	1	1
Mental impairment	12	18
Migraine	222	249
Migraine with aura	7	8
Mononeuropathy	3	3
Monoparesis	3	3
Monoplegia	4	4
Motor dysfunction	4	4
Movement disorder	35	38
Multiple sclerosis	3	3
Multiple sclerosis relapse	5	5
Muscle contractions involuntary	9	9
Muscle spasticity	1	1
Muscle tone disorder	1	1
Myelitis transverse	1	2
Myoclonus	2	2
Narcolepsy	1	1
Nerve compression	6	6
Nerve degeneration	1	1
Nervous system disorder	2	2
Neuralgia	32	36
Neuralgic amyotrophy	3	3
Neuritis	5	5
Neurological symptom	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		100	123	95	104
				1	1
		1	1	74	85
				1	1
		8	11	7	8
		1	1		
				12	18
		133	156	89	93
		3	4	4	4
				3	3
		2	2	1	1
				4	4
		1	1	3	3
		27	30	8	8
				3	3
				5	5
		6	6	3	3
				1	1
				1	1
				1	2
		1	1	1	1
				1	1
		6	6		
				1	1
				2	2
		26	29	6	7
		2	2	1	1
		3	3	2	2
				1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neuropathy peripheral	13	14
Noninfective encephalitis	1	1
Nystagmus	4	4
Occipital neuralgia	1	1
Optic neuritis	2	2
Orthostatic intolerance	1	1
Paraesthesia	445	590
Paraesthesia mucosal		1
Paralysis	13	15
Paraparesis	1	1
Paraplegia	1	1
Paresis	3	4
Paresis cranial nerve	1	1
Parosmia	17	24
Partial seizures	1	1
Patient elopement	1	1
Peripheral motor neuropathy	1	1
Peripheral sensory neuropathy	1	1
Peroneal nerve palsy	2	3
Petit mal epilepsy	3	3
Polyneuropathy	2	2
Poor quality sleep	29	38
Posterior revers ble encephalopathy syndrome	1	1
Postictal state		1
Presyncope	106	131
Primary cough headache	2	2
Primary headache associated with sexual activity	1	1
Psychomotor hyperactivity	3	3
Radiculopathy	3	3
Reduced facial expression	1	2
Restless legs syndrome	6	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				13	14
				1	1
		2	2	2	2
		1	1		
				2	2
				1	1
		319	442	126	148
			1		
				13	15
				1	1
				1	1
		2	3	1	1
		1	1		
		14	20	3	4
				1	1
				1	1
				1	1
			1	2	2
				3	3
				2	2
		21	30	8	8
				1	1
			1		
		65	81	41	50
				2	2
				1	1
		2	2	1	1
				3	3
			1	1	1
		3	3	3	3

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Retinal migraine	1	1
Sciatica	5	5
Sciatic nerve neuropathy	1	1
Sedation	2	3
Seizure	38	43
Sensory disturbance	18	22
Sensory loss	13	15
Serotonin syndrome	2	2
Sinus headache	14	18
Sleep deficit	1	1
Sleep paralysis	1	1
Slow response to stimuli	2	3
Somnolence	178	214
Speech disorder	23	29
Status epilepticus	1	1
Stiff leg syndrome	1	1
Stupor	2	2
Subarachnoid haemorrhage	2	2
Syncope	139	167
Taste disorder	31	44
Tension headache	30	32
Thunderclap headache	1	1
Tonic clonic movements	1	1
Transient global amnesia	1	1
Transient ischaemic attack	9	11
Tremor	233	284
Trigeminal nerve disorder		1
Trigeminal neuralgia	3	3
Trigeminal neuritis	1	1
Tunnel vision	3	5
Unresponsive to stimuli	19	21
Vestibular migraine	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	2	3	3
				1	1
		2	3		
		1	1	37	42
		16	19	2	3
		9	11	4	4
				2	2
		4	8	10	10
				1	1
		1	1		
		1	2	1	1
		124	156	54	58
		15	21	8	8
				1	1
				1	1
		2	2		
				2	2
				139	167
		25	38	6	6
		11	13	19	19
				1	1
				1	1
		1	1		
				9	11
		135	170	98	114
			1		
		1	1	2	2
		1	1		
				3	5
				19	21
				1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual field defect	4	4			3	3	1	1
Writer's cramp	1	1					1	1
	8,104	10,044	9	9	5135	6684	2969	3360

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	8	8			8	8
Morning sickness	1	1			1	1
Premature rupture of membranes	1	1			1	1
Uterine contractions during pregnancy	1	1	1	1		
	11	11	1	1	10	10

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device breakage	1	1			1	1
Liquid product physical issue	8	24	8	24		
Needle issue	5	8	5	8		
Product colour issue	36	36	36	36		
Product complaint		2		2		
Product deposit		1		1		
Product formulation issue		1				1
Product leakage	6	10	6	10		
Product packaging quantity issue	1	20	1	20		
Product quality issue	1	2	1	2		

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\* AE=Adverse Event  
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System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product temperature excursion issue	25	115	25	115		
Suspected counterfeit product		1		1		
Syringe issue	1	2	1	2		
	84	223	83	221	1	2

System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	2	2	1	1	1	1
Abnormal dreams	17	22	13	18	4	4
Affect lability	1	1	1	1		
Aggression	3	3	2	2	1	1
Agitation	20	25	11	16	9	9
Anger	6	6	5	5	1	1
Anxiety	95	128	65	92	30	36
Apathy	5	5			5	5
Bradyphrenia	1	1			1	1
Bruxism	1	1	1	1		
Communication disorder	1	2		1	1	1
Confusional state	77	86	35	40	42	46
Decreased interest	2	2	1	1	1	1
Delirium	19	20			19	20
Delusion	1	1			1	1
Delusional perception	2	2	1	1	1	1
Depersonalisation/derealisation disorder	3	3	2	2	1	1
Depressed mood	12	15	8	11	4	4
Depression	10	11	5	5	5	6
Derealisation	3	3	2	2	1	1
Disorganised speech	1	1	1	1		

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Disorientation	19	25
Dissociation	3	4
Distractibility	1	1
Dysphemia		1
Dysphoria	1	1
Eating disorder	7	11
Emotional disorder	3	5
Emotional distress	3	3
Enuresis	3	3
Euphoric mood	4	4
Fear	11	16
Fear of death	1	1
Fear of injection	1	1
Frustration tolerance decreased	2	3
Hallucination	21	22
Hallucination, auditory	2	2
Hallucination, olfactory		1
Hallucination, tactile	1	1
Hallucination, visual	8	8
Helplessness	1	1
Hydrophobia	1	1
Hypervigilance	1	1
Illness anxiety disorder	1	1
Immunisation anxiety related reaction	2	2
Impulsive behaviour	1	1
Indifference	1	1
Initial insomnia	5	7
Insomnia	177	204
Intentional self-injury	1	1
Intrusive thoughts	1	1
Irritability	13	14
Laziness	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
8	13	11	12
2	3	1	1
1	1		
	1		
		1	1
5	8	2	3
3	5		
2	2	1	1
1	1	2	2
3	3	1	1
9	12	2	4
1	1		
1	1		
2	3		
		21	22
		2	2
			1
		1	1
		8	8
		1	1
1	1		
1	1		
1	1		
2	2		
1	1		
		1	1
4	6	1	1
131	156	46	48
		1	1
1	1		
9	10	4	4
1	2		

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mania	1	1
Mental disorder	3	5
Mental fatigue	8	8
Middle insomnia	22	24
Mood altered	3	3
Mutism	1	1
Negative thoughts	1	1
Nervousness	26	42
Nightmare	12	15
Obsessive-compulsive symptom	1	1
Panic attack	8	13
Panic disorder	1	1
Panic reaction	4	5
Paranoia	2	3
Personality change	2	2
Phonophobia	1	1
Post-traumatic stress disorder	1	2
Pressure of speech	1	1
Psychiatric symptom	1	1
Psychological factor affecting medical condition	1	1
Psychotic behaviour	1	1
Restlessness	32	41
Sitophobia	1	1
Sleep attacks	2	2
Sleep disorder	51	59
Sleep disorder due to a general medical condition	6	7
Sleep disorder due to general medical condition, insomnia type	4	6
Sleep talking	2	2
Sleep terror	1	1
Somatic symptom disorder	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
2	4	1	1
4	4	4	4
19	20	3	4
2	2	1	1
		1	1
		1	1
22	35	4	7
9	12	3	3
		1	1
4	8	4	5
		1	1
4	4		1
1	2	1	1
1	1	1	1
1	1		
1	2		
		1	1
1	1		
		1	1
24	29	8	12
1	1		
		2	2
36	43	15	16
3	4	3	3
3	5	1	1
1	1	1	1
		1	1
1	1		

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Staring	1	2			1	2
Stress	10	12	10	12		
Substance abuse	1	1			1	1
Tachyphrenia	4	4	4	4		
Tearfulness	2	2	1	1	1	1
Tension	2	2	1	1	1	1
Terminal insomnia	2	3	2	3		
Thinking abnormal	6	8	4	6	2	2
Tic	1	1	1	1		
Vomiting psychogenic	1	1			1	1
	810	979	507	643	303	336

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	13	13			13	13
Bladder discomfort	3	3	3	3		
Bladder pain	2	2	1	1	1	1
Chromaturia	8	9	5	6	3	3
Chronic kidney disease	1	1			1	1
Costovertebral angle tenderness	2	2	2	2		
Dysuria	6	7	5	6	1	1
Haematuria	1	3	1	2		1
Haemorrhage urinary tract	1	1			1	1
Hypertonic bladder		1		1		
Incontinence	3	4	1	1	2	3
Micturition disorder	1	1			1	1
Micturition urgency	1	2	1	2		
Nephrolithiasis	1	1			1	1

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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nephrotic syndrome	1	1			1	1
Nocturia	2	2	2	2		
Pollakiuria	12	13	11	12	1	1
Polyuria	5	5	5	5		
Renal disorder	3	3	2	2	1	1
Renal failure	6	6			6	6
Renal impairment	1	1			1	1
Renal pain	19	20	14	15	5	5
Urethral pain	1	1	1	1		
Urge incontinence		1		1		
Urinary incontinence	7	8	2	3	5	5
Urinary retention	7	7			7	7
Urinary tract disorder	1	1			1	1
	108	119	56	65	52	54

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain	1	1	1	1		
Breast discomfort	4	4	3	3	1	1
Breast mass	2	2	1	1	1	1
Breast milk discolouration	1	1	1	1		
Breast pain	23	24	15	16	8	8
Breast swelling	6	7	5	6	1	1
Breast tenderness	2	3	2	2		1
Cervix oedema	1	1	1	1		
Dysmenorrhoea	5	7	4	6	1	1
Erectile dysfunction	2	2			2	2
Genital blister	1	1	1	1		

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System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infertility	1	1			1	1
Menopausal symptoms	2	2	2	2		
Menorrhagia	4	6	1	3	3	3
Menstrual disorder	8	9	8	9		
Menstruation irregular	9	10	8	9	1	1
Metrorrhagia	4	6	4	6		
Nipple pain	4	6	3	5	1	1
Nipple swelling	1	4	1	4		
Pelvic pain	5	5	5	5		
Penile haemorrhage	1	1			1	1
Penile swelling	1	1			1	1
Polymenorrhoea	2	2	1	1	1	1
Prostatomegaly	1	1	1	1		
Pruritus genital	1	1			1	1
Scrotal erythema		1				1
Scrotal exfoliation		1				1
Scrotal pain	1	2	1	1		1
Scrotal swelling		1				1
Suppressed lactation	4	4	3	3	1	1
Uterine haemorrhage	1	1			1	1
Vaginal discharge	2	2	2	2		
Vaginal haemorrhage	11	12	3	4	8	8
Vulval disorder	1	1			1	1
Vulvovaginal pruritus	2	2	1	1	1	1
Vulvovaginal rash	1	1			1	1
Vulvovaginal swelling	1	1			1	1
	116	137	78	94	38	43

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Non Interventional Study	Spontaneous
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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Acute pulmonary oedema	1	1
Acute respiratory distress syndrome	2	2
Acute respiratory failure	10	10
Allergic cough	2	2
Allergic respiratory symptom	1	1
Aphonia	4	7
Asphyxia	2	2
Aspiration	3	3
Asthma	32	37
Bronchial disorder	1	1
Bronchial obstruction	1	1
Bronchospasm	12	13
Catarrh		1
Choking	6	6
Choking sensation	2	2
Chronic obstructive pulmonary disease	3	3
Cough	349	443
Dry throat	28	38
Dysphonia	36	50
Dyspnoea	496	610
Dyspnoea at rest	1	1
Dyspnoea exertional	16	22
Epiglottic oedema	1	1
Epistaxis	40	49
Grunting	1	1
Haemoptysis	10	11
Hiccups	2	3
Hypersensitivity pneumonitis	1	1
Hyperventilation	11	15
Hypopnoea	5	5
Hypoventilation	1	1
Hypoxia	5	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	2
				10	10
				2	2
				1	1
		1	2	3	5
				2	2
				3	3
		16	19	16	18
		1	1		
				1	1
		3	4	9	9
			1		
				6	6
				2	2
				3	3
		229	305	120	138
		18	26	10	12
		17	23	19	27
1	1	219	284	277	326
				1	1
		8	14	8	8
				1	1
		29	35	11	14
				1	1
		6	6	4	5
		2	3		
				1	1
		6	8	5	7
		2	2	3	3
				1	1
				5	7

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased bronchial secretion	1	2
Increased upper airway secretion	6	8
Increased viscosity of upper respiratory secretion	2	2
Intranasal hypoaesthesia	2	2
Intranasal paraesthesia	2	3
Irregular breathing	1	1
Laryngeal oedema	21	22
Laryngeal pain	2	2
Laryngospasm	3	4
Lower respiratory tract congestion		1
Lung consolidation	1	1
Lung disorder	4	4
Lung infiltration	1	2
Lung opacity	1	1
Nasal congestion	101	149
Nasal discharge discolouration	1	1
Nasal discomfort	6	10
Nasal disorder		1
Nasal dryness	3	4
Nasal obstruction	3	3
Nasal odour	1	1
Nasal oedema	7	9
Nasal pruritus	1	1
Obstructive airways disorder	4	5
Organising pneumonia		1
Oropharyngeal blistering	3	3
Oropharyngeal discomfort	16	25
Oropharyngeal oedema	2	2
Oropharyngeal pain	289	382
Oropharyngeal spasm	1	1
Oropharyngeal swelling	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	1	1
		4	5	2	3
		1	1	1	1
		1	1	1	1
		2	3		
				1	1
				21	22
		2	2		
			1	3	3
			1		
				1	1
		3	3	1	1
				1	2
				1	1
		89	135	12	14
		1	1		
		5	8	1	2
			1		
		1	2	2	2
		1	1	2	2
		1	1		
		6	7	1	2
		1	1		
		1	1	3	4
					1
				3	3
		8	13	8	12
		1	1	1	1
		209	292	80	90
				1	1
		1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orthopnoea	2	2
Painful respiration	6	9
Paranasal sinus discomfort	10	12
Paranasal sinus hypersecretion	2	2
Paranasal sinus inflammation	1	1
Pharyngeal disorder	4	4
Pharyngeal erythema	7	7
Pharyngeal hypoesthesia	9	15
Pharyngeal inflammation	8	8
Pharyngeal oedema	7	7
Pharyngeal paraesthesia	17	28
Pharyngeal swelling	76	103
Pharyngeal ulceration	1	1
Pleural effusion	4	4
Pleurisy	3	3
Pleuritic pain	4	6
Pneumonia aspiration	7	7
Pneumonitis	3	3
Productive cough	21	25
Prolonged expiration	1	1
Pulmonary congestion	3	4
Pulmonary embolism	9	10
Pulmonary oedema	5	6
Pulmonary pain	4	7
Pulmonary thrombosis	2	2
Rales	5	5
Respiration abnormal	3	5
Respiratory arrest	10	10
Respiratory depression	1	1
Respiratory disorder	6	7
Respiratory distress	22	25
Respiratory failure	7	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
		4	6	2	3
		10	12		
		2	2		
				1	1
		3	3	1	1
		5	5	2	2
		4	8	5	7
		4	4	4	4
				7	7
		6	16	11	12
		35	51	41	52
				1	1
		1	1	3	3
				3	3
		1	2	3	4
				7	7
		1	1	2	2
		10	13	11	12
				1	1
				3	4
				9	10
				5	6
		2	4	2	3
				2	2
				5	5
		1	2	2	3
				10	10
				1	1
		1	2	5	5
		1	1	21	24
				7	7

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory symptom	1	2
Respiratory tract congestion	9	11
Respiratory tract irritation	1	1
Respiratory tract oedema	1	1
Rhinalgia	7	9
Rhinitis allergic	2	2
Rhinorrhoea	138	166
Rhonchi	2	2
Sinonasal obstruction	1	1
Sinus congestion	15	19
Sinus disorder	9	12
Sinus pain	18	20
Sneezing	47	57
Snoring	2	3
Sputum discoloured	3	3
Status asthmaticus	1	1
Stridor	6	7
Suffocation feeling	1	2
Tachypnoea	19	22
Throat clearing	3	4
Throat irritation	88	129
Throat tightness	107	146
Tonsillar erythema	2	2
Tonsillar hypertrophy	7	9
Tonsillar inflammation	1	1
Tonsillolith	1	1
Tracheomalacia		1
Upper-airway cough syndrome	8	13
Upper airway obstruction	1	1
Upper respiratory tract congestion	14	23
Vasomotor rhinitis	1	1
Vocal cord disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		1
		8	10	1	1
		1	1		
				1	1
		7	9		
		1	1	1	1
		119	146	19	20
				2	2
				1	1
		13	17	2	2
		8	11	1	1
		11	12	7	8
		40	50	7	7
			1	2	2
		2	2	1	1
				1	1
				6	7
		1	2		
		7	8	12	14
		1	1	2	3
		65	98	23	31
		45	63	62	83
		2	2		
		5	6	2	3
		1	1		
		1	1		
					1
		7	12	1	1
				1	1
		12	21	2	2
		1	1		
				1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Wheezing	44	63			15	27	29	36
Yawning	1	1			1	1		
	2,404	3,079	1	1	1363	1856	1041	1223

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	4	5	4	5		
Alopecia	5	5	5	5		
Angioedema	39	51			39	51
Blister	23	29	20	26	3	3
Circumoral oedema	1	1			1	1
Circumoral swelling	2	2	2	2		
Cold sweat	77	100	41	55	36	45
Dermatitis	13	13	10	10	3	3
Dermatitis allergic	17	28	8	16	9	12
Dermatitis bullous	1	1			1	1
Dermatitis contact	4	4	4	4		
Dermatitis exfoliative	1	1			1	1
Dermatitis exfoliative generalised	1	1			1	1
Drug eruption	3	4		1	3	3
Dry skin	10	11	10	11		
Ecchymosis	1	1	1	1		
Eczema	8	10	5	7	3	3
Erythema	296	371	211	272	85	99
Erythema multiforme	2	2			2	2
Erythema nodosum	1	1	1	1		
Fixed eruption	1	1	1	1		
Haemorrhage subcutaneous	1	1			1	1

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System Organ Class

**Skin and subcutaneous tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hair colour changes	1	1
Hidradenitis	1	2
Hyperhidrosis	285	355
Itching scar	1	1
Leukoplakia	1	1
Livedo reticularis	4	6
Macule	1	1
Mechanical urticaria	3	4
Miliaria	3	5
Nail discolouration	2	2
Night sweats	73	85
Pain of skin	23	28
Palmar erythema	3	4
Palmar-plantar erythrodysesthesia syndrome	1	1
Papule	5	7
Peau d'orange	1	1
Petechiae	15	16
Photosensitivity reaction	5	9
Piloerection	5	8
Pityriasis rosea	1	1
Plantar erythema	1	1
Pruritus	460	607
Pruritus allergic	1	1
Psoriasis	2	3
Purpura	4	4
Rash	471	596
Rash erythematous	91	127
Rash macular	65	85
Rash maculo-papular	16	19
Rash morbilliform	1	1
Rash papular	24	33
Rash pruritic	97	118

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	2		
194	255	91	100
		1	1
1	1		
2	3	2	3
1	1		
3	4		
2	2	1	3
		2	2
49	59	24	26
15	18	8	10
2	3	1	1
		1	1
2	4	3	3
1	1		
10	11	5	5
5	8		1
3	5	2	3
1	1		
1	1		
329	452	131	155
1	1		
1	2	1	1
3	3	1	1
339	435	132	161
55	79	36	48
49	65	16	20
14	16	2	3
		1	1
19	27	5	6
64	80	33	38

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash vesicular	13	13	9	9	4	4
Rosacea	2	2	1	1	1	1
Scab		1		1		
Scar pain	1	1	1	1		
Sensitive skin	13	13	9	9	4	4
Skin burning sensation	29	31	18	20	11	11
Skin discolouration	22	27	16	19	6	8
Skin disorder	11	16	11	15		1
Skin erosion	2	2	1	1	1	1
Skin exfoliation	11	11	4	4	7	7
Skin indentation	1	1	1	1		
Skin induration	1	1	1	1		
Skin irritation	11	12	9	10	2	2
Skin lesion	9	10	9	10		
Skin mass	3	4	2	3	1	1
Skin odour abnormal	1	1	1	1		
Skin reaction	7	9	4	6	3	3
Skin sensitisation	2	2			2	2
Skin swelling	6	7	5	6	1	1
Skin tightness	6	9	2	4	4	5
Skin ulcer	2	2			2	2
Skin warm	21	24	10	10	11	14
Skin weeping	1	1			1	1
Stevens-Johnson syndrome	2	2			2	2
Toxic epidermal necrolysis	1	1			1	1
Toxic skin eruption	1	1			1	1
Urticaria	311	403	215	296	96	107
Urticaria cholinergic	1	1	1	1		
Urticaria papular	1	1	1	1		
Vasculitic rash	1	1			1	1
	2,671	3,386	1822	2387	849	999

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System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	10	10	6	6	4	4
Contraindication to vaccination	2	2	2	2		
Exercise lack of	1	1	1	1		
Immobile	1	1			1	1
Impaired driving ability	4	5	3	4	1	1
Impaired quality of life	1	1	1	1		
Impaired work ability	6	8	6	8		
Loss of personal independence in daily activities	32	38	22	26	10	12
	57	66	41	48	16	18

System Organ Class

**SOC Not Yet Coded**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	14	16	14	16
	14	16	14	16

System Organ Class

**Surgical and medical procedures**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma prophylaxis	1	1			1	1
Limb immobilisation	1	1	1	1		
Spinal fusion surgery	1	1			1	1
Weight loss diet	1	1			1	1
	4	4	1	1	3	3

System Organ Class

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aneurysm	1	1
Aortic aneurysm	1	1
Aortic aneurysm rupture	1	1
Aortic dissection	2	2
Arteriosclerosis	1	1
Blood pressure fluctuation	6	7
Blood pressure inadequately controlled	1	1
Circulatory collapse	28	29
Cyanosis	12	14
Deep vein thrombosis	12	12
Diastolic hypertension	1	1
Diastolic hypotension		1
Embolism	1	1
Flushing	144	242
Giant cell arteritis	1	1
Haematoma	6	6
Haemorrhage	5	7
Hot flush	92	123
Hyperaemia		1
Hypertension	141	184
Hypertensive crisis	13	14
Hypertensive emergency	2	4
Hypotension	83	92
Hypovolaemic shock	1	1
Infarction	1	1
Labile hypertension	1	1
Lymphoedema	12	14
Malignant hypertension	1	1
Microembolism	1	1
Neurogenic shock	4	4
Orthostatic hypotension	4	4
Pallor	54	71

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	1
		2	2
		1	1
3	4	3	3
1	1		
		28	29
5	7	7	7
		12	12
		1	1
			1
		1	1
89	163	55	79
1	1		
5	5	1	1
		5	7
65	89	27	34
	1		
62	88	79	96
		13	14
		2	4
30	35	53	57
		1	1
		1	1
1	1		
7	9	5	5
		1	1
		1	1
		4	4
1	1	3	3
31	39	23	32

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral circulatory failure	1	2			1	2
Peripheral coldness	50	70	34	50	16	20
Peripheral embolism	1	1	1	1		
Peripheral ischaemia	2	2			2	2
Peripheral vascular disorder	7	7	3	3	4	4
Phlebitis	2	2	1	1	1	1
Poor peripheral circulation	2	3	1	2	1	1
Raynaud's phenomenon	2	3	1	2	1	1
Shock symptom	1	2			1	2
Superficial vein prominence	2	2	2	2		
Systolic hypertension	2	2			2	2
Thrombosis	11	11			11	11
Varicose vein	2	2	2	2		
Vascular pain	1	1	1	1		
Vasculitis	2	2	1	1	1	1
Vasoconstriction	1	1	1	1		
Vasodilatation	2	3		1	2	2
Vein discolouration	1	1	1	1		
Vein disorder	1	1			1	1
Vein rupture	1	1			1	1
Vena cava thrombosis	1	1			1	1
	728	964	350	512	378	452

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**APPENDIX 2.5.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by Preferred Term per Country**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval) / 18,061 (Cumulative)

Total Number of Adverse Events (PT): 51,740 (Interval) / 63,975 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AFGHANISTAN**

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills		1		1
Feeling of body temperature change		1		1
Swelling face		1		1
		3		3

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle tightness		1		1
		1		1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial paralysis		1				1
Paraesthesia		1		1		
		2		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythema		1		1
Pruritus		1		1
Rash		1		1
		3		3

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Country Where Event Occurred  
**ANDORRA**

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administered to patient of inappropriate age	1	1	1	1
	1	1	1	1

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- \* I=Interval, C=Cumulative
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- \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**AUSTRIA**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular disorder	1	1	1	1		
Myocardial infarction	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	2	2	2	2
Nausea	4	4	4	4
Vomiting	3	3	3	3
	9	9	9	9

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	3	1	1	2	2
Death	3	3			3	3
Drug ineffective	1	1			1	1
Fatigue	4	4	3	3	1	1
Feeling drunk	1	1	1	1		
Hangover	1	1	1	1		
Malaise	1	1	1	1		
Vaccination site pain	5	5	5	5		
Vaccination site pruritus	1	1	1	1		
	20	20	13	13	7	7

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction	1	1	1	1
	1	1	1	1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Influenza	1	1	1	1
	1	1	1	1

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect route of product administration	1	1	1	1
Poor quality product administered	1	1	1	1
Product preparation error	1	1	1	1
Wrong technique in product usage process	1	1	1	1
	4	4	4	4

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
SARS-CoV-2 test positive	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	1	1	1	1
	1	1	1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1	1	1		
Headache	2	2	2	2		
Migraine	2	2	2	2		
Somnolence	1	1			1	1
	6	6	5	5	1	1

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Urinary retention	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaginal discharge	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pulmonary embolism	1	1	1	1
Rales	1	1	1	1
Respiratory depression	1	1	1	1
	3	3	3	3

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus	2	2	2	2
Urticaria	1	1	1	1
	3	3	3	3

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Country Where Event Occurred

**BAHRAIN**

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**BELGIUM**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukocytosis	1	1	1	1
Neutropenia	1	1	1	1
	2	2	2	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia	1	1			1	1
Cardiovascular disorder	4	4			4	4
Palpitations	1	1	1	1		
Tachycardia	1	1			1	1
	7	7	1	1	6	6

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Eye movement disorder	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Intestinal dilatation	1	1			1	1
Intestinal ischaemia	2	2			2	2
Nausea	1	1	1	1		
Swollen tongue	1	1	1	1		
	6	6	2	2	4	4

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Death	1	1			1	1
Drug ineffective	5	5			5	5
Fatigue	4	4	4	4		
General physical health deterioration	1	1			1	1
Illness	1	1	1	1		
Malaise	5	5	2	2	3	3
Pyrexia	1	1			1	1
Sudden death	2	2			2	2
Vaccination site erythema	2	2	2	2		
Vaccination site pain	2	2	2	2		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
	28	28	15	15	13	13

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	5	5	5	5
Sepsis	1	1	1	1
Septic shock	1	1	1	1
	7	7	7	7

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via skin contact	1	1	1	1
Occupational exposure to product	1	1	1	1
	2	2	2	2

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood lactic acid increased	1	1	1	1
Liver function test abnormal	1	1	1	1
Oxygen saturation decreased	1	1	1	1
	3	3	3	3

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypoglycaemia	1	1	1	1
Metabolic acidosis	1	1	1	1
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal stiffness	2	2	2	2
Pain in extremity	2	2	2	2
	4	4	4	4

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amnesia	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dizziness	1	1	1	1		
Haemorrhage intracranial	1	1			1	1
Headache	1	1	1	1		
Memory impairment	1	1	1	1		
Nervous system disorder	1	1			1	1
Patient elopement	1	1			1	1
Poor quality sleep	1	1	1	1		
Presyncope	2	2			2	2
Sensory disturbance	1	1	1	1		
	12	12	5	5	7	7

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Agitation	2	2	2	2
Confusional state	2	2	2	2
Disorientation	1	1	1	1
Staring	1	1	1	1
	6	6	6	6

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	1	1	1	1
Renal disorder	1	1	1	1
	2	2	2	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute respiratory failure	1	1	1	1
Dyspnoea	1	1	1	1
Lung infiltration	1	1	1	1
Pneumonitis	1	1	1	1
Pulmonary embolism	1	1	1	1
Respiratory disorder	2	2	2	2
Tachypnoea	1	1	1	1
	8	8	8	8

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypotension	1	1	1	1
Hypovolaemic shock	1	1	1	1
	2	2	2	2

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Country Where Event Occurred  
**BERMUDA**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**BULGARIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	3	3	3	3
Lymph node pain	1	1	1	1
	4	4	4	4

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Palpitations	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	2	2	2	2		
Nausea	3	3	2	2	1	1
Paraesthesia oral	1	1	1	1		
Vomiting	1	1	1	1		
	7	7	6	6	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	3	3	3		
Chills	2	3	1	2	1	1
Drug ineffective	3	4			3	4
Fatigue	1	1	1	1		
Pain	1	1	1	1		
Pyrexia	2	2	2	2		
Swelling	2	2	2	2		
Vaccination site erythema	2	2	2	2		
Vaccination site pain	8	8	8	8		
Vaccination site swelling	2	2	2	2		
	26	28	22	23	4	5

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	3	4	3	4
	3	4	3	4

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure diastolic decreased	1	1	1	1
Body temperature increased	3	3	3	3
	4	4	4	4

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	3	3	3	3
Back pain	1	1	1	1
Myalgia	5	5	5	5
Neck pain	1	1	1	1
Pain in extremity		1		1
	10	11	10	11

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		1		1		
Dizziness	3	3	2	2	1	1
Dizziness postural	1	1	1	1		
Headache	5	5	4	4	1	1
Head discomfort	1	1			1	1
Paraesthesia	1	1	1	1		
	11	13	8	10	3	3

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea	1	1	1	1
	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	1	1	1		
Hyperhidrosis	1	2		1	1	1
Rash	1	1	1	1		
Rash erythematous	1	1	1	1		
Rash pruritic	1	1	1	1		
	5	6	4	5	1	1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pallor	1	1	1	1
Peripheral coldness	1	1	1	1
	2	2	2	2

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Country Where Event Occurred  
**CANADA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	6	7	6	7
	6	7	6	7

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	1	1	1	1		
Tachycardia	5	5	3	3	2	2
	6	6	4	4	2	2

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Ear discomfort	1	1	1	1		
	2	2	1	1	1	1

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye pain	1	1	1	1
Eye pruritus	1	1	1	1
Eye swelling	1	1	1	1
Vision blurred	1	1	1	1
Visual impairment	1	1	1	1
	5	5	5	5

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	2	2	2	2		
Aphthous ulcer	1	1	1	1		
Diarrhoea	8	10	8	10		
Dysphagia	2	3	2	3		
Gastroesophageal reflux disease	1	1	1	1		
Lip swelling	2	2	2	2		
Nausea	10	12	10	12		
Odynophagia		1		1		
Oral mucosal blistering	1	1	1	1		
Paraesthesia oral	2	5	2	4		1
Swollen tongue	2	3	1	2	1	1
Tongue disorder	1	1			1	1
Tongue pruritus		1		1		
Vomiting	5	5	5	5		
	39	50	37	47	2	3

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site pain	1	1	1	1		
Adverse event	1	1	1	1		
Asthenia	3	4	3	4		
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	8	10	8	10		
Disease recurrence	1	1	1	1		
Drug ineffective	7	7			7	7
Face oedema	1	1			1	1
Fatigue	20	22	19	21	1	1
Feeling abnormal	3	4	3	4		
Feeling cold	2	2	1	1	1	1
Feeling hot	1	1	1	1		
Illness	1	1	1	1		
Influenza like illness	2	2	2	2		
Malaise	4	4	4	4		
Pain	7	9	7	9		
Peripheral swelling	1	1	1	1		
Pyrexia	16	18	16	18		
Swelling	1	2		1	1	1
Thirst		1		1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	13	14	12	13	1	1
Vaccination site rash	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		
	101	114	87	100	14	14

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1		1		
Anaphylactic reaction	2	2	1	1	1	1
Hypersensitivity	4	4	3	3	1	1
Type IV hypersensitivity reaction	1	1	1	1		
	7	8	5	6	2	2

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cellulitis	1	1			1	1
COVID-19	4	4			4	4
Gastroenteritis	1	1	1	1		
Herpes zoster	3	3	3	3		
Localised infection	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Rash pustular	1	1	1	1		
Varicella	1	1	1	1		
	13	13	8	8	5	5

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Buttock injury	1	1	1	1
Exposure during pregnancy	4	4	4	4
Exposure via breast milk	6	6	6	6
Inappropriate schedule of product administration	2	2	2	2
Incomplete course of vaccination	1	1	1	1
Maternal exposure during pregnancy	11	11	11	11
Maternal exposure timing unspecified	2	2	2	2
Off label use	17	17	17	17
Overdose	6	6	6	6
Product administered at inappropriate site	1	1	1	1
Product preparation issue	10	10	10	10
Product use issue	15	15	15	15
Underdose	4	4	4	4
	80	80	80	80

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	1	1	1	1		
Heart rate increased	1	2	1	2		
SARS-CoV-2 test positive	3	3			3	3
Vital functions abnormal	1	1			1	1
	6	7	2	3	4	4

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	3	3	3	3
Fluid retention		1		1
	3	4	3	4

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	11	11	10	10	1	1
Back pain	1	1	1	1		
Fibromyalgia	1	1	1	1		
Joint swelling	2	2	1	1	1	1
Muscle spasms	1	1	1	1		
Muscle twitching	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	3	3	3	3		
Myalgia	16	16	15	15	1	1
Neck pain	2	2	2	2		
Pain in extremity	14	17	14	17		
Rheumatoid arthritis	1	1			1	1
	55	58	51	54	4	4

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbance in attention	1	1	1	1		
Dizziness	6	6	6	6		
Dysgeusia		1		1		
Facial paralysis		1				1
Headache	28	31	28	31		
Hyperaesthesia	1	1	1	1		
Hypersomnia		1		1		
Hypoaesthesia	4	4	3	3	1	1
Lethargy	2	2	2	2		
Migraine	1	1	1	1		
Paraesthesia	5	7	4	5	1	2
Presyncope	1	2		1	1	1
Somnolence	1	1	1	1		
Syncope	1	2			1	2
Taste disorder	1	1	1	1		
Tremor	2	2	2	2		
	54	64	50	57	4	7

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Affect lability	1	1	1	1
Agitation	1	1	1	1
Anxiety	2	2	2	2
Depression	1	1	1	1
Distract bility	1	1	1	1
Fear	1	1	1	1
Insomnia	1	1	1	1
Stress	1	1	1	1
	9	9	9	9

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Genital blister	1	1	1	1		
Metrorrhagia	1	1	1	1		
Vulval disorder	1	1			1	1
	3	3	2	2	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	1	1	1		
Lung disorder	1	1			1	1
Nasal congestion	1	1	1	1		
Oropharyngeal pain	2	3	2	3		
Pharyngeal hypoesthesia	1	1	1	1		
Pharyngeal swelling	2	2	1	1	1	1
Pulmonary pain	1	1			1	1
Sinus pain	1	1	1	1		
Sneezing	1	1	1	1		
Tachypnoea	1	1	1	1		
Throat irritation	1	1	1	1		
	13	14	10	11	3	3

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Cold sweat	1	1	1	1		
Eczema	1	1	1	1		
Erythema	2	2	1	1	1	1
Hyperhidrosis	1	1	1	1		
Leukoplakia	1	1	1	1		
Pain of skin	1	1	1	1		
Petechiae	1	1	1	1		
Pruritus	6	6	5	5	1	1
Rash	4	4	3	3	1	1
Rash macular	2	2	2	2		
Skin burning sensation	1	1	1	1		
Skin lesion	2	2	2	2		
Urticaria	3	4	3	4		
	27	28	23	24	4	4

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Impaired work ability	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	1	1	1		
Flushing	1	1			1	1
Hot flush	1	1	1	1		
Hypertension	2	3	1	2	1	1
Hypotension	1	1			1	1
	6	7	3	4	3	3

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Country Where Event Occurred

**CHILE**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	3	4	2	3	1	1
Lymph node pain	2	2	2	2		
	5	6	4	5	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pruritus	1	1			1	1
Eye swelling	1	1	1	1		
Ocular hyperaemia	1	1			1	1
Photophobia	1	1			1	1
	4	4	1	1	3	3

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1			1	1
Diarrhoea	4	4	4	4		
Dry mouth		1				1
Nausea	1	2		1	1	1
Pancreatitis	1	1			1	1
	7	9	4	5	3	4

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chills	2	2	1	1	1	1
Crying		1				1
Disease recurrence	1	1	1	1		
Fatigue	1	2	1	2		
Feeling cold	1	1	1	1		
Malaise	1	2	1	2		
Pain		1		1		
Peripheral swelling	1	1	1	1		
Pyrexia	3	4	2	3	1	1
Swelling face	1	1	1	1		
Vaccination site pain	2	3	1	2	1	1
	14	20	11	16	3	4

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity	1	1	1	1
	1	1	1	1

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration	1	1	1	1
Maternal exposure timing unspecified	1	1	1	1
Off label use	2	2	2	2
Product use issue	2	2	2	2
	6	6	6	6

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Urine analysis abnormal	1	1	1	1
	1	1	1	1

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Polydipsia	1	1	1	1
	1	1	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	1	1	1	1
Arthritis	1	1			1	1
Back pain	1	1	1	1		
Joint swelling	2	2	1	1	1	1
Muscle spasms	1	1	1	1		
Myalgia	2	3	1	2	1	1
Pain in extremity	2	2	2	2		
	11	12	7	8	4	4

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	2	2	2	2		
Dizziness		1		1		
Headache	6	7	5	6	1	1
Paraesthesia		1				1
Sensory loss	1	1	1	1		
	9	12	8	10	1	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	1			1	1
Nasal congestion	1	1	1	1		
	2	2	1	1	1	1

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Dermatitis allergic		4		4		
Erythema	1	1	1	1		
Hyperhidrosis	1	1	1	1		
	3	7	2	6	1	1

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Country Where Event Occurred  
**COLOMBIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Leukocytosis	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Mouth swelling	1	1	1	1
Stomatitis	1	1	1	1
	2	2	2	2

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity	1	1	1	1
	1	1	1	1

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Candida infection	1	1	1	1
Gingivitis	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**COSTA RICA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymph node pain	1	1	1	1		
Splenomegaly	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Tachycardia	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye allergy	1	1	1	1
Eye inflammation	1	1	1	1
	2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chills	2	2	2	2		
Energy increased	1	1	1	1		
Fatigue	1	1	1	1		
Feeling abnormal	1	1	1	1		
Feeling hot	1	1	1	1		
Malaise	2	2	1	1	1	1
Pain	1	1	1	1		
Pyrexia	3	3	2	2	1	1
Vaccination site pain	3	3	3	3		
	16	16	14	14	2	2

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate irregular	1	1	1	1		
Hepatic enzyme increased	1	1			1	1
Red blood cell sedimentation rate increased	1	1	1	1		
	3	3	2	2	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint range of motion decreased	1	1			1	1
Limb discomfort	1	1	1	1		
Mobility decreased	1	1			1	1
Myalgia	2	2	1	1	1	1
Pain in extremity	2	2	2	2		
	7	7	4	4	3	3

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	6	6	6	6
	6	6	6	6

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Euphoric mood	1	1	1	1
Insomnia	1	1	1	1
Sleep disorder	1	1	1	1
	3	3	3	3

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus	1	1	1	1
Rash	1	1	1	1
	2	2	2	2

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vasculitis	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**CROATIA**

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid ptosis	1	1			1	1
Eye pain	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Hypoaesthesia oral	1	1			1	1
Lip disorder	1	1			1	1
Swollen tongue	1	1			1	1
Tongue oedema	1	1			1	1
	5	5	1	1	4	4

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	2	2	2	2		
Fatigue	2	4	2	4		
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Malaise	1	1	1	1		
Multi-organ disorder	1	1			1	1
Pain	1	1	1	1		
Peripheral swelling	1	1	1	1		
Pyrexia	6	8	6	8		
Swelling face	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	7	9	6	8	1	1
Vaccination site swelling	1	1	1	1		
	27	33	23	29	4	4

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to chemicals	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Type I hypersensitivity	1	1			1	1
	4	4	1	1	3	3

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System Organ Class

Investigations	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Preferred Term				
Body temperature increased	2	3	2	3
	2	3	2	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia		2		2
Neck pain	1	1	1	1
Pain in extremity		1		1
	1	4	1	4

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1			1	1
Dizziness	1	1	1	1		
Dysgeusia	1	1			1	1
Facial paresthesia	1	1			1	1
Headache	7	8	6	7	1	1
Paraesthesia	1	1			1	1
Tremor	1	1			1	1
	13	14	7	8	6	6

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bronchospasm	1	1	1	1
Dyspnoea	1	1	1	1
Pharyngeal paraesthesia	1	1	1	1
Respiratory tract oedema	1	1	1	1
Tachypnoea	1	1	1	1
Wheezing	1	1	1	1
	6	6	6	6

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Erythema	2	2	1	1	1	1
Pruritus	1	1			1	1
Rash	2	2	1	1	1	1
Rash erythematous	1	1			1	1
	7	7	2	2	5	5

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Country Where Event Occurred  
**CYPRUS**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Myocardial infarction		1		1
Tachyarrhythmia	1	1	1	1
Tachycardia	1	1	1	1
	2	3	2	3

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid ptosis	1	1	1	1		
Hypoaesthesia eye	1	1			1	1
	2	2	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral	1	1			1	1
Swollen tongue	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pyrexia	1	1	1	1
Vaccination site pain	2	2	2	2
	3	3	3	3

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood pressure increased	1	1	1	1
	1	1	1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	1	1	1	1		
Dysgeusia	1	1	1	1		
Facial paralysis	1	1			1	1
Facial paresis	1	1	1	1		
Headache	2	2	2	2		
Hypoaesthesia	1	1			1	1
Migraine	1	1	1	1		
	8	8	6	6	2	2

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cervix oedema	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dyspnoea	1	1	1	1
	1	1	1	1

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rash	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertension	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**CZECH REPUBLIC**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vertigo	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Photophobia	1	1	1	1
Vision blurred	1	1	1	1
	2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	1	1	1		
Lip swelling	1	1			1	1
Nausea	4	4	3	3	1	1
Swollen tongue	2	2			2	2
Vomiting	1	1			1	1
	9	9	4	4	5	5

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	2	2	2		
Chills	2	2	1	1	1	1
Drug ineffective	3	3			3	3
Fatigue	9	9	9	9		
Malaise	1	1	1	1		
Pain	1	1	1	1		
Peripheral swelling	1	1			1	1
Pyrexia	4	4	4	4		
Swelling	1	1			1	1
Swelling face	1	1			1	1
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	2	2	2	2		
	28	28	21	21	7	7

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System Organ Class

**Immune system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2			2	2
Anaphylactic reaction	2	2			2	2
Hypersensitivity	2	2	1	1	1	1
	6	6	1	1	5	5

System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	2			2	2
Rhinitis	1	1	1	1		
	3	3	1	1	2	2

System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1			1	1
Body temperature increased	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
	3	3	1	1	2	2

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	2	2	2	2
Back pain	1	1	1	1
Joint stiffness	1	1	1	1
Mobility decreased	1	1	1	1
Musculoskeletal chest pain	1	1	1	1
Musculoskeletal pain	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Myalgia	2	2	2	2
Pain in extremity	2	2	2	2
	12	12	12	12

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	2	1	1	1	1
Facial paresis	1	1			1	1
Headache	5	5	5	5		
Hypoaesthesia	1	1	1	1		
Paraesthesia	2	2	1	1	1	1
Somnolence	2	2	2	2		
	13	13	10	10	3	3

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma	1	1			1	1
Cough	1	1	1	1		
Dyspnoea	3	3	1	1	2	2
Hyperventilation	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Rhinorrhoea	1	1	1	1		
Tachypnoea	1	1			1	1
Throat tightness	1	1			1	1
	10	10	4	4	6	6

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Erythema	2	2	2	2		
Pruritus	1	1	1	1		
Rash	1	1	1	1		
	5	5	4	4	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse	1	1			1	1
Hypertension	1	1	1	1		
	2	2	1	1	1	1

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Country Where Event Occurred  
**DENMARK**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	3	3	3	3
Lymph node pain	1	1	1	1
	4	4	4	4

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	1	1			1	1
Palpitations	9	9	5	5	4	4
Sinus tachycardia	1	1	1	1		
Tachycardia	3	3	1	1	2	2
	14	14	7	7	7	7

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo	1	1	1	1
	1	1	1	1

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye	1	1	1	1		
Eye pain	3	3	3	3		
Eye pruritus	1	1	1	1		
Vision blurred	1	1			1	1
Visual impairment	1	1	1	1		
	7	7	6	6	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Diarrhoea	5	5	5	5		
Dysphagia	1	1			1	1
Gastroesophageal reflux disease	1	1	1	1		
Glossodynia	1	1	1	1		
Nausea	19	19	11	11	8	8
Odynophagia	1	1	1	1		
Paraesthesia oral	1	1			1	1
Swollen tongue	3	3			3	3
Vomiting	7	7	3	3	4	4
	41	41	24	24	17	17

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	4	2	2	2	2
Axillary pain	1	1	1	1		
Chest discomfort	4	4	1	1	3	3
Chills	12	12	9	9	3	3
Condition aggravated	1	1			1	1
Death	1	1			1	1
Discomfort	3	3			3	3
Drug ineffective	1	1			1	1
Drug interaction	1	1			1	1
Facial pain	1	1	1	1		
Fatigue	14	14	10	10	4	4
Feeling drunk	1	1	1	1		
Feeling hot	7	7	3	3	4	4
Foaming at mouth	1	1	1	1		
General physical health deterioration	3	3			3	3
Influenza like illness	3	3	3	3		
Malaise	25	25	15	15	10	10
Pain	4	4	3	3	1	1
Pyrexia	31	31	26	26	5	5
Sudden death	1	1			1	1
Swelling face	5	5	1	1	4	4
Vaccination site erythema	6	6	5	5	1	1
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site irritation	1	1			1	1
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site pain	39	39	37	37	2	2
Vaccination site pruritus	2	2	2	2		
Vaccination site rash	1	1			1	1
Vaccination site swelling	8	8	7	7	1	1
Vaccination site warmth	2	2	2	2		
	186	186	133	133	53	53

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction	6	6	6	6
Anaphylactic shock	1	1	1	1
Hypersensitivity	5	5	5	5
	12	12	12	12

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacteraemia	1	1			1	1
COVID-19	1	1			1	1
Nasopharyngitis	1	1	1	1		
Pneumonia	1	1			1	1
Sepsis	1	1			1	1
Severe acute respiratory syndrome	1	1			1	1
	6	6	1	1	5	5

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect route of product administration	2	2	2	2
Product administration error	1	1	1	1
Underdose	1	1	1	1
	4	4	4	4

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	2	2			2	2
Blood pressure systolic increased	1	1	1	1		
Body temperature increased	2	2	2	2		
Heart rate increased	3	3	2	2	1	1
Oxygen saturation decreased	1	1			1	1
	10	10	5	5	5	5

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fluid intake reduced	1	1	1	1
Hypophagia	1	1	1	1
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	9	9	9	9		
Mobility decreased	1	1			1	1
Muscle discomfort	1	1	1	1		
Muscle fatigue	1	1	1	1		
Myalgia	19	19	18	18	1	1
Neck pain	1	1	1	1		
Pain in extremity	7	7	7	7		
	39	39	37	37	2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coma	1	1			1	1
Depressed level of consciousness	1	1			1	1
Disturbance in attention	2	2	1	1	1	1
Dizziness	23	23	12	12	11	11
Dizziness postural	1	1			1	1
Dysaesthesia	1	1	1	1		
Dysgeusia	1	1	1	1		
Headache	37	37	31	31	6	6
Hemiparesis	1	1			1	1
Hypoaesthesia	1	1	1	1		
Loss of consciousness	1	1			1	1
Migraine	1	1	1	1		
Paraesthesia	6	6	2	2	4	4
Presyncope	9	9	2	2	7	7
Sensory disturbance	1	1	1	1		
Somnolence	1	1			1	1
Syncope	2	2			2	2
Tremor	2	2			2	2
	92	92	53	53	39	39

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression	1	1			1	1
Anxiety	1	1			1	1
Confusional state	1	1			1	1
Derealisation	1	1	1	1		
Insomnia	1	1	1	1		
Restlessness	3	3	3	3		
Thinking abnormal	1	1			1	1
	9	9	5	5	4	4

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Urinary incontinence	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aspiration	1	1			1	1
Bronchospasm	1	1			1	1
Chronic obstructive pulmonary disease	1	1			1	1
Cough	2	2			2	2
Dysphonia	2	2			2	2
Dyspnoea	9	9	1	1	8	8
Dyspnoea at rest	1	1			1	1
Hyperventilation	1	1			1	1
Nasal obstruction	1	1	1	1		
Obstructive airways disorder	1	1			1	1
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	3	3	3	3		
Pharyngeal swelling	4	4			4	4
Pneumonia aspiration	1	1			1	1
Prolonged expiration	1	1			1	1
Pulmonary oedema	1	1			1	1
Rales	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory failure	2	2			2	2
Stridor	1	1			1	1
Tachypnoea	1	1			1	1
Throat irritation	1	1	1	1		
Throat tightness	2	2	1	1	1	1
	40	40	8	8	32	32

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	3	3			3	3
Cold sweat	1	1	1	1		
Dermatitis allergic	1	1			1	1
Erythema	2	2			2	2
Hyperhidrosis	2	2	1	1	1	1
Pruritus	4	4	3	3	1	1
Rash	5	5	1	1	4	4
Rash erythematous	5	5	2	2	3	3
Rash pruritic	2	2	1	1	1	1
Skin lesion	1	1	1	1		
Urticaria	4	4	1	1	3	3
	30	30	11	11	19	19

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	5	5	2	2	3	3
Hot flush	1	1	1	1		
Hypertension	2	2	1	1	1	1
Hypotension	2	2			2	2
Pallor	6	6	3	3	3	3
	16	16	7	7	9	9

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Country Where Event Occurred

**ESTONIA**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Palpitations	1	1	1	1
Tachycardia	1	1	1	1
	2	2	2	2

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Drug ineffective	1	1			1	1
Feeling hot	1	1	1	1		
Malaise	1	1	1	1		
Vaccination site pain	1	1	1	1		
	5	5	4	4	1	1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Asymptomatic COVID-19	1	1	1	1
	1	1	1	1

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fracture	1	1			1	1
Maternal exposure during pregnancy	4	4	4	4		
Off label use	1	1	1	1		
Product use issue	1	1	1	1		
Underdose	1	1	1	1		
	8	8	7	7	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Facial nerve disorder	1	1	1	1
Headache	1	1	1	1
Hypoaesthesia	2	2	2	2
Paraesthesia	3	3	3	3
	7	7	7	7

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System Organ Class

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Syringe issue	1	1	1	1
	1	1	1	1

System Organ Class

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Immunisation anxiety related reaction	2	2	2	2
Restlessness	1	1	1	1
	3	3	3	3

System Organ Class

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypertension	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**FINLAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	3	3	3	3
	3	3	3	3

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Extrasystoles	1	1	1	1
Tachycardia	1	1	1	1
	2	2	2	2

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypoaesthesia oral	1	1	1	1		
Nausea	2	2	1	1	1	1
Paraesthesia oral	1	1	1	1		
Vomiting	1	1			1	1
	5	5	3	3	2	2

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	1	1	1	1		
Chest discomfort	2	2			2	2
Death	1	1			1	1
Fatigue	2	2	1	1	1	1
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Gait disturbance	1	1	1	1		
Irritability postvaccinal	1	1	1	1		
Malaise	4	4	3	3	1	1
Nodule	1	1	1	1		
Pyrexia	2	2	2	2		
Tenderness	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site haematoma	1	1	1	1		
Vaccination site oedema	2	2	2	2		
Vaccination site pain	3	3	3	3		
Vaccination site plaque	1	1	1	1		
Vaccination site warmth	2	2	2	2		
	28	28	23	23	5	5

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	2			2	2
Anaphylactic shock	1	1			1	1
Type IV hypersensitivity reaction	1	1	1	1		
	4	4	1	1	3	3

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System Organ Class

Investigations	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
C-reactive protein increased	1	1	1	1		
Heart rate increased	2	2			2	2
	3	3	1	1	2	2

System Organ Class

Metabolism and nutrition disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypokalaemia	2	2	2	2
	2	2	2	2

System Organ Class

Musculoskeletal and connective tissue disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Myalgia	2	2	2	2
Nuchal rigidity	1	1	1	1
Pain in extremity	1	1	1	1
	7	7	7	7

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	1	1	1	1		
Headache	2	2			2	2
Hypoaesthesia	1	1	1	1		
Migraine	1	1			1	1
Paraesthesia	1	1			1	1
Presyncope	1	1	1	1		
Seizure	1	1			1	1
Somnolence	1	1	1	1		
Subarachnoid haemorrhage	1	1			1	1
Syncope	1	1			1	1
Tremor	1	1			1	1
	12	12	4	4	8	8

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Derealisation	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1			1	1
Dyspnoea	3	3	1	1	2	2
Pharyngeal oedema	1	1			1	1
Pharyngeal swelling	1	1			1	1
Throat irritation	1	1			1	1
	7	7	1	1	6	6

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	3	3	1	1	2	2
Rash	1	1			1	1
Rash erythematous	1	1	1	1		
Urticaria	1	1			1	1
	6	6	2	2	4	4

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Aneurysm	1	1	1	1
Hypotension	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**FRANCE**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hyperleukocytosis	1	1			1	1
Lymphadenopathy	1	1	1	1		
Lymphopenia	1	1	1	1		
Thrombocytopenia	1	1			1	1
	4	4	2	2	2	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arrhythmia	1	1			1	1
Arrhythmia supraventricular	1	1			1	1
Atrial f brillation	2	2			2	2
Cardiac arrest	1	1			1	1
Cardiac failure	2	2			2	2
Cardio-respiratory arrest	2	2			2	2
Palpitations	1	1	1	1		
Tachycardia	3	3	2	2	1	1
	13	13	3	3	10	10

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eyelid irritation	1	1	1	1
Ocular discomfort	1	1	1	1
	2	2	2	2

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Aphthous ulcer	1	1	1	1		
Constipation	1	1	1	1		
Diarrhoea	2	2			2	2
Dysphagia	2	2			2	2
Lip oedema	1	1			1	1
Nausea	6	6	4	4	2	2
Paraesthesia oral	1	1	1	1		
Tongue haematoma	2	2	2	2		
Vomiting	2	2			2	2
	19	19	9	9	10	10

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chest pain	1	1			1	1
Chills	2	2	2	2		
Condition aggravated	1	1			1	1
Death	10	10			10	10
Drug ineffective	10	10	1	1	9	9
Fatigue	4	4	4	4		
Injection site erythema	1	1	1	1		
Injection site pain	1	1	1	1		
Malaise	8	8	3	3	5	5
Oedema peripheral	1	1			1	1
Pain	1	1	1	1		
Pyrexia	6	6	5	5	1	1
Sudden death	6	6			6	6
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	6	6	6	6		
Vaccination site pruritus	1	1	1	1		
	62	62	28	28	34	34

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock	1	1	1	1
Hypersensitivity	1	1	1	1
	2	2	2	2

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bronchitis	1	1			1	1
COVID-19	7	7			7	7
Herpes zoster	1	1	1	1		
Otitis externa	1	1	1	1		
Suspected COVID-19	2	2			2	2
	12	12	2	2	10	10

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Exposure via breast milk	2	2	2	2		
Fall	1	1			1	1
Inappropriate schedule of product administration	2	2	2	2		
Incorrect route of product administration	2	2	2	2		
Intercepted product preparation error	1	1	1	1		
Occupational exposure to product	1	1	1	1		
Off label use	1	1	1	1		
Overdose	6	6	6	6		
Poor quality product administered	2	2	2	2		
Product administered at inappropriate site	1	1	1	1		
Product preparation error	1	1	1	1		
Product preparation issue	17	17	17	17		
Product use issue	1	1	1	1		
Underdose	13	13	13	13		
Vaccination complication	1	1	1	1		
Wrong technique in product usage process	2	2	2	2		
	55	55	54	54	1	1

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure systolic increased	1	1			1	1
Blood uric acid increased	1	1	1	1		
Coronavirus test positive	1	1	1	1		
C-reactive protein increased	2	2	1	1	1	1
Glycosylated haemoglobin increased	1	1	1	1		
International normalised ratio abnormal	1	1			1	1
Oxygen saturation decreased	1	1			1	1
	8	8	4	4	4	4

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	2	2	2	2
Musculoskeletal stiffness	1	1	1	1
Myalgia	2	2	2	2
Neck pain	1	1	1	1
Pain in extremity	2	2	2	2
	8	8	8	8

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Cerebrovascular accident	2	2			2	2
Cognitive disorder	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dizziness	2	2	1	1	1	1
Dysarthria	1	1			1	1
Formication	1	1			1	1
Haemorrhagic stroke	1	1			1	1
Headache	4	4	4	4		
Hypertonia	1	1			1	1
Ischaemic stroke	1	1			1	1
Loss of consciousness	2	2			2	2
Paraesthesia	1	1	1	1		
Petit mal epilepsy	1	1			1	1
	21	21	8	8	13	13

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Needle issue	1	1	1	1
Product temperature excursion issue	1	1	1	1
	2	2	2	2

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	2	2			2	2
Confusional state	1	1			1	1
Fear	1	1			1	1
Insomnia	2	2	2	2		
	6	6	2	2	4	4

System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Renal failure	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Bronchial obstruction	1	1			1	1
Cough	1	1	1	1		
Dyspnoea	3	3			3	3
Haemoptysis	1	1			1	1
Increased bronchial secretion	1	1			1	1
Nasal congestion	1	1	1	1		
Oropharyngeal discomfort	1	1			1	1
Productive cough	1	1			1	1
Rales	1	1			1	1
	13	13	2	2	11	11

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Erythema	2	2	2	2		
Hyperhidrosis	1	1	1	1		
Papule	1	1	1	1		
Pruritus	3	3	3	3		
Rash erythematous	1	1	1	1		
Rash maculo-papular	1	1	1	1		
Urticaria	2	2			2	2
	12	12	9	9	3	3

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic dissection	2	2			2	2
Hot flush	1	1	1	1		
Hypertension	2	2	2	2		
Hypertensive crisis	1	1			1	1
Hypotension	1	1			1	1
	7	7	3	3	4	4

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Country Where Event Occurred  
**GERMANY**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenia		1				1
Lymphadenopathy	12	12	12	12		
Lymph node pain	4	4	4	4		
	16	17	16	16		1

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System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	6	6			6	6
Angina pectoris	2	2			2	2
Arrhythmia	4	4	1	1	3	3
Atrial fibrillation	1	1			1	1
Bradycardia	2	2			2	2
Cardiac arrest	1	1			1	1
Cardiac failure	6	6			6	6
Cardiac failure congestive	1	1			1	1
Cardiac fibrillation	1	1			1	1
Cardiogenic shock	1	1			1	1
Cardiovascular disorder	5	5	5	5		
Cardiovascular insufficiency	1	1			1	1
Myocardial infarction	1	1			1	1
Palpitations	15	17	13	15	2	2
Sinus tachycardia	1	1			1	1
Tachyarrhythmia	3	3			3	3
Tachycardia	16	17	8	8	8	9
Ventricular fibrillation	2	2			2	2
	69	72	27	29	42	43

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Huntington's disease	3	3	3	3
	3	3	3	3

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System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness	1	1			1	1
Ear pain	3	3	3	3		
Sudden hearing loss	1	1			1	1
Vertigo	4	4	4	4		
	9	9	7	7	2	2

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia	1	1	1	1		
Diplopia	1	1			1	1
Dry eye	1	1	1	1		
Episcleritis	1	1	1	1		
Eye haemorrhage	1	1			1	1
Eye irritation	2	2	2	2		
Eye pain	1	1	1	1		
Eye pruritus	2	2	1	1	1	1
Eye swelling	2	2	1	1	1	1
Lacrimation increased	1	1	1	1		
Vision blurred	2	2	1	1	1	1
Visual impairment	2	2	1	1	1	1
	17	17	11	11	6	6

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	5	5	5	5		
Abdominal pain lower	4	4	4	4		
Abdominal pain upper	3	3	3	3		
Abnormal faeces	5	5	5	5		
Constipation	1	1	1	1		
Diarrhoea	22	22	21	21	1	1
Dry mouth	1	1	1	1		
Dyspepsia	1	1	1	1		
Dysphagia	4	4			4	4
Flatulence	2	2	2	2		
Hypoaesthesia oral	2	2	2	2		
Lip oedema	1	1	1	1		
Lip swelling	2	2	1	1	1	1
Mesenteric vein thrombosis	1	1			1	1
Nausea	34	36	30	32	4	4
Oral mucosa erosion	1	1	1	1		
Paraesthesia oral	3	3	3	3		
Retching	1	1	1	1		
Swollen tongue	3	3	1	1	2	2
Tongue discomfort	1	1	1	1		
Tongue disorder	1	1	1	1		
Vomiting	15	15	10	10	5	5
	113	115	95	97	18	18

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Asthenia	29	36			25	31	4	5
Chest discomfort	3	4			3	4		
Chills	37	38			36	37	1	1
Condition aggravated	2	2					2	2
Crepitations	1	1					1	1
Death	32	32					32	32
Disease recurrence	1	1			1	1		
Drug ineffective	113	113					113	113
Drug interaction	1	1			1	1		
Face oedema	1	1					1	1
Facial pain	1	1			1	1		
Fatigue	115	119	1	1	113	116	2	3
Feeling cold	8	8			7	7	1	1
Feeling hot	4	4			4	4		
Feeling of body temperature change	1	1			1	1		
Gait disturbance	2	2			2	2		
General physical health deterioration	10	10			1	1	9	9
Hunger	1	1			1	1		
Hyperpyrexia	2	2					2	2
Illness	2	2			2	2		
Induration	1	1			1	1		
Influenza like illness	19	19			18	18	1	1
Injection site discomfort	1	1			1	1		
Injection site pain	1	1			1	1		
Local reaction	5	5			5	5		
Malaise	15	17	1	1	12	12	3	5
Multimorbidity	1	1					1	1
Multiple organ dysfunction syndrome	1	1					1	1
Oedema	1	1					1	1
Pain	15	16			13	13	2	3
Performance status decreased		1				1		
Peripheral swelling	3	3			2	2	1	1

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pyrexia	50	52
Sensation of foreign body	3	3
Sense of oppression	1	1
Sudden cardiac death	1	1
Sudden death	7	7
Swelling	6	7
Swelling face	3	3
Thirst	1	1
Vaccination site bruising	2	2
Vaccination site dermatitis	1	1
Vaccination site discomfort	2	2
Vaccination site erythema	9	10
Vaccination site haematoma	2	2
Vaccination site hyperaesthesia	2	3
Vaccination site induration	3	3
Vaccination site irritation	1	1
Vaccination site joint movement impairment	1	1
Vaccination site movement impairment	6	6
Vaccination site pain	170	174
Vaccination site paraesthesia	1	1
Vaccination site pruritus	4	4
Vaccination site rash	1	1
Vaccination site reaction	3	3
Vaccination site swelling	20	23
Vaccination site warmth	6	6
	735	764

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1	44	45	6	7
				3	3
		1	1		
				1	1
				7	7
		5	6	1	1
		1	1	2	2
		1	1		
		2	2		
		1	1		
		2	2		
		9	10		
		2	2		
		2	3		
		3	3		
		1	1		
		1	1		
		6	6		
		169	173	1	1
		1	1		
		4	4		
		1	1		
		3	3		
		20	23		
		6	6		
		3	3		
		536	559	199	205

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	1	1	1	1		
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	9	10			9	10
Anaphylactic shock	3	3			3	3
Anaphylactoid reaction	1	1			1	1
Hypersensitivity	14	14	5	5	9	9
Reaction to excipient	1	1	1	1		
	30	31	7	7	23	24

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	1	1			1	1
Atypical pneumonia	1	1			1	1
Bronchitis	1	1			1	1
Coronavirus infection	2	2	1	1	1	1
COVID-19	76	76			76	76
COVID-19 pneumonia	4	4			4	4
Febrile infection	2	2			2	2
Genital herpes	1	1	1	1		
Herpes zoster	3	3	3	3		
Hordeolum	1	1	1	1		
Infective exacerbation of chronic obstructive airways disease	1	1			1	1
Nasopharyngitis	6	6	6	6		
Otitis media	1	1	1	1		
Pathogen resistance	1	1			1	1
Pneumonia	4	4	1	1	3	3
Pulmonary sepsis	1	1			1	1
Respiratory tract infection	2	2			2	2
Rhinitis	1	2	1	2		
Sepsis	1	1			1	1
Septic shock	1	1			1	1
Sinusitis	1	1	1	1		
Staphylococcal sepsis	1	1			1	1
Suspected COVID-19	6	6			6	6
	119	120	16	17	103	103

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	5	13	4	11	1	2
Circumstance or information capable of leading to medication error	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Exposure via breast milk	1	1	1	1		
Fall	4	4			4	4
Femoral neck fracture	1	1			1	1
Head injury	1	1			1	1
Inappropriate schedule of product administration	3	3	3	3		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	8	8	8	8		
Maternal exposure during pregnancy	14	14	14	14		
Occupational exposure to product	1	1	1	1		
Off label use	8	8	8	8		
Poor quality product administered	1	1	1	1		
Product administered at inappropriate site	2	2	1	1	1	1
Product preparation error	2	2	2	2		
Product preparation issue	1	1	1	1		
Product use issue	8	8	8	8		
Scratch	1	1	1	1		
Underdose	9	9	9	9		
Wrong technique in product usage process	1	1	1	1		
	74	82	66	73	8	9

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose fluctuation	1	1	1	1		
Blood pressure decreased	3	3	1	1	2	2
Blood pressure increased	3	3	2	2	1	1
Blood urine present	1	1			1	1
Body temperature increased	11	11	9	9	2	2
General physical condition abnormal	1	1			1	1
Heart rate increased	1	2		1	1	1
Oxygen saturation decreased	4	4			4	4
Protein urine present	1	1	1	1		
SARS-CoV-2 ant body test positive	4	4	3	3	1	1
SARS-CoV-2 test false positive	3	3	3	3		
SARS-CoV-2 test positive	36	36	6	6	30	30
	69	70	26	27	43	43

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	2	1	1	1	1
Diabetes mellitus		1				1
Diet refusal	2	2			2	2
Food refusal	2	2			2	2
Hypercalcaemia	1	1			1	1
	7	8	1	1	6	7

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthralgia	18	18			18	18		
Back pain	3	3			3	3		
Bone pain	1	1			1	1		
Jaw clicking	1	1					1	1
Limb discomfort	7	8			7	8		
Mobility decreased	4	4			3	3	1	1
Muscle swelling	1	1			1	1		
Muscle tightness	1	1			1	1		
Muscle twitching	1	1			1	1		
Muscular weakness	6	6			6	6		
Musculoskeletal disorder	1	1					1	1
Musculoskeletal stiffness	1	1			1	1		
Myalgia	55	55	1	1	55	55		
Neck pain	9	9			9	9		
Pain in extremity	63	64			62	63	1	1
Weight bearing difficulty	1	1					1	1
	173	175	1	1	168	170	5	5

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ageusia	2	2			2	2		
Anosmia	1	1			1	1		
Burning sensation	2	2			1	1	1	1
Cerebral haemorrhage	1	1					1	1
Cerebral infarction	1	1					1	1
Cerebrovascular accident	2	2					2	2
Cranial nerve disorder	1	1			1	1		
Dementia	1	1					1	1
Dementia of the Alzheimer's type, with delirium	1	1					1	1
Depressed level of consciousness	1	1					1	1
Disturbance in attention	5	5			4	4	1	1
Dizziness	48	52			42	45	6	7
Dizziness postural	1	1			1	1		
Dysaesthesia	1	1					1	1
Dysgeusia	2	2			2	2		
Dysstasia	1	1			1	1		
Epilepsy	2	3					2	3
Facial paralysis	1	2					1	2
Headache	110	118	1	1	106	113	4	5
Head discomfort	1	1			1	1		
Hemiparesis	1	1					1	1
Hyperaesthesia	1	1			1	1		
Hypersomnia	1	1			1	1		
Hypoaesthesia	9	9			8	8	1	1
Hypotonia	2	2			1	1	1	1
Ischaemic stroke	1	1					1	1
Language disorder	1	1					1	1
Loss of consciousness	2	2			1	1	1	1
Migraine		1				1		
Motor dysfunction	1	1					1	1
Movement disorder	3	4			2	3	1	1
Neuralgia	1	1			1	1		

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Neuralgic amyotrophy	1	1					1	1
Orthostatic intolerance	1	1					1	1
Paraesthesia	10	10			10	10		
Paresis		1				1		
Poor quality sleep	2	2			1	1	1	1
Presyncope	1	1			1	1		
Seizure	4	5			1	1	3	4
Sensory disturbance	3	3			3	3		
Sensory loss	1	1					1	1
Somnolence	5	5			4	4	1	1
Speech disorder	1	1					1	1
Status epilepticus	1	1					1	1
Syncope	4	4					4	4
Taste disorder	1	1			1	1		
Tension headache	1	1					1	1
Transient ischaemic attack	1	1					1	1
Tremor	7	7			5	5	2	2
Unresponsive to stimuli	2	2					2	2
	254	272	1	1	203	216	51	56

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product leakage	1	1	1	1
	1	1	1	1

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation		1		1		
Anxiety		1		1		
Apathy	2	2			2	2
Confusional state	1	1	1	1		
Disorientation	1	1	1	1		
Insomnia	1	1	1	1		
Middle insomnia	1	1	1	1		
Personality change	1	1			1	1
Psychological factor affecting medical condition	1	1			1	1
Restlessness	2	2	2	2		
Sleep disorder	2	2	2	2		
	12	14	8	10	4	4

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	4	4			4	4
Bladder discomfort	1	1	1	1		
Bladder pain	1	1	1	1		
Chronic kidney disease	1	1			1	1
Haematuria	1	1	1	1		
Pollakiuria	1	1	1	1		
Renal failure	2	2			2	2
Renal pain	1	1	1	1		
	12	12	5	5	7	7

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Asthma	2	2	1	1	1	1
Bronchial disorder	1	1	1	1		
Bronchospasm	1	1	1	1		
Cough	7	9	7	8		1
Dysphonia	2	2	2	2		
Dyspnoea	17	19	8	9	9	10
Dyspnoea exertional	1	1			1	1
Epistaxis	3	3	3	3		
Haemoptysis	1	1	1	1		
Increased upper airway secretion	1	1	1	1		
Irregular breathing	1	1			1	1
Laryngeal oedema	2	2			2	2
Nasal congestion	1	1	1	1		
Oropharyngeal pain	7	7	7	7		
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal inflammation	1	1	1	1		
Pharyngeal swelling	3	3			3	3
Pneumonia aspiration	3	3			3	3
Pulmonary embolism	3	3			3	3
Respiratory distress	9	9	1	1	8	8
Respiratory failure	2	2			2	2
Respiratory symptom	1	1	1	1		
Rhinalgia	2	2	2	2		
Rhinorrhoea	9	9	8	8	1	1
Rhonchi	2	2			2	2
Sneezing	3	3	3	3		
Stridor	1	1			1	1
Tachypnoea	1	1	1	1		
Throat irritation	4	4	4	4		
Throat tightness	4	4	2	2	2	2
	97	101	57	59	40	42

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	1	1	1	1		
Angioedema	2	2			2	2
Blister	1	1	1	1		
Cold sweat	1	1			1	1
Dermatitis allergic	2	2	2	2		
Dry skin	1	1	1	1		
Eczema	1	1	1	1		
Erythema	10	10	10	10		
Hyperhidrosis	7	8	7	8		
Livedo reticularis	1	1	1	1		
Photosensitivity reaction	1	1	1	1		
Pruritus	11	11	7	7	4	4
Pruritus allergic	1	1	1	1		
Psoriasis	1	1	1	1		
Rash	17	17	9	9	8	8
Rash macular	2	2	1	1	1	1
Rash maculo-papular	1	1	1	1		
Rash pruritic	3	3	3	3		
Rosacea	1	1			1	1
Skin discolouration	1	1	1	1		
Urticaria	4	4	2	2	2	2
	70	71	51	52	19	19

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bedridden	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	1	1	1		
Circulatory collapse	4	4			4	4
Cyanosis	1	1			1	1
Flushing	5	6	2	2	3	4
Haematoma	1	1	1	1		
Hot flush	1	1	1	1		
Hypertension	12	14	4	5	8	9
Hypotension	7	7	1	1	6	6
Peripheral embolism	1	1	1	1		
Peripheral vascular disorder	6	6	2	2	4	4
	39	42	13	14	26	28

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Country Where Event Occurred

**GREECE**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukocytosis	1	1			1	1
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
	3	3	2	2	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Atrial f brillation	1	1			1	1
Cardiac arrest	3	3			3	3
Cardiac disorder	1	1			1	1
Cardiac valve disease	1	1			1	1
Palpitations	2	2	2	2		
Tachycardia	9	10	6	6	3	4
	18	19	8	8	10	11

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness unilateral	1	1			1	1
Tinnitus	2	2	2	2		
	3	3	2	2	1	1

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Eyelid ptosis	1	1	1	1
Eye oedema	1	1	1	1
	2	2	2	2

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Defaecation urgency		1				1
Diarrhoea	3	3	2	2	1	1
Dry mouth	2	2	2	2		
Dysphagia	4	4	2	2	2	2
Flatulence		1				1
Gastrointestinal disorder	2	2	2	2		
Gastrointestinal hypermotility		1				1
Hypoaesthesia oral	7	7	4	4	3	3
Nausea	6	6	4	4	2	2
Tongue ulceration	1	1	1	1		
Vomiting	4	4	4	4		
	31	34	23	23	8	11

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	4	4	4		
Chest pain	3	3	1	1	2	2
Chills	4	4	3	3	1	1
Condition aggravated	1	1			1	1
Discomfort	1	1	1	1		
Drug ineffective	1	1			1	1
Drug interaction	1	1			1	1
Fatigue	8	8	6	6	2	2
Feeling cold	1	1	1	1		
Feeling hot	1	1			1	1
Gait disturbance	2	2	2	2		
Injection site pain	1	1	1	1		
Local reaction	1	1	1	1		
Malaise	1	1	1	1		
Mucosal dryness		1				1
No adverse event	1	1	1	1		
Pain	1	1	1	1		
Pyrexia	12	12	10	10	2	2
Sudden death	2	2			2	2
Therapeutic response unexpected	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site induration	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	13	13	13	13		
Vaccination site warmth	1	1	1	1		
	63	65	50	51	13	14

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	2			1	2
Anaphylactic shock	3	3			3	3
Anaphylactoid reaction	1	1			1	1
Hypersensitivity	9	9	6	6	3	3
	14	15	6	6	8	9

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Oral herpes	1	1	1	1		
Pneumonia	1	1			1	1
Respiratory tract infection	1	1			1	1
	4	4	1	1	3	3

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	1	1			1	1
Incomplete course of vaccination	1	1	1	1		
Injury	1	1	1	1		
Maternal exposure during pregnancy	1	1	1	1		
Off label use	1	1	1	1		
Poor quality product administered	3	3	3	3		
	8	8	7	7	1	1

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auscultation	1	1	1	1		
Blood pressure decreased	2	2	2	2		
Blood pressure diastolic increased	1	1	1	1		
Blood pressure increased	2	2	1	1	1	1
	6	6	5	5	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Limb discomfort	1	1	1	1		
Muscle spasms	1	1	1	1		
Muscular weakness	1	1	1	1		
Myalgia	3	3	2	2	1	1
Pain in extremity	6	6	6	6		
Rheumatoid arthritis	1	1			1	1
	15	15	13	13	2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	2	2	2	2		
Dizziness	10	10	7	7	3	3
Dysgeusia	5	5	3	3	2	2
Headache	12	12	11	11	1	1
Hypoaesthesia	6	6	5	5	1	1
Loss of consciousness	1	1			1	1
Migraine	1	1	1	1		
Poor quality sleep	1	1	1	1		
Presyncope	3	3	1	1	2	2
Seizure	1	1			1	1
Somnolence	1	1	1	1		
Tremor	1	2			1	2
	44	45	32	32	12	13

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue	3	3	3	3
Product quality issue	1	1	1	1
	4	4	4	4

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Dysphoria	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Bronchospasm	2	2			2	2
Cough	3	3			3	3
Dry throat	1	1	1	1		
Dysphonia	3	3			3	3
Dyspnoea	6	6	2	2	4	4
Laryngeal oedema	1	1			1	1
Nasal congestion	1	1	1	1		
Pulmonary thrombosis	1	1			1	1
Rhinitis allergic	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Tachypnoea	1	1	1	1		
Throat irritation	2	2	2	2		
	25	25	9	9	16	16

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	2	2			2	2
Blister	1	1	1	1		
Erythema	1	2	1	1		1
Hyperhidrosis	3	3	2	2	1	1
Pruritus	3	3	2	2	1	1
Rash	8	8	7	7	1	1
Rash pruritic	1	1	1	1		
Skin burning sensation	1	1	1	1		
	20	21	15	15	5	6

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure inadequately controlled	1	1	1	1		
Cyanosis	1	1	1	1		
Diastolic hypertension	1	1			1	1
Flushing	2	3	1	1	1	2
Hypertension	4	4	3	3	1	1
Hypertensive crisis	1	1			1	1
Hypertensive emergency	1	1			1	1
Hypotension	1	1	1	1		
Orthostatic hypotension	1	1	1	1		
	13	14	8	8	5	6

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Country Where Event Occurred  
**HUNGARY**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	4	4	3	3	1	1
Lymph node pain	2	2	2	2		
	6	6	5	5	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Palpitations	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear discomfort	1	1	1	1
Ear pain	1	1	1	1
Ear pruritus	2	2	2	2
Tinnitus	1	1	1	1
	5	5	5	5

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lacrimation increased	1	1	1	1
Vision blurred	1	1	1	1
	2	2	2	2

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth		1				1
Hypoaesthesia oral	2	2	2	2		
Nausea	6	6	6	6		
Vomiting	4	4	4	4		
	12	13	12	12		1

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	9	10	9	10		
Axillary pain	1	1	1	1		
Chest discomfort	1	1	1	1		
Chest pain	2	2	2	2		
Chills	6	7	5	6	1	1
Drug ineffective	3	3			3	3
Fatigue	4	5	4	5		
Feeling abnormal	2	2	2	2		
Feeling hot	3	4	3	3		1
Gait disturbance	2	2	2	2		
Malaise	9	9	7	7	2	2
No adverse event	1	1	1	1		
Oedema peripheral	1	1			1	1
Pain	2	2	2	2		
Peripheral swelling	1	1	1	1		
Pyrexia	12	12	10	10	2	2
Sensation of foreign body	1	1			1	1
Swelling face	2	2	2	2		
Thirst		1				1
Vaccination site coldness	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	8	8	8	8		
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site nodule	2	2	2	2		
Vaccination site pain	10	10	10	10		
Vaccination site pruritus	2	2	2	2		
Vaccination site swelling	4	4	4	4		
Vaccination site warmth	1	1	1	1		
	93	98	83	86	10	12

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Hypersensitivity		1		1		
	1	2		1	1	1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	2			2	2
Herpes virus infection	1	1	1	1		
Nasopharyngitis	1	1	1	1		
	4	4	2	2	2	2

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	1	1	1	1
Incorrect route of product administration	1	1	1	1
Off label use	1	1	1	1
	3	3	3	3

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased		1		1		
Blood pressure increased	1	2	1	1		1
Body temperature increased	2	2	2	2		
Heart rate increased	1	2	1	2		
SARS-CoV-2 test positive	1	1			1	1
	5	8	4	6	1	2

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemia	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1			1	1
Back pain	3	3	3	3		
Mobility decreased	1	1	1	1		
Muscle fatigue	1	1	1	1		
Myalgia	7	7	6	6	1	1
Pain in extremity	12	12	12	12		
	25	25	23	23	2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	2	2		
Anosmia	1	1	1	1		
Burning sensation	2	2	2	2		
Dizziness	7	7	7	7		
Dysgeusia	1	1	1	1		
Headache	17	17	15	15	2	2
Hyperaesthesia	1	2	1	2		
Hypoaesthesia	4	4	4	4		
Paraesthesia	1	2	1	1		1
Presyncope	1	1	1	1		
Somnolence	1	1	1	1		
Tremor	1	2	1	1		1
	39	42	37	38	2	4

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusional state	1	1	1	1
Depression	1	1	1	1
Panic attack	1	1	1	1
	3	3	3	3

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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Micturition urgency		1		1
		1		1

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infertility	1	1			1	1
Vaginal discharge	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	1			1	1
Laryngeal oedema	1	1			1	1
Oropharyngeal pain	2	2	2	2		
	4	4	2	2	2	2

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blister	1	1	1	1		
Cold sweat	1	1	1	1		
Eczema	1	1	1	1		
Erythema	2	2	2	2		
Hyperhidrosis	1	1	1	1		
Pain of skin	1	1	1	1		
Pruritus	3	3	3	3		
Rash	2	2	2	2		
Rash maculo-papular	1	1			1	1
Rash pruritic	1	1	1	1		
Rash vesicular	1	1	1	1		
Skin lesion		1		1		
Urticaria	1	2	1	2		
	16	18	15	17	1	1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhage	1	1			1	1
Pallor	1	1	1	1		
	2	2	1	1	1	1

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Country Where Event Occurred  
**ICELAND**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia	1	1			1	1
Cardiac failure	2	2			2	2
Myocardial infarction	1	1			1	1
Tachycardia	1	1	1	1		
	5	5	1	1	4	4

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear pain	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular discomfort	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dry mouth	1	1	1	1
Nausea	5	5	5	5
Vomiting	1	1	1	1
	7	7	7	7

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	4	4	4		
Chest discomfort	1	1	1	1		
Chills	2	2	2	2		
Death	2	2			2	2
Discomfort	1	1	1	1		
Disease progression	1	1			1	1
Fatigue	7	7	7	7		
Feeling cold	2	2	2	2		
Malaise	7	7	5	5	2	2
Pain	1	1	1	1		
Pyrexia	15	15	13	13	2	2
Sudden death	1	1			1	1
Swelling	1	1	1	1		
Thirst	1	1	1	1		
Vaccination site erythema	3	3	3	3		
Vaccination site inflammation	1	1	1	1		
Vaccination site pain	5	5	5	5		
Vaccination site swelling	1	1	1	1		
	56	56	48	48	8	8

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nasopharyngitis	5	5	5	5		
Pneumonia	2	2			2	2
Sepsis	1	1			1	1
	8	8	5	5	3	3

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	1	1	1	1
Heart rate increased	1	1	1	1
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain	1	1	1	1
Bone pain	2	2	2	2
Limb discomfort	1	1	1	1
Myalgia	3	3	3	3
	8	8	8	8

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	4	4	4	4
Headache	13	13	13	13
Head discomfort	1	1	1	1
Hypoaesthesia	4	4	4	4
Migraine	1	1	1	1
Sensory loss	1	1	1	1
Tremor	1	1	1	1
	25	25	25	25

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	3	3	2	2	1	1
Dry throat	1	1	1	1		
Dyspnoea	1	1	1	1		
Oropharyngeal pain	3	3	3	3		
Pharyngeal swelling	1	1	1	1		
Respiration abnormal	1	1			1	1
Rhinorrhoea	2	2	2	2		
	12	12	10	10	2	2

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cold sweat	1	1	1	1
Erythema	1	1	1	1
Pruritus	1	1	1	1
	3	3	3	3

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm	1	1			1	1
Hot flush	1	1	1	1		
Pallor	1	1	1	1		
	3	3	2	2	1	1

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Country Where Event Occurred

**INDIA**

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Suspected counterfeit product		1		1
		1		1

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Country Where Event Occurred  
**IRELAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Deafness	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blindness	1	1	1	1
Visual impairment	1	1	1	1
	2	2	2	2

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Death	1	1			1	1
Fatigue	2	2	2	2		
Injected limb mobility decreased	1	1			1	1
No adverse event	1	1	1	1		
Pain	1	1			1	1
Pyrexia	1	1	1	1		
Sudden death	1	1			1	1
	9	9	5	5	4	4

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart rate increased	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Periarthritis	1	1	1	1
	1	1	1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	1	1			1	1
Headache	2	2	2	2		
IVth nerve paralysis	1	1			1	1
Syncope	2	2			2	2
	6	6	2	2	4	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea	1	1	1	1
	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cold sweat	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**ISRAEL**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemolytic anaemia	1	1			1	1
Leukocytosis	1	1			1	1
Lymphadenopathy	4	5	4	5		
Lymphocytosis	1	1	1	1		
Lymphopenia	1	1			1	1
	8	9	5	6	3	3

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Angina pectoris	1	1			1	1
Arrhythmia	2	2			2	2
Atrial fibrillation	1	2			1	2
Cardiac arrest	5	6			5	6
Cardiac disorder	2	2			2	2
Cardiac failure		1				1
Myocardial infarction	2	2			2	2
Palpitations	8	8	8	8		
Pericarditis	1	2			1	2
Sinus tachycardia	1	1	1	1		
Tachycardia	4	4	3	3	1	1
	28	32	12	12	16	20

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System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear discomfort	1	1	1	1
Ear pain	3	3	3	3
Tinnitus	1	1	1	1
	5	5	5	5

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyschromatopsia	1	1			1	1
Eye haemorrhage	1	1			1	1
Eye irritation	2	2	1	1	1	1
Eye pain	2	2			2	2
Lacrimation increased	2	2	1	1	1	1
Vision blurred	3	3	3	3		
	11	11	5	5	6	6

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	3	1	3		
Abdominal pain upper	1	1	1	1		
Anaesthesia oral		1		1		
Diarrhoea	7	7	6	6	1	1
Dry mouth	1	1	1	1		
Dyspepsia	5	5	5	5		
Dysphagia	5	5	4	4	1	1
Eosinophilic oesophagitis	1	1	1	1		
Gingival pain	1	1	1	1		
Hypoaesthesia oral	6	8	5	7	1	1
Hypoaesthesia teeth	1	1	1	1		
Lip pruritus	1	2	1	2		
Lip swelling	2	2	1	1	1	1
Nausea	20	23	19	22	1	1
Odynophagia	2	2	2	2		
Pancreatitis	1	1			1	1
Paraesthesia oral	9	11	8	10	1	1
Swollen tongue	3	4			3	4
Tongue discomfort	1	1	1	1		
Toothache	1	1	1	1		
Vomiting	9	10	9	10		
	78	91	68	80	10	11

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Adverse event	1	1
Adverse reaction	1	1
Asthenia	50	56
Chest discomfort		1
Chest pain	2	2
Chills	24	25
Condition aggravated	1	1
Crying	1	1
Death	4	6
Disease recurrence	1	2
Drug ineffective	14	16
Fatigue	22	29
Feeling abnormal	8	10
Feeling cold	5	7
Feeling hot	3	5
Feeling of body temperature change		1
Gait disturbance	2	2
Hangover	1	1
Illness	1	1
Influenza like illness	8	8
Malaise	17	19
Pain	12	12
Peripheral swelling	2	2
Pyrexia	37	39
Sudden cardiac death	1	1
Swelling face	1	1
Systemic inflammatory response syndrome	1	1
Tenderness		1
Therapeutic response unexpected	2	2
Vaccination site bruising	1	1
Vaccination site erythema	4	5
Vaccination site hypersensitivity		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		50	56		
			1		
		1	1	1	1
		23	24	1	1
		1	1		
		1	1		
				4	6
		1	1		1
1	1	2	2	12	14
		21	28	1	1
		6	7	2	3
		5	7		
		3	5		
			1		
				2	2
		1	1		
		1	1		
		8	8		
		13	15	4	4
		12	12		
		1	1	1	1
		34	36	3	3
				1	1
		1	1		
				1	1
			1		
		2	2		
		1	1		
		4	5		
			1		

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site joint movement impairment	1	1			1	1		
Vaccination site movement impairment	1	2			1	2		
Vaccination site pain	43	58			43	58		
Vaccination site pruritus	1	1			1	1		
Vaccination site reaction	1	1			1	1		
Vaccination site swelling	6	8			6	8		
	280	332	1	1	247	293	33	39

System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hepatitis	1	1			1	1
Jaundice	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	3	3	1	1	2	2
Anaphylactic reaction	3	3			3	3
Anaphylactic shock	1	1			1	1
Hypersensitivity	2	4		1	2	3
	9	11	1	2	8	9

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Coronavirus infection	1	2			1	1		1
COVID-19	6	6	1	1	1	1	5	5
Eye infection		1				1		
Gastroenteritis viral	1	1			1	1		
Herpes zoster	1	1			1	1		
Infection	1	1			1	1		
Influenza	1	2			1	2		
Nasopharyngitis	2	2			2	2		
Oral herpes	3	3			2	2	1	1
Otitis media	1	1			1	1		
Sepsis	1	1					1	1
Suspected COVID-19	1	1					1	1
	19	22	1	1	11	13	8	9

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Contusion	1	1					1	1
Exposure during pregnancy		1				1		
Exposure to SARS-CoV-2			1	1				
Exposure via breast milk	2	4			2	4		
Fall	3	3			1	1	2	2
Head injury	1	1					1	1
Hip fracture	1	1					1	1
Inappropriate schedule of product administration	5	5			5	5		
Incomplete course of vaccination	1	1			1	1		
Incorrect route of product administration	1	1			1	1		
Off label use	1	2			1	2		
Overdose	2	4			2	4		
Pelvic fracture	1	1					1	1
Poor quality product administered	2	29			2	29		
Product preparation error	2	4			2	4		
Product preparation issue	1	1			1	1		
Product use issue	1	2			1	2		
Rib fracture	1	1					1	1
Underdose	2	3			2	3		
Wrong technique in product usage process	3	3			3	3		
	31	68	1	1	24	61	7	7

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood chloride increased	2	2	1	1	1	1
Blood glucose increased	3	3	1	1	2	2
Blood pressure decreased	1	1	1	1		
Blood pressure increased	8	9	3	4	5	5
Blood pressure systolic increased	1	1	1	1		
Coronavirus test positive	1	1			1	1
C-reactive protein increased	1	1	1	1		
Glomerular filtration rate decreased	1	1			1	1
Heart rate increased	6	7	6	7		
Inflammatory marker increased		1				1
International normalised ratio increased	1	1			1	1
Lymphocyte count increased	1	1	1	1		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Mean cell haemoglobin decreased	3	3	2	2	1	1
Mean cell volume decreased	1	1	1	1		
Mean platelet volume increased	1	1	1	1		
Neutrophil count increased	1	1			1	1
Oxygen saturation decreased	2	2	1	1	1	1
Pulse abnormal	1	1			1	1
Red blood cell count increased	1	1	1	1		
Respiratory rate increased	1	1			1	1
SARS-CoV-2 ant body test negative	1	1	1	1		
SARS-CoV-2 test positive	5	6			5	6
Weight decreased	2	2	1	1	1	1
	46	50	24	26	22	24

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	4	4	3	3	1	1
Food craving	1	1	1	1		
	5	5	4	4	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	10	11	8	9	2	2
Arthropathy	1	1	1	1		
Back pain	7	7	7	7		
Bone pain		1		1		
Facial asymmetry	1	1	1	1		
Joint swelling	1	1	1	1		
Limb discomfort	2	2	2	2		
Mobility decreased		1				1
Muscle twitching	1	1	1	1		
Muscular weakness	1	1	1	1		
Myalgia	27	29	25	27	2	2
Neck pain	2	3	2	3		
Pain in extremity	28	31	28	31		
Pain in jaw	3	3	3	3		
	84	93	80	88	4	5

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	2	1	2		
Balance disorder		1		1		
Cerebellar haemorrhage	1	1			1	1
Cerebral ischaemia	1	1			1	1
Cerebrovascular accident	2	2			2	2
Depressed level of consciousness	1	1			1	1
Dizziness	22	28	19	25	3	3
Dysgeusia	7	8	7	8		
Dysstasia	1	1			1	1
Facial paralysis	10	11			10	11
Formication	2	2	2	2		
Headache	43	45	40	42	3	3
Head discomfort	2	2	2	2		
Hypoaesthesia	19	23	19	23		
Loss of consciousness	1	2			1	2
Migraine	1	1	1	1		
Movement disorder	2	2	1	1	1	1
Multiple sclerosis	1	1			1	1
Multiple sclerosis relapse	3	3			3	3
Muscle contractions involuntary	2	2	2	2		
Neuralgia	1	1	1	1		
Neuralgic amyotrophy	2	2	2	2		
Neuritis	1	1	1	1		
Paraesthesia	16	20	15	19	1	1
Paralysis		1				1
Paraplegia	1	1			1	1
Parosmia	1	1	1	1		
Poor quality sleep		1		1		
Presyncope	1	1	1	1		
Seizure	1	1			1	1
Sensory disturbance	1	1	1	1		

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory loss		1		1		
Somnolence	1	1	1	1		
Speech disorder	1	1	1	1		
Syncope	7	8			7	8
Taste disorder	1	1	1	1		
Tremor	3	4	3	4		
	161	187	123	145	38	42

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue		14		14
Product complaint		1		1
Product deposit		1		1
Product packaging quantity issue	1	12	1	12
	1	28	1	28

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anger	1	1	1	1
Anxiety	1	1	1	1
Confusional state	1	1	1	1
Depressed mood	1	1	1	1
Depression	1	1	1	1
Initial insomnia		1		1
Insomnia	1	2	1	2
Personality change	1	1	1	1
Sleep disorder due to general medical condition, insomnia type		1		1
Stress	1	1	1	1
	8	11	8	11

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pelvic pain	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	1	1			1	1
Asthma	1	1	1	1		
Choking	2	2			2	2
Cough	6	6	6	6		
Dyspnoea	13	15	6	8	7	7
Dyspnoea exertional	1	1	1	1		
Hypoventilation	1	1			1	1
Lung disorder	1	1	1	1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	8	8	8	8		
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling	1	2	1	2		
Pleural effusion	1	1			1	1
Pleuritic pain		1				1
Respiratory arrest	1	1			1	1
Respiratory distress	1	1			1	1
Rhinalgia		1		1		
Rhinorrhoea	3	3	3	3		
Sneezing	2	2	2	2		
Suffocation feeling	1	1	1	1		
Throat tightness	1	1			1	1
Wheezing	1	1			1	1
Yawning	1	1	1	1		
	47	54	31	37	16	17

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia	1	1	1	1		
Cold sweat	1	1	1	1		
Erythema	6	7	6	7		
Hyperhidrosis	3	3	3	3		
Miliaria	1	1	1	1		
Pruritus	3	3	2	2	1	1
Rash	8	10	6	7	2	3
Rash macular	1	1	1	1		
Rash pruritic	1	1	1	1		
Skin burning sensation	2	2	2	2		
Skin disorder		1		1		
Urticaria	5	6	2	3	3	3
	32	37	26	30	6	7

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Impaired quality of life	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse	1	1			1	1
Hot flush	1	1	1	1		
Hypertension	4	5	1	2	3	3
Hypotension	1	1	1	1		
Thrombosis	3	3			3	3
	10	11	3	4	7	7

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Country Where Event Occurred

**ITALY**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	2	2	2	2		
Lymphadenopathy	32	32	29	29	3	3
Lymph node pain	5	5	5	5		
	39	39	36	36	3	3

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	3	3			3	3
Acute myocardial infarction	2	2			2	2
Atrioventricular block complete	1	1			1	1
Bradycardia	2	2			2	2
Cardiac failure	1	1			1	1
Myocardial ischaemia	1	1			1	1
Palpitations	3	3	3	3		
Sinus tachycardia	2	2	1	1	1	1
Tachycardia	27	27	22	22	5	5
Tachycardia paroxysmal	2	2	1	1	1	1
	44	44	27	27	17	17

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System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Deafness bilateral	1	1			1	1
Ear pain	1	1	1	1		
Ear pruritus	1	1	1	1		
Vertigo	23	23	21	21	2	2
	26	26	23	23	3	3

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenopia	1	1	1	1		
Corneal bleeding	1	1			1	1
Eye irritation	2	2	2	2		
Eyelid oedema	1	1			1	1
Eye pain	2	2	2	2		
Eye pruritus	2	2	2	2		
Lacrimation increased	2	2	2	2		
Ocular hyperaemia	1	1	1	1		
Periorbital oedema	1	1			1	1
Periorbital swelling	2	2	2	2		
Photophobia	1	1	1	1		
Swelling of eyelid	1	1	1	1		
Vision blurred	5	5	5	5		
Visual impairment	1	1	1	1		
	23	23	20	20	3	3

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	11	12	11	12		
Abdominal pain upper	8	8	8	8		
Anal incontinence	1	1	1	1		
Constipation	1	1	1	1		
Diarrhoea	25	25	25	25		
Dry mouth	13	13	11	11	2	2
Dyspepsia	1	1	1	1		
Dysphagia	10	10	6	6	4	4
Flatulence	2	2	2	2		
Gastritis	1	1	1	1		
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal sounds abnormal	1	1	1	1		
Gingival swelling	1	1	1	1		
Hypoaesthesia oral	8	8	8	8		
Lip oedema	8	8	6	6	2	2
Lip pruritus	2	2	2	2		
Lip swelling	2	2	2	2		
Nausea	50	50	48	48	2	2
Oedema mouth	2	2	1	1	1	1
Oral discomfort	1	1	1	1		
Oral dysaesthesia	1	1	1	1		
Palatal oedema	1	1			1	1
Palatal swelling	1	1	1	1		
Paraesthesia oral	21	21	17	17	4	4
Parotid gland enlargement	1	1	1	1		
Retching	1	1	1	1		
Swollen tongue	3	3	2	2	1	1
Tongue discomfort	1	1	1	1		
Tongue disorder	1	1	1	1		
Tongue dry	3	3	1	1	2	2
Tongue oedema	3	3	1	1	2	2

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
			Tongue pruritus	1	1	1
Vomiting	12	12	10	10	2	2
	200	201	177	178	23	23

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Administration site reaction	1	1
Asthenia	40	41
Axillary pain	5	5
Chest discomfort	4	4
Chest pain	1	1
Chills	38	39
Condition aggravated	1	1
Crying	1	1
Death	3	3
Discomfort	1	1
Drug ineffective	11	11
Face oedema	2	2
Facial pain	1	1
Fatigue	23	23
Feeling abnormal	2	2
Feeling cold	5	5
Feeling hot	16	16
Feeling of body temperature change	1	1
General physical health deterioration	1	1
Hyperpyrexia	2	2
Hyperthermia	2	2
Inflammation	1	1
Influenza like illness	5	7
Injection site pain	5	5
Localised oedema	2	2
Malaise	21	22
Mucosal dryness	1	1
Oedema peripheral	1	1
Pain	14	14
Peripheral swelling	1	1
Pyrexia	106	106
Sensation of foreign body	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		37	38	3	3
		4	4	1	1
		3	3	1	1
		1	1		
1	1	36	37	2	2
				1	1
		1	1		
				3	3
		1	1		
				11	11
		1	1	1	1
		1	1		
1	1	22	22	1	1
		2	2		
1	1	4	4	1	1
		14	14	2	2
		1	1		
				1	1
				2	2
		1	1	1	1
				1	1
		5	7		
		4	4	1	1
		2	2		
		19	20	2	2
		1	1		
		1	1		
		12	12	2	2
		1	1		
1	1	101	101	5	5
		1	1		

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sudden death	1	1
Swelling	4	4
Swelling face	3	3
Tenderness	1	1
Vaccination site discolouration	1	1
Vaccination site discomfort	3	3
Vaccination site erythema	12	13
Vaccination site hypoaesthesia	1	1
Vaccination site induration	1	1
Vaccination site joint swelling	1	1
Vaccination site joint warmth	1	1
Vaccination site lymphadenopathy	2	2
Vaccination site movement impairment	3	3
Vaccination site oedema	6	6
Vaccination site pain	162	163
Vaccination site paraesthesia	5	5
Vaccination site pruritus	4	4
Vaccination site rash	1	1
Vaccination site swelling	12	12
Vaccination site urticaria	6	6
Vaccination site warmth	4	5
	<b>553</b>	<b>561</b>

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		3	3	1	1
		2	2	1	1
		1	1		
		1	1		
		3	3		
		11	12	1	1
		1	1		
		1	1		
		1	1		
		1	1		
		1	1	1	1
		3	3		
		6	6		
		160	161	2	2
		5	5		
		3	3	1	1
		1	1		
		11	11	1	1
		5	5	1	1
		3	4	1	1
		<b>4</b>	<b>4</b>	<b>54</b>	<b>54</b>

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	6	6			6	6
Anaphylactic shock	7	7			7	7
Hypersensitivity	3	3	1	1	2	2
	17	17	1	1	16	16

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	5	5			5	5
Herpes zoster	2	2	1	1	1	1
Lymphangitis	1	1			1	1
Mastitis	1	1			1	1
Nasopharyngitis	2	2	1	1	1	1
Oral herpes	2	2	2	2		
Pharyngitis	2	2	2	2		
Q fever	1	1			1	1
	16	16	6	6	10	10

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circumstance or information capable of leading to medication error		1		1		
Exposure via breast milk	1	1	1	1		
Fall	1	1			1	1
Incorrect dose administered	3	3	3	3		
Incorrect route of product administration	2	2	2	2		
Off label use	3	3	3	3		
Overdose	4	4	4	4		
Poor quality product administered	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Product administered to patient of inappropriate age	1	1	1	1		
Product administration error	1	1	1	1		
Product label confusion		1		1		
Product preparation issue	1	1	1	1		
Product use issue	2	2	2	2		
Underdose	7	7	7	7		
Wrong technique in product usage process	2	2	2	2		
	30	32	29	31	1	1

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure diastolic increased	1	1	1	1		
Blood pressure increased	7	7	5	5	2	2
Body temperature decreased	2	2	2	2		
Body temperature increased	2	3	1	2	1	1
Coma scale abnormal	1	1			1	1
Heart rate decreased	1	1	1	1		
Inspiratory capacity abnormal	1	1	1	1		
Oxygen saturation decreased	2	2	1	1	1	1
SARS-CoV-2 ant body test positive	2	2	2	2		
SARS-CoV-2 test positive	6	6			6	6
Weight decreased	1	1			1	1
	28	29	15	16	13	13

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	2	2	2		
Dehydration	1	1			1	1
Hypoglycaemia	1	1	1	1		
	4	4	3	3	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	40	41	38	39	2	2
Back pain	5	5	3	3	2	2
Bone pain	4	4	4	4		
Extremity contracture	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Limb discomfort	6	6	6	6		
Muscle rigidity	1	1			1	1
Muscle spasms	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal pain	9	9	9	9		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	46	46	44	44	2	2
Neck pain	4	4	4	4		
Nuchal rigidity	1	1			1	1
Pain in extremity	34	34	32	32	2	2
Spinal pain	4	4	4	4		
Torticollis	1	1	1	1		
	160	161	150	151	10	10

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ageusia	1	1			1	1		
Allodynia	1	1			1	1		
Anaesthesia	2	2			1	1	1	1
Anosmia	1	1			1	1		
Aura	1	1			1	1		
Balance disorder	2	2			2	2		
Band sensation	1	1			1	1		
Burning sensation	1	1			1	1		
Cerebellar haemorrhage	1	1					1	1
Cerebrovascular accident	1	1					1	1
Cranial nerve disorder	1	1					1	1
Depressed level of consciousness	3	3			1	1	2	2
Dizziness	20	20			20	20		
Dysaesthesia	2	2			2	2		
Dysgeusia	15	15			13	13	2	2
Facial paralysis	1	1					1	1
Facial spasm	1	1					1	1
Headache	119	120	1	1	116	117	3	3
Head discomfort	1	1			1	1		
Hemiparesis	1	1					1	1
Hyperaesthesia	1	1			1	1		
Hypoaesthesia	9	9			9	9		
Loss of consciousness	1	1					1	1
Migraine	8	8			8	8		
Monoparesis	1	1			1	1		
Muscle contractions involuntary	1	1					1	1
Neuralgia	2	2			2	2		
Neuritis	1	1			1	1		
Paraesthesia	29	29			25	25	4	4
Paresis	1	1			1	1		
Paresis cranial nerve	1	1			1	1		
Parosmia	1	1			1	1		

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Presyncope	9	9			8	8	1	1
Reduced facial expression	1	1					1	1
Sciatica	1	1			1	1		
Somnolence	15	15			15	15		
Speech disorder	1	1			1	1		
Stupor	2	2			2	2		
Syncope	2	2					2	2
Tonic clonic movements	1	1					1	1
Tremor	10	10			9	9	1	1
	274	275	1	1	248	249	26	26

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Agitation	3	3	3	3		
Anxiety	2	2	2	2		
Confusional state	7	7	6	6	1	1
Disorientation	1	1	1	1		
Insomnia	4	4	4	4		
Irritability	1	1	1	1		
Restlessness	1	1			1	1
	19	19	17	17	2	2

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System Organ Class

**Renal and urinary disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysuria	1	1			1	1
Polyuria	1	1	1	1		
Renal failure	1	1			1	1
Renal pain	1	1	1	1		
	4	4	2	2	2	2

System Organ Class

**Reproductive system and breast disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Breast discomfort	1	1	1	1
Breast pain	1	1	1	1
Breast swelling	1	1	1	1
	3	3	3	3

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Acute respiratory failure	1	1
Allergic respiratory symptom	1	1
Asphyxia	1	1
Bronchospasm	1	1
Cough	9	9
Dry throat	1	1
Dysphonia	2	2
Dyspnoea	17	17
Hyperventilation	1	1
Intranasal hypoaesthesia	1	1
Intranasal paraesthesia	1	1
Laryngeal oedema	9	9
Laryngeal pain	1	1
Laryngospasm	1	1
Nasal congestion	2	2
Obstructive airways disorder	1	1
Oropharyngeal pain	4	4
Oropharyngeal swelling	1	1
Pharyngeal erythema	1	1
Pharyngeal paraesthesia	2	2
Pharyngeal swelling	1	1
Pulmonary embolism	1	1
Respiratory arrest	1	1
Respiratory distress	1	1
Rhinorrhoea	4	4
Sneezing	1	1
Tachypnoea	1	1
Throat irritation	4	4
Throat tightness	12	12
Tonsillar erythema	1	1
Tonsillar hypertrophy	1	1
Vasomotor rhinitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	1
				1	1
		8	8	1	1
		1	1		
		2	2		
1	1	8	8	9	9
		1	1		
		1	1		
		1	1		
				9	9
		1	1		
				1	1
		2	2		
				1	1
		4	4		
		1	1		
		1	1		
		2	2		
				1	1
				1	1
				1	1
		4	4		
		1	1		
		1	1		
		3	3	1	1
		8	8	4	4
		1	1		
		1	1		
		1	1		

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
	87	87	1	1	53	53	34	34

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	2	2			2	2
Dermatitis	1	1			1	1
Dermatitis allergic	1	1			1	1
Dermatitis exfoliative generalised	1	1			1	1
Erythema	31	31	26	26	5	5
Hyperhidrosis	12	12	11	11	1	1
Mechanical urticaria	1	1	1	1		
Night sweats	1	1	1	1		
Pityriasis rosea	1	1	1	1		
Pruritus	27	27	24	24	3	3
Rash	25	25	24	24	1	1
Rash erythematous	3	3	3	3		
Rash pruritic	1	1	1	1		
Skin reaction	2	2	2	2		
Urticaria	33	33	30	30	3	3
	142	142	124	124	18	18

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arteriosclerosis	1	1			1	1
Circulatory collapse	1	1			1	1
Deep vein thrombosis	1	1			1	1
Flushing	9	9	9	9		
Haematoma	1	1	1	1		
Hot flush	8	8	8	8		
Hypertension	7	7	3	3	4	4
Hypertensive crisis	6	6			6	6
Hypotension	11	11	8	8	3	3
Lymphoedema	1	1	1	1		
Pallor	3	3	3	3		
Peripheral coldness	5	5	5	5		
Systolic hypertension	1	1			1	1
Vasoconstriction	1	1	1	1		
	56	56	39	39	17	17

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Country Where Event Occurred

**KUWAIT**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Pyrexia	1	1	1	1
Swelling	1	1	1	1
Tenderness	1	1	1	1
Vaccination site pain	1	1	1	1
Vaccination site swelling	1	1	1	1
	6	6	6	6

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	1	1	1	1
Neck pain	1	1	1	1
	2	2	2	2

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Country Where Event Occurred  
**LATVIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	1	1	1	1		
Lymph node pain	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye pain	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	1	1	1		
Dry mouth	1	1			1	1
Nausea	1	1	1	1		
Palatal swelling	1	1	1	1		
Vomiting	1	1	1	1		
	5	5	4	4	1	1

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	4	3	3	1	1
Chest pain	1	1	1	1		
Chills	1	1	1	1		
Drug ineffective	5	5			5	5
Fatigue	3	3	3	3		
Feeling hot	1	1	1	1		
Illness	1	1	1	1		
Malaise	1	1	1	1		
Pyrexia	3	3	2	2	1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	6	6	6	6		
Vaccination site pruritus	2	2	2	2		
Vaccination site swelling	1	1	1	1		
	31	31	23	23	8	8

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	4	4	4	4
	4	4	4	4

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System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	1	1	1		
Blood pressure increased	2	2	1	1	1	1
Body temperature increased	6	6	5	5	1	1
SARS-CoV-2 test positive	1	1			1	1
	10	10	7	7	3	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	5	5	4	4	1	1
Musculoskeletal discomfort	1	1	1	1		
Myalgia	4	4	4	4		
Pain in extremity	3	3	2	2	1	1
	13	13	11	11	2	2

System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1			1	1
Dizziness	1	1	1	1		
Dysgeusia	1	1			1	1
Headache	5	5	3	3	2	2
Neuralgia	1	1			1	1
Paraesthesia	1	1			1	1
Syncope	1	1			1	1
	11	11	4	4	7	7

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anxiety	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthma	1	1	1	1
Cough	1	1	1	1
Dyspnoea	1	1	1	1
Throat irritation	1	1	1	1
	4	4	4	4

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cold sweat	1	1			1	1
Erythema	1	1			1	1
Night sweats	1	1	1	1		
Pruritus	1	1			1	1
	4	4	1	1	3	3

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	2	2	1	1	1	1
	2	2	1	1	1	1

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Country Where Event Occurred  
**LITHUANIA**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Tachycardia	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	2	2	2	2
Peripheral swelling	1	1	1	1
Pyrexia	6	6	6	6
Vaccination site erythema	1	1	1	1
Vaccination site pain	2	2	2	2
	12	12	12	12

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Overdose	1	1	1	1
Underdose	1	1	1	1
Vaccination complication	1	1	1	1
	3	3	3	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	2	2	2	2
Back pain	1	1	1	1
Myalgia	5	5	5	5
Neck pain	1	1	1	1
Pain in extremity	2	2	2	2
	11	11	11	11

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	2	2	2	2
Headache	4	4	4	4
Hypoaesthesia	1	1	1	1
Tremor	1	1	1	1
	8	8	8	8

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Sensitive skin	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**LUXEMBOURG**

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Herpes zoster	1	1	1	1
Oral herpes	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**MALTA**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		1		1		
Tachycardia		1				1
		2		1		1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Nausea	1	2	1	2
Vomiting		1		1
	1	4	1	4

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	1	1			1	1
Fatigue	1	2	1	2		
Malaise	1	1	1	1		
Pain	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vaccination site urticaria		1		1		
	5	7	4	6	1	1

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypersensitivity		1		1
		1		1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	2	2	2	2
	2	2	2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness		1		1
Facial paralysis	1	1	1	1
Hypoaesthesia	1	1	1	1
Lethargy	1	2	1	2
Paraesthesia	1	2	1	2
Somnolence	1	1	1	1
	5	8	5	8

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dyspnoea	1	1	1	1
Wheezing	1	1	1	1
	2	2	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema		1		1		
Rash erythematous		1		1		
Rash pruritic	1	1			1	1
	1	3		2	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hot flush		1		1		
Hypertension		1				1
		2		1		1

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Country Where Event Occurred  
**MEXICO**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	3	3	3	3		
Lymphopenia	1	1			1	1
	4	4	3	3	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Palpitations	1	1	1	1		
Tachycardia	11	11	10	10	1	1
	13	13	11	11	2	2

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear pain	1	1	1	1
Vertigo	1	1	1	1
	2	2	2	2

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye inflammation	1	1	1	1		
Eye pain	1	1	1	1		
Eye swelling	1	2		1	1	1
	3	4	2	3	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	4	4	4	4		
Abdominal pain upper	2	2	2	2		
Diarrhoea	6	6	5	5	1	1
Epigastric discomfort	1	1	1	1		
Gastrointestinal disorder	1	1			1	1
Gastrointestinal motility disorder	1	1	1	1		
Lip oedema	1	1	1	1		
Nausea	16	16	14	14	2	2
Paraesthesia oral	2	2	1	1	1	1
Parotid gland enlargement	1	1	1	1		
Vomiting	4	4	3	3	1	1
	39	39	33	33	6	6

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	23	23	21	21	2	2
Chest discomfort	1	1	1	1		
Chest pain	1	1	1	1		
Chills	15	15	15	15		
Discomfort	7	7	7	7		
Drug ineffective	11	11			11	11
Face oedema	1	1	1	1		
Fatigue	5	6	5	6		
Feeling cold	1	1	1	1		
Feeling hot	2	2	2	2		
Inflammation	2	2	1	1	1	1
Local reaction	2	2	2	2		
Nodule	1	1	1	1		
Oedema	7	7	7	7		
Pain	14	14	13	13	1	1
Pyrexia	31	31	30	30	1	1
Swelling	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site induration	2	2	2	2		
Vaccination site inflammation	1	1	1	1		
Vaccination site nodule	3	3	3	3		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	40	41	39	40	1	1
Vaccination site rash	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site warmth	1	1	1	1		
	179	181	162	164	17	17

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	3	3	3	3		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock		1				1
Hypersensitivity	2	3	2	3		
	6	8	5	6	1	2

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	6	6			6	6
COVID-19 pneumonia	3	3			3	3
Parotitis	1	1	1	1		
Pneumonia	3	3			3	3
Suspected COVID-19	1	1			1	1
	14	14	1	1	13	13

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Inappropriate schedule of product administration	1	1	1	1		
Maternal exposure during pregnancy	1	1	1	1		
Off label use	2	2	2	2		
Peroneal nerve injury	1	1			1	1
Product use issue	2	2	2	2		
	7	7	6	6	1	1

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System Organ Class

**Investigations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1			1	1
Body temperature increased	4	4	4	4		
Coagulation time prolonged	1	1			1	1
Oxygen saturation decreased	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
	8	8	4	4	4	4

System Organ Class

**Metabolism and nutrition disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	2	2	2	2
	2	2	2	2

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	36	36	35	35	1	1
Back pain	1	1	1	1		
Masticatory pain	1	1	1	1		
Mobility decreased	3	3	3	3		
Muscle contracture	1	1	1	1		
Muscle spasms	2	3	2	2		1
Muscular weakness	1	1	1	1		
Myalgia	33	33	32	32	1	1
Neck pain	1	1	1	1		
Pain in extremity	2	3	2	3		
Sacroiliitis	1	1			1	1
	82	84	79	80	3	4

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Akathisia	1	1	1	1		
Anosmia	1	1	1	1		
Axonal neuropathy	1	1			1	1
Burning sensation	2	2			2	2
Demyelination	2	2			2	2
Dizziness	18	18	17	17	1	1
Dysgeusia	2	2	2	2		
Encephalitis post immunisation		1				1
Epilepsy	1	1			1	1
Headache	54	55	51	52	3	3
Hypoaesthesia	3	3	2	2	1	1
Loss of consciousness		1				1
Mononeuropathy	1	1			1	1
Muscle contractions involuntary	1	1	1	1		
Muscle spasticity	1	1			1	1
Myelitis transverse		1				1
Nerve degeneration	1	1			1	1
Neuritis	2	2			2	2
Paraesthesia	8	9	6	6	2	3
Paralysis		1				1
Peripheral motor neuropathy	1	1			1	1
Radiculopathy	2	2			2	2
Sciatica	1	1			1	1
Sciatic nerve neuropathy	1	1			1	1
Seizure	5	6			5	6
Sensory loss	2	2	1	1	1	1
Slow response to stimuli	1	1	1	1		
Somnolence	1	1	1	1		
Syncope	2	2			2	2
	116	123	85	86	31	37

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System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pelvic pain	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma	1	1	1	1		
Cough	9	9	9	9		
Dyspnoea	7	8	4	5	3	3
Laryngospasm		1		1		
Nasal congestion		1		1		
Oropharyngeal pain	3	3	3	3		
Respiratory distress	1	2			1	2
Rhinorrhoea	6	6	6	6		
Sneezing		1		1		
Throat irritation	1	2	1	2		
	28	34	24	29	4	5

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	2			1	2
Erythema	2	2	2	2		
Hyperhidrosis	1	1	1	1		
Mechanical urticaria	1	1	1	1		
Pruritus	4	5	3	4	1	1
Rash	13	14	11	11	2	3
Rash maculo-papular	1	1	1	1		
	23	26	19	20	4	6

System Organ Class

**Social circumstances**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Loss of personal independence in daily activities	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis		1		1		
Hot flush	1	1	1	1		
Hypertension	2	2	1	1	1	1
Hypertensive crisis	2	2			2	2
	5	6	2	3	3	3

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Country Where Event Occurred  
**NETHERLANDS**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Palpitations	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Diarrhoea	1	1	1	1		
Dysphagia	1	1			1	1
Nausea	2	2	2	2		
Paraesthesia oral	1	1	1	1		
Tongue oedema	1	1			1	1
Vomiting	1	1	1	1		
	8	8	6	6	2	2

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Axillary pain	1	1	1	1		
Chest discomfort	1	1			1	1
Chills	2	2	1	1	1	1
Influenza like illness	1	1	1	1		
Malaise	1	1			1	1
Vaccination site pain	1	1	1	1		
	7	7	4	4	3	3

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergy to vaccine	1	1	1	1
Anaphylactic reaction	2	2	2	2
	3	3	3	3

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error	1	1	1	1
Exposure via breast milk	1	1	1	1
Incorrect route of product administration	1	1	1	1
Product label confusion	1	1	1	1
Product preparation error	1	1	1	1
	5	5	5	5

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	2	2	2	2
	2	2	2	2

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	2	2	1	1	1	1
Headache	4	4	4	4		
Head discomfort	1	1			1	1
Paraesthesia	1	1			1	1
	8	8	5	5	3	3

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anxiety	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1	1	1		
Hyperventilation	1	1			1	1
Oropharyngeal pain	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Sneezing	1	1	1	1		
	5	5	3	3	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Erythema	2	2	1	1	1	1
Pruritus	1	1			1	1
Rash	1	1			1	1
Rash maculo-papular	1	1	1	1		
Urticaria	2	2	1	1	1	1
	8	8	3	3	5	5

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Peripheral coldness	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

*System Organ Class*

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Chest discomfort	1	1	1	1
Chills	1	1	1	1
Fatigue	1	1	1	1
	3	3	3	3

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Pain in extremity	1	1	1	1
	2	2	2	2

*System Organ Class*

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
Headache	1	1	1	1
Poor quality sleep	1	1	1	1
	3	3	3	3

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disorientation	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**NORWAY**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute coronary syndrome	1	1	1	1
Acute myocardial infarction	1	1	1	1
Cardiac failure	1	1	1	1
Cardiovascular disorder	1	1	1	1
Intracardiac thrombus	1	1	1	1
	5	5	5	5

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm	1	1	1	1		
Pupil fixed	2	2			2	2
	3	3	1	1	2	2

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	2	2			2	2
Dysphagia	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
Nausea	3	3	1	1	2	2
Retching	1	1	1	1		
Vomiting	5	5	1	1	4	4
	13	13	3	3	10	10

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	1	1			1	1
Chills	1	1	1	1		
Concomitant disease aggravated	1	1			1	1
Condition aggravated	1	1			1	1
Death	8	8			8	8
Disease recurrence	1	1			1	1
Fatigue	6	6	3	3	3	3
Feeling hot	2	2	1	1	1	1
General physical health deterioration	8	8			8	8
Influenza like illness	1	1			1	1
Injection site muscle weakness	1	1	1	1		
Local reaction	1	1			1	1
Malaise	3	3	1	1	2	2
Pyrexia	6	6	2	2	4	4
Sudden death	3	3			3	3
Vaccination site erythema	1	1			1	1
Vaccination site pain	3	3	2	2	1	1
Vaccination site swelling	2	2	1	1	1	1
	50	50	12	12	38	38

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypersensitivity	1	1	1	1
	1	1	1	1

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infection	1	1			1	1
Pneumonia	3	3			3	3
Urinary tract infection	1	1	1	1		
	5	5	1	1	4	4

System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Incorrect dose administered	1	1	1	1
Poor quality product administered	6	6	6	6
Product administered at inappropriate site	1	1	1	1
Product preparation error	2	2	2	2
Wrong technique in product usage process	1	1	1	1
	11	11	11	11

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System Organ Class

Investigations	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
<i>Preferred Term</i>						
Blood pressure decreased	2	2			2	2
Blood pressure diastolic decreased	1	1	1	1		
Body temperature decreased	1	1	1	1		
Body temperature increased	1	1	1	1		
Heart rate increased	2	2			2	2
Heart rate irregular	1	1	1	1		
Oxygen saturation decreased	3	3			3	3
Respiratory rate increased	3	3			3	3
	14	14	4	4	10	10

System Organ Class

Metabolism and nutrition disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
<i>Preferred Term</i>				
Decreased appetite	2	2	2	2
Hypophagia	1	1	1	1
	3	3	3	3

System Organ Class

Musculoskeletal and connective tissue disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
<i>Preferred Term</i>				
Arthralgia	1	1	1	1
Pain in extremity	1	1	1	1
	2	2	2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	2	2			2	2
Coordination abnormal	1	1			1	1
Depressed level of consciousness	2	2			2	2
Dizziness	2	2	1	1	1	1
Headache	2	2	2	2		
Loss of consciousness	1	1			1	1
Somnolence	2	2			2	2
Syncope	2	2			2	2
Tremor	1	1			1	1
	17	17	3	3	14	14

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product temperature excursion issue	6	6	6	6
	6	6	6	6

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Apathy	1	1			1	1
Confusional state	3	3			3	3
Delirium	1	1			1	1
Hallucination	1	1			1	1
Restlessness	1	1	1	1		
	8	8	2	2	6	6

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	1	1			1	1
Dyspnoea	4	4			4	4
Hyperventilation	1	1	1	1		
Rales	1	1			1	1
Respiratory arrest	1	1			1	1
	8	8	1	1	7	7

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cold sweat	3	3	3	3
	3	3	3	3

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	1	1	1		
Hypotension	2	2			2	2
Malignant hypertension	1	1			1	1
Pallor	2	2			2	2
	6	6	1	1	5	5

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Country Where Event Occurred  
**OMAN**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Gastritis		1		1
		2		2

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue		1		1
Pain		1		1
Pyrexia		1		1
		3		3

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache		1		1
		1		1

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Country Where Event Occurred  
**POLAND**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	6	6	6	6
Lymph node pain	1	1	1	1
	7	7	7	7

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Arrhythmia	1	1	1	1
Tachycardia	2	2	2	2
	3	3	3	3

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear pain	1	1	1	1
	1	1	1	1

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Conjunctival hyperaemia	1	1	1	1
Eye pain	1	1	1	1
Iritis	1	1	1	1
Vision blurred	1	1	1	1
	4	4	4	4

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	3	3	3		
Abdominal pain upper	1	1			1	1
Diarrhoea	5	5	5	5		
Dry mouth	1	1	1	1		
Hyperaesthesia teeth	1	1	1	1		
Hypoesthesia oral	2	2	1	1	1	1
Nausea	10	10	10	10		
Pancreatitis	1	1			1	1
Retching	1	1	1	1		
Toothache		1		1		
Vomiting	4	4	4	4		
	29	30	26	27	3	3

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	26	27	25	26	1	1
Axillary pain	3	3	3	3		
Chest discomfort	2	2	2	2		
Chills	14	14	13	13	1	1
Crying	1	1	1	1		
Decreased activity	1	1	1	1		
Disease recurrence	1	1			1	1
Drug ineffective	13	13			13	13
Fatigue	6	6	6	6		
Feeling abnormal	4	4	4	4		
Feeling cold	2	2	1	1	1	1
Feeling hot	1	1	1	1		
Gait disturbance	1	1	1	1		
Inflammation	2	2	2	2		
Influenza like illness	4	4	4	4		
Malaise	8	8	8	8		
Oedema	1	1	1	1		
Pain	3	3	2	2	1	1
Peripheral swelling	1	1	1	1		
Pyrexia	33	34	29	30	4	4
Swelling	3	3	2	2	1	1
Therapeutic response unexpected	1	1	1	1		
Vaccination site erythema	4	4	4	4		
Vaccination site extravasation	1	1	1	1		
Vaccination site induration	2	2	2	2		
Vaccination site macule	1	1	1	1		
Vaccination site movement impairment	2	2	2	2		
Vaccination site pain	37	38	36	37	1	1
Vaccination site pruritus	4	4	4	4		
Vaccination site reaction	7	7	7	7		
Vaccination site scab	1	1	1	1		
Vaccination site swelling	6	6	6	6		

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site vesicles	1	1	1	1		
Vaccination site warmth	2	2	2	2		
	199	202	175	178	24	24

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypersensitivity	2	2	2	2
	2	2	2	2

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	1			1	1
COVID-19	11	11			11	11
Cystitis	1	1	1	1		
Herpes virus infection	3	3	3	3		
Herpes zoster	1	1	1	1		
Pneumonia	1	1			1	1
Pulpitis dental		1		1		
Sinusitis	1	1	1	1		
Vaccination site infection	1	1	1	1		
	20	21	7	8	13	13

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circumstance or information capable of leading to medication error	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Exposure via breast milk	7	7	7	7		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	2	2	2	2		
Maternal exposure during pregnancy	1	1	1	1		
Off label use	8	8	7	7	1	1
Product label confusion	2	2	2	2		
Product use issue	8	8	7	7	1	1
	32	32	30	30	2	2

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	1	1	1	1		
Blood pressure increased	2	2	1	1	1	1
Blood urine present	1	1	1	1		
Body temperature increased	2	2	2	2		
Heart rate increased	2	2	1	1	1	1
Oxygen saturation decreased	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
	10	10	6	6	4	4

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite	2	2	2	2
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	19	20	18	19	1	1
Arthritis		1		1		
Back pain	2	2	2	2		
Bone pain	3	3	3	3		
Joint range of motion decreased	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	20	20	19	19	1	1
Neck pain	3	3	2	2	1	1
Pain in extremity	17	18	15	16	2	2
Spinal pain	2	2	1	1	1	1
	68	71	62	65	6	6

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	2	2		
Anosmia	3	3	3	3		
Burning sensation	1	1	1	1		
Dizziness	5	5	5	5		
Dysgeusia	2	2	2	2		
Dysstasia	1	1	1	1		
Headache	25	26	24	25	1	1
Hyperaesthesia	1	1			1	1
Hypoaesthesia	3	3	2	2	1	1
Migraine	1	1	1	1		
Paraesthesia	1	1	1	1		
Paralysis	1	1			1	1
Paraparesis	1	1			1	1
Paresis	2	2	1	1	1	1
Poor quality sleep	1	1	1	1		
Presyncope	1	1	1	1		
Somnolence	3	3	3	3		
Taste disorder	2	2	2	2		
Tremor	2	2	2	2		
Visual field defect	1	1	1	1		
	59	60	53	54	6	6

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Needle issue	1	1	1	1
	1	1	1	1

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	2	2	2	2		
Helplessness	1	1			1	1
Initial insomnia	1	1	1	1		
Insomnia	2	2	2	2		
	6	6	5	5	1	1

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dysuria	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast pain	1	1	1	1		
Suppressed lactation	2	2	1	1	1	1
	3	3	2	2	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	3	3	3	3
Dyspnoea	2	2	2	2
Epistaxis	2	2	2	2
Oropharyngeal pain	3	3	3	3
Painful respiration	1	1	1	1
Rhinorrhoea	2	2	2	2
Throat irritation	1	1	1	1
Tonsillar hypertrophy	1	1	1	1
	15	15	15	15

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	1			1	1
Hyperhidrosis	1	1	1	1		
Pain of skin	1	1	1	1		
Pruritus	1	1	1	1		
Rash	2	2	2	2		
Rash macular	1	1	1	1		
Urticaria	2	2	2	2		
	9	9	8	8	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematoma	1	1	1	1		
Hot flush	3	3	2	2	1	1
Pallor	2	2	1	1	1	1
	6	6	4	4	2	2

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Country Where Event Occurred

**PORTUGAL**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenitis	1	1	1	1		
Lymphadenopathy	7	7	4	4	3	3
	8	8	5	5	3	3

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardio-respiratory arrest	1	1			1	1
Palpitations	1	1	1	1		
Sinus tachycardia		1				1
Tachycardia	5	5	3	3	2	2
	7	8	4	4	3	4

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo positional	1	1	1	1
	1	1	1	1

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System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypothyroidism	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry eye	1	1	1	1		
Exophthalmos	1	1	1	1		
Eye irritation	1	1	1	1		
Eyelid oedema	1	1			1	1
Eye movement disorder	1	1			1	1
Eye pain	1	1	1	1		
Eye paraesthesia	1	1			1	1
Ocular discomfort	1	1	1	1		
	8	8	5	5	3	3

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	3	3	2	2	1	1
Abdominal pain	1	1			1	1
Abdominal pain upper	1	1	1	1		
Diarrhoea	2	2	2	2		
Dysphagia	1	1			1	1
Eructation	2	2	2	2		
Functional gastrointestinal disorder	1	1			1	1
Hypoaesthesia oral	6	6	1	1	5	5
Lip oedema	4	4			4	4
Lip pruritus	1	1			1	1
Nausea	11	12	7	7	4	5
Odynophagia	3	4		1	3	3
Oral disorder	1	1			1	1
Paraesthesia oral	4	4	1	1	3	3
Stomatitis	2	2	2	2		
Tongue disorder	1	1	1	1		
Tongue dry	1	1			1	1
Tongue eruption	1	1			1	1
Tongue oedema	3	3			3	3
Tongue pruritus	1	1			1	1
Vomiting	3	3	1	1	2	2
	53	55	20	21	33	34

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chest discomfort	1	1			1	1
Chest pain	3	3	1	1	2	2
Chills	6	6	3	3	3	3
Death	2	2			2	2
Drug ineffective	18	18			18	18
Face oedema	4	4	1	1	3	3
Fatigue	7	7	5	5	2	2
Feeling abnormal	1	1	1	1		
Feeling hot	1	1			1	1
Localised oedema	1	1	1	1		
Malaise	6	7	5	5	1	2
Pain	1	1	1	1		
Pyrexia	12	12	8	8	4	4
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	3	3	3	3		
Vaccination site oedema	3	3	1	1	2	2
Vaccination site pain	38	38	31	31	7	7
Vaccination site pruritus		1				1
Vaccination site swelling	2	2	2	2		
	111	113	65	65	46	48

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2			2	2
Anaphylactic reaction	1	1			1	1
Hypersensitivity	6	7	4	4	2	3
	9	10	4	4	5	6

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	15	15	15	15
	15	15	15	15

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	3	4	3	4
Inappropriate schedule of product administration	1	1	1	1
Incorrect route of product administration	2	2	2	2
Maternal exposure during pregnancy	1	1	1	1
Off label use	3	3	3	3
Overdose	4	4	4	4
Product use issue	2	2	2	2
Scar	1	1	1	1
	17	18	17	18

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1			1	1
Body temperature increased	1	1	1	1		
SARS-CoV-2 test positive	4	4			4	4
Thyroid function test abnormal	1	1	1	1		
Weight decreased	1	1	1	1		
	8	8	3	3	5	5

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	2	2	2	2		
Hyperglycaemia	1	1			1	1
	3	3	2	2	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Arthritis reactive	1	1			1	1
Muscular weakness	1	1			1	1
Myalgia	20	20	14	14	6	6
Pain in extremity	2	2	1	1	1	1
Pain in jaw	1	1			1	1
Tenosynovitis	1	1	1	1		
	27	27	17	17	10	10

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amnesia	1	1	1	1		
Balance disorder		1				1
Dizziness	2	3	2	2		1
Dysarthria	1	1	1	1		
Dysgeusia	2	2	1	1	1	1
Facial paralysis	1	1	1	1		
Generalised tonic-clonic seizure	1	1			1	1
Headache	19	20	14	15	5	5
Hypoaesthesia	2	2	2	2		
Intercostal neuralgia	1	1	1	1		
Migraine	4	4	1	1	3	3
Nystagmus	1	1			1	1
Paraesthesia	6	6	3	3	3	3
Presyncope	4	4	3	3	1	1
Sensory loss	1	1			1	1
Somnolence	6	6	3	3	3	3
Taste disorder	2	2	2	2		
Tremor	2	2	2	2		
	56	59	37	38	19	21

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	2	2			2	2
Laryngeal oedema	4	4			4	4
Nasal obstruction	1	1			1	1
Oropharyngeal discomfort	1	1			1	1
Oropharyngeal oedema	2	2	1	1	1	1
Oropharyngeal pain	1	1			1	1
Pharyngeal hypoesthesia	1	1			1	1
Pharyngeal paraesthesia	1	1			1	1
Productive cough	2	2			2	2
Respiratory tract congestion	1	1			1	1
Rhinorrhoea	3	3			3	3
Tachypnoea	1	1			1	1
Throat irritation	3	3	3	3		
Throat tightness	1	1			1	1
Upper-airway cough syndrome	1	1			1	1
	25	25	4	4	21	21

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circumoral oedema	1	1			1	1
Dermatitis allergic	1	1			1	1
Erythema	7	8	3	3	4	5
Hyperhidrosis	1	1			1	1
Palmar-plantar erythrodysesthesia syndrome	1	1			1	1
Pruritus	6	7	2	2	4	5
Rash	11	12	7	7	4	5
Rash maculo-papular	2	2	2	2		
Rash pruritic	2	2	2	2		
Urticaria	3	3	1	1	2	2
Urticaria cholinergic	1	1	1	1		
	36	39	18	18	18	21

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Embolism	1	1			1	1
Flushing	2	2			2	2
Pallor	3	3	2	2	1	1
Peripheral coldness	1	1			1	1
	7	7	2	2	5	5

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Country Where Event Occurred

**PUERTO RICO**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations		1		1		
Sinus arrhythmia	1	1			1	1
Tachycardia		1		1		
	1	3		2	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort	1	1	1	1
Abdominal pain		1		1
Diarrhoea	1	2	1	2
Gingival bleeding	1	1	1	1
Nausea		3		3
	3	8	3	8

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia		1		1
Axillary pain	1	1	1	1
Chills	4	4	4	4
Fatigue	5	6	5	6
Gait disturbance		1		1
Inflammation		1		1
Malaise		1		1
Nodule		1		1
Pain	1	3	1	3
Pyrexia	5	7	5	7
Swelling face		1		1
Vaccination site discomfort		1		1
Vaccination site erythema	1	1	1	1
Vaccination site induration		1		1
Vaccination site inflammation	1	1	1	1
Vaccination site pain	1	4	1	4
Vaccination site swelling	1	2	1	2
	20	37	20	37

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration	1	1	1	1
Maternal exposure during pregnancy	1	1	1	1
Off label use	1	1	1	1
	3	3	3	3

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System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate decreased	1	1			1	1
Respiratory rate decreased	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Decreased appetite		1		1
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	3	1	3
Bone disorder	1	1	1	1
Bone pain	1	1	1	1
Joint range of motion decreased		1		1
Limb discomfort		1		1
Muscle spasms	1	1	1	1
Musculoskeletal stiffness		1		1
Myalgia	1	1	1	1
Neck pain	1	1	1	1
Pain in extremity	2	5	2	5
	8	16	8	16

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	2	2	2	2		
Dyskinesia	1	1			1	1
Facial paralysis	1	1			1	1
Headache	5	9	5	9		
Head discomfort	1	1	1	1		
Hypoaesthesia	1	4	1	4		
Migraine	1	1			1	1
Movement disorder	1	1	1	1		
Neuralgia		1		1		
Paraesthesia	1	2	1	2		
Speech disorder		1		1		
Taste disorder		1		1		
	14	25	11	22	3	3

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Depression	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dysphonia		1		1
		1		1

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	1	1	1		
Night sweats	1	1			1	1
Pruritus	1	1	1	1		
Rash	1	1	1	1		
	4	4	3	3	1	1

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Haematoma	1	1	1	1
Hypertension		1		1
	1	2	1	2

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Country Where Event Occurred  
**QATAR**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea		1		1
		1		1

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Overdose	1	1	1	1
Product preparation error	1	1	1	1
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia		1		1
		1		1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dizziness		1		1
		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erythema		1		1
		1		1

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Country Where Event Occurred

**ROMANIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	9	9	9	9
	9	9	9	9

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Palpitations	2	2			2	2
Tachycardia	5	5	2	2	3	3
Ventricular extrasystoles	1	1	1	1		
	9	9	3	3	6	6

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear pain	1	1	1	1		
Paraesthesia ear	1	1	1	1		
Vertigo	3	3	2	2	1	1
Vestibular disorder	1	1	1	1		
	6	6	5	5	1	1

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System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angle closure glaucoma	1	1			1	1
Eyelid oedema	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	1	1	1		
Dry mouth	1	1			1	1
Dysphagia	1	1			1	1
Lip oedema	3	3	2	2	1	1
Lip swelling	1	1			1	1
Nausea	13	13	11	11	2	2
Odynophagia	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Tongue oedema	1	1			1	1
Vomiting	3	3	2	2	1	1
	26	26	18	18	8	8

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	10	10	9	9	1	1
Axillary pain	1	1	1	1		
Chest discomfort	2	2	2	2		
Chest pain	1	1			1	1
Chills	20	21	18	19	2	2
Crying	1	1	1	1		
Drug ineffective	19	19			19	19
Facial pain	1	1	1	1		
Fatigue	18	18	16	16	2	2
Feeling abnormal	1	1	1	1		
Feeling cold	2	2	1	1	1	1
Feeling hot	2	2	1	1	1	1
General physical health deterioration		1		1		
Hyperthermia	1	1	1	1		
Inflammation	1	1	1	1		
Injected limb mobility decreased	3	3	3	3		
Malaise	5	5	5	5		
Oedema	1	1	1	1		
Oedema peripheral	1	1			1	1
Pain	7	7	7	7		
Pyrexia	32	32	32	32		
Thirst	1	1			1	1
Vaccination site discomfort	3	3	3	3		
Vaccination site erythema	15	15	15	15		
Vaccination site induration	2	2	2	2		
Vaccination site inflammation	1	1	1	1		
Vaccination site lymphadenopathy	2	2	2	2		
Vaccination site movement impairment	3	3	3	3		
Vaccination site nodule	1	1	1	1		
Vaccination site pain	49	51	49	51		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	1	1	1	1		

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
	210	214	181	185	29	29

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Anaphylactoid reaction	1	1			1	1
Hypersensitivity	2	2	2	2		
	6	6	3	3	3	3

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	11	11	11	11
Suspected COVID-19	1	1	1	1
	12	12	12	12

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circumstance or information capable of leading to medication error	3	3	3	3		
Drug administered in wrong device	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Incorrect route of product administration	2	2	2	2		
Intercepted medication error	1	1	1	1		
Limb injury	1	1			1	1
Maternal exposure during pregnancy	1	1	1	1		
Medication error	3	3	3	3		
Off label use	3	3	3	3		
Product preparation error	7	11	7	11		
Product preparation issue	5	6	5	6		
Product use issue	2	2	2	2		
Underdose	1	1	1	1		
Wrong technique in product usage process	12	13	12	13		
	43	49	42	48	1	1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure abnormal	1	1	1	1		
Blood pressure increased		1		1		
Body temperature abnormal	1	1	1	1		
Body temperature increased	1	1	1	1		
Heart rate increased	1	1	1	1		
SARS-CoV-2 test negative	1	1	1	1		
SARS-CoV-2 test positive	7	7			7	7
Transaminases increased	1	1	1	1		
	13	14	6	7	7	7

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	1	1	1	1		
Hypocalcaemia	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	14	14	12	12	2	2
Back pain	2	2	2	2		
Joint ankylosis	1	1			1	1
Muscle swelling	1	1	1	1		
Muscular weakness	2	2	2	2		
Myalgia	25	26	23	24	2	2
Pain in extremity	21	27	20	26	1	1
Spinal pain	1	1	1	1		
	67	74	61	68	6	6

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	1	1	1	1
Anosmia	2	2	1	1	1	1
Balance disorder	1	1			1	1
Disturbance in attention	1	1	1	1		
Dizziness	7	7	7	7		
Dysgeusia	1	1			1	1
Facial paralysis	3	3			3	3
Headache	31	32	28	29	3	3
Horner's syndrome	1	1			1	1
Hypoaesthesia	2	2	1	1	1	1
Migraine	2	2	1	1	1	1
Muscle contractions involuntary	1	1	1	1		
Nystagmus	1	1	1	1		
Paraesthesia	8	8	7	7	1	1
Presyncope	3	3	3	3		
Seizure	1	1			1	1
Somnolence	4	4	4	4		
Syncope	1	1			1	1
Tremor	2	2	1	1	1	1
	74	75	57	58	17	17

System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issue		1		1
		1		1

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	6	6	4	4	2	2
Emotional distress	1	1	1	1		
Fear	1	1	1	1		
Insomnia	1	1	1	1		
Panic attack	1	2	1	2		
	10	11	8	9	2	2

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast pain	1	1	1	1
Suppressed lactation	1	1	1	1
	2	2	2	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cough	3	3	1	1	2	2
Dysphonia	1	1	1	1		
Dyspnoea	2	2			2	2
Epiglottic oedema	1	1			1	1
Laryngeal oedema	1	1			1	1
Nasal discomfort	1	1	1	1		
Nasal oedema	1	1			1	1
Oropharyngeal discomfort	1	1			1	1
	11	11	3	3	8	8

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	9	10	8	9	1	1
Erythema nodosum	1	1	1	1		
Hyperhidrosis	4	4	3	3	1	1
Pruritus	5	5	4	4	1	1
Rash	7	7	7	7		
Rash erythematous	2	2			2	2
Rash pruritic	1	1	1	1		
Scar pain	1	1	1	1		
Skin discolouration	1	1	1	1		
Urticaria	2	3	2	3		
Urticaria papular	1	1	1	1		
	34	36	29	31	5	5

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	1	1	1		
Hypertension	5	5			5	5
Hypertensive crisis	1	1			1	1
Peripheral coldness	1	1	1	1		
Systolic hypertension	1	1			1	1
	9	9	2	2	7	7

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Country Where Event Occurred

**SAUDI ARABIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	1	1	1	1
Mouth ulceration	1	1	1	1
	2	2	2	2

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Fatigue	4	4	4	4
Malaise	1	1	1	1
Pain	1	1	1	1
Pyrexia	2	2	2	2
Vaccination site pain	2	2	2	2
	11	11	11	11

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Herpes zoster	1	1	1	1
Nasopharyngitis	1	1	1	1
Vaginal infection	1	1	1	1
	3	3	3	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Myalgia	2	2	2	2
Pain in extremity	1	1	1	1
	5	5	5	5

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	1	1	1	1		
Headache	2	2	2	2		
Movement disorder	1	1	1	1		
Syncope	1	1			1	1
	5	5	4	4	1	1

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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pollakiuria	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rhinorrhoea	1	1	1	1
	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hyperhidrosis	2	2	2	2
Pain of skin	1	1	1	1
	3	3	3	3

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	1	1			1	1
Peripheral coldness	1	1	1	1		
	2	2	1	1	1	1

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Country Where Event Occurred  
**SERBIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Palpitations	1	1	1	1		
Tachycardia	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Huntington's disease	1	1	1	1
	1	1	1	1

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System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Tinnitus	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Swelling of eyelid	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
Dry mouth	1	1	1	1
Nausea	6	6	6	6
Vomiting	2	2	2	2
	10	10	10	10

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	4	4	4	4		
Axillary pain	1	1	1	1		
Chest discomfort	1	1	1	1		
Chest pain	1	1	1	1		
Chills	3	3	2	2	1	1
Fatigue	4	4	4	4		
Influenza like illness	1	1	1	1		
Malaise	3	3	3	3		
Peripheral swelling	1	1			1	1
Pyrexia	17	17	16	16	1	1
Vaccination site erythema	1	1	1	1		
Vaccination site haematoma	1	1			1	1
Vaccination site induration	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	11	11	11	11		
Vaccination site swelling	1	1	1	1		
	52	52	48	48	4	4

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactoid reaction	1	1			1	1
Hypersensitivity	2	2	1	1	1	1
	3	3	1	1	2	2

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abscess	1	1	1	1
	1	1	1	1

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fall	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1	1	1		
Body temperature increased	3	3	2	2	1	1
Inflammatory marker increased	1	1	1	1		
Intraocular pressure increased	1	1			1	1
Monocyte count increased	1	1	1	1		
	7	7	5	5	2	2

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	3	3	3	3
Bone pain	2	2	2	2
Muscular weakness	2	2	2	2
Myalgia	5	5	5	5
Pain in extremity	4	4	4	4
Pain in jaw	1	1	1	1
	17	17	17	17

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Dizziness	1	1	1	1		
Headache	4	4	4	4		
Loss of consciousness	1	1			1	1
Paraesthesia	1	1	1	1		
	9	9	8	8	1	1

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety	1	1	1	1
Confusional state	1	1	1	1
Fear of death	1	1	1	1
Sleep disorder	1	1	1	1
	4	4	4	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asphyxia	1	1			1	1
Cough	1	1			1	1
Oropharyngeal pain	1	1	1	1		
	3	3	1	1	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	3	3	3	3		
Hyperhidrosis	2	2	2	2		
Rash	2	2	1	1	1	1
Rash macular	1	1			1	1
Skin reaction	1	1			1	1
Urticaria	1	1	1	1		
	10	10	7	7	3	3

\* I=Interval, C=Cumulative  
\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	2	2	1	1	1	1
Phlebitis	1	1			1	1
	3	3	1	1	2	2

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Country Where Event Occurred  
**SINGAPORE**

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye swelling	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Pyrexia	1	1	1	1
	2	2	2	2

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic shock	5	5	5	5
	5	5	5	5

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urticaria	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**SLOVAKIA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Palpitations	1	1	1	1
Tachycardia	1	1	1	1
	2	2	2	2

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diplopia	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vomiting	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chills	7	7	6	6	1	1
Drug ineffective	6	6			6	6
Fatigue	1	1	1	1		
Pyrexia	4	4	4	4		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site pain	6	6	5	5	1	1
Vaccination site swelling	1	1			1	1
Vaccination site urticaria	1	1	1	1		
	28	28	19	19	9	9

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	3	3			3	3
Rhinitis	1	1	1	1		
	4	4	1	1	3	3

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	1	1	1	1
Product administered at inappropriate site	1	1	1	1
	2	2	2	2

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1	1	1		
Body temperature	1	1			1	1
Body temperature increased	1	1	1	1		
SARS-CoV-2 ant body test positive	1	1			1	1
SARS-CoV-2 test positive	3	3			3	3
	7	7	2	2	5	5

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	1	1	1	1
Pain in extremity	5	5	5	5
	6	6	6	6

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1	1	1		
Dizziness	2	2	2	2		
Headache	5	5	4	4	1	1
Hypoaesthesia	1	1	1	1		
Paraesthesia	1	1			1	1
Syncope	1	1			1	1
	11	11	8	8	3	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	2	2	2	2
Dyspnoea	1	1	1	1
Oropharyngeal pain	1	1	1	1
Throat irritation	1	1	1	1
Throat tightness	1	1	1	1
	6	6	6	6

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	1			1	1
Hyperhidrosis	1	1	1	1		
Pruritus	1	1			1	1
Rash	1	1	1	1		
Rash pruritic	1	1	1	1		
	5	5	3	3	2	2

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypertension	2	2	2	2
	2	2	2	2

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Country Where Event Occurred  
**SLOVENIA**

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute myocardial infarction	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vertigo	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea	1	1	1	1
Vomiting	1	1	1	1
	2	2	2	2

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site pain	1	1	1	1		
Asthenia	2	2	2	2		
Disease recurrence	1	1			1	1
Fatigue	1	1	1	1		
Sudden death	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
	8	8	6	6	2	2

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Wrong technique in product usage process	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
White blood cell count increased	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypertension	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**SPAIN**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	2	2	2	2
	2	2	2	2

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardio-respiratory distress	1	1			1	1
Palpitations	4	4	2	2	2	2
Tachycardia	2	2	1	1	1	1
	7	7	3	3	4	4

System Organ Class

**Eye disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eye pruritus	1	1	1	1
Periorbital oedema	1	1	1	1
	2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	3	3	2	2	1	1
Abdominal pain upper	1	1	1	1		
Angular cheilitis	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Diarrhoea	15	16	14	15	1	1
Dry mouth	2	2	1	1	1	1
Dysphagia	1	1			1	1
Flatulence	1	1			1	1
Glossitis	1	1			1	1
Hypoaesthesia oral	1	1	1	1		
Intestinal ischaemia	1	1			1	1
Lip oedema	1	1	1	1		
Lip pruritus	1	1	1	1		
Nausea	11	11	9	9	2	2
Oral discomfort	1	1	1	1		
Palatal oedema	1	1			1	1
Paraesthesia oral	1	1	1	1		
Rectal haemorrhage	1	1			1	1
Stomatitis	3	3	2	2	1	1
Tongue discomfort	1	1	1	1		
Tongue eruption	1	1	1	1		
Tongue oedema	1	1	1	1		
Tongue pruritus	2	2	1	1	1	1
Tongue ulceration	1	1	1	1		
Vomiting	8	9	7	8	1	1
	63	65	49	51	14	14

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	3	3	3		
Chest discomfort	1	1			1	1
Chest pain	3	3	1	1	2	2
Chills	8	8	8	8		
Death	1	1			1	1
Discomfort	3	3	3	3		
Drug ineffective	7	7			7	7
Drug interaction	1	1	1	1		
Face oedema	1	1			1	1
Fatigue	7	7	5	5	2	2
Feeling abnormal	1	1	1	1		
Feeling cold	1	1			1	1
Feeling drunk	1	1	1	1		
Feeling hot	1	1	1	1		
Influenza like illness	1	1	1	1		
Malaise	15	15	12	12	3	3
Multiple organ dysfunction syndrome	1	1			1	1
Pain	4	4	4	4		
Peripheral swelling	2	2	1	1	1	1
Pyrexia	45	45	42	42	3	3
Sudden death	3	3			3	3
Temperature regulation disorder	2	2	2	2		
Vaccination site erythema	2	2	2	2		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site inflammation	7	7	6	6	1	1
Vaccination site joint erythema	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	26	26	25	25	1	1
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		
	153	153	125	125	28	28

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	2			1	2
Anaphylactic shock	3	3			3	3
Hypersensitivity	1	1			1	1
Immunisation reaction	1	1	1	1		
	6	7	1	1	5	6

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	6	6			6	6
Nasopharyngitis	1	1	1	1		
Pneumonia	1	1			1	1
Rhinitis	1	1	1	1		
Sepsis	1	1			1	1
Urinary tract infection	1	1	1	1		
	11	11	3	3	8	8

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposure during pregnancy	1	1	1	1		
Exposure via breast milk	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Off label use	2	2	2	2		
Overdose	1	1	1	1		
Product use issue	2	2	2	2		
Underdose	1	1	1	1		
Vaccination complication	2	2	1	1	1	1
Wrong technique in product usage process	1	1	1	1		
	14	14	13	13	1	1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1			1	1
Body temperature increased	1	1	1	1		
SARS-CoV-2 test positive	2	2	1	1	1	1
Troponin T increased	1	1			1	1
	5	5	2	2	3	3

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hyperglycaemia	1	1	1	1
Insulin resistance	1	1	1	1
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	6	6	5	5	1	1
Back pain	1	1	1	1		
Haematoma muscle	1	1			1	1
Jaw disorder	1	1	1	1		
Joint contracture	1	1	1	1		
Joint range of motion decreased	1	1			1	1
Mobility decreased	1	1			1	1
Muscle contracture	1	1	1	1		
Muscle tightness	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	2	1	1	1	1
Myalgia	14	14	14	14		
Neck pain	1	1			1	1
Pain in extremity	7	7	5	5	2	2
	40	40	32	32	8	8

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Balance disorder	1	1	1	1		
Burning sensation mucosal	1	1	1	1		
Dizziness	11	11	9	9	2	2
Dysarthria	1	1	1	1		
Dysgeusia	3	3	2	2	1	1
Facial paralysis	1	1			1	1
Formication	2	2	2	2		
Headache	33	33	28	28	5	5
Hypoaesthesia	1	1	1	1		
Loss of consciousness	1	1			1	1
Migraine	2	2	1	1	1	1
Movement disorder	1	1	1	1		
Muscle contractions involuntary	1	1	1	1		
Myoclonus	1	1			1	1
Paraesthesia	7	7	7	7		
Presyncope	1	1			1	1
Psychomotor hyperactivity	1	1	1	1		
Sensory loss	1	1	1	1		
Somnolence	4	4	4	4		
Speech disorder	1	1			1	1
Tension headache	2	2	2	2		
	77	77	63	63	14	14

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Bruxism	1	1	1	1		
Confusional state	1	1			1	1
Depressed mood	2	2	2	2		
Euphoric mood	1	1	1	1		
Nervousness	1	1	1	1		
	7	7	6	6	1	1

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pelvic pain	1	1	1	1
Vaginal haemorrhage	1	1	1	1
	2	2	2	2

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	3	3			3	3
Aspiration	1	1			1	1
Cough	2	2	2	2		
Dry throat	1	1	1	1		
Dyspnoea	7	7			7	7
Hypoxia	1	1			1	1
Laryngeal oedema	2	2			2	2
Nasal congestion	2	2	2	2		
Oropharyngeal pain	1	1	1	1		
Respiratory arrest	1	1			1	1
Respiratory distress	1	1			1	1
Respiratory failure	1	1			1	1
Rhinorrhoea	2	2	2	2		
Throat irritation	3	3	3	3		
	28	28	11	11	17	17

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Circumoral swelling	1	1	1	1		
Erythema	3	3	3	3		
Hyperhidrosis	1	1	1	1		
Petechiae	1	1	1	1		
Pruritus	6	6	4	4	2	2
Rash	7	7	7	7		
Rash pruritic	1	1			1	1
Skin lesion	1	1	1	1		
Urticaria	2	2	1	1	1	1
	24	24	19	19	5	5

System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	4	4	2	2	2	2
Peripheral ischaemia	1	1			1	1
	5	5	2	2	3	3

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Country Where Event Occurred

**SWEDEN**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	3	4			3	4
Cardiac disorder	1	1			1	1
Cardiac failure	1	1			1	1
Myocardial infarction	1	1			1	1
Palpitations	3	3	3	3		
Tachycardia	1	1			1	1
	10	11	3	3	7	8

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vertigo positional	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	2	2	2		
Abdominal pain upper	1	1	1	1		
Diarrhoea	6	6	4	4	2	2
Hypoaesthesia oral	1	1	1	1		
Lip swelling	1	1			1	1
Nausea	8	8	7	7	1	1
Oral pruritus	1	1			1	1
Paraesthesia oral	1	1	1	1		
Tongue pruritus	1	1			1	1
Vomiting	2	2	2	2		
	25	25	19	19	6	6

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Axillary pain	1	1	1	1		
Chills	9	9	8	8	1	1
Crepitations	1	1	1	1		
Death	10	10			10	10
Drug ineffective	1	1			1	1
Fatigue	11	11	8	8	3	3
Feeling abnormal	2	2	2	2		
Feeling hot	1	1	1	1		
General physical health deterioration	5	5	1	1	4	4
Injected limb mobility decreased	1	1	1	1		
Malaise	1	1	1	1		
Pain	3	3	2	2	1	1
Pyrexia	17	17	11	11	6	6
Sensation of foreign body	1	1			1	1
Sudden death	3	3			3	3
Swelling	1	1	1	1		
Swelling face	2	2	2	2		
Systemic inflammatory response syndrome	1	1			1	1
Vaccination site erythema	3	3	2	2	1	1
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site pain	7	7	6	6	1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	4	4	3	3	1	1
Vaccination site warmth	3	3	2	2	1	1
	91	91	56	56	35	35

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction	1	1	1	1
Anaphylactic shock	1	1	1	1
	2	2	2	2

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Erysipelas	1	1			1	1
Escherichia sepsis	1	1			1	1
Infection	3	3			3	3
Pharyngitis	1	1	1	1		
Pneumonia	1	1			1	1
Pneumonia bacterial	1	1			1	1
Post viral fatigue syndrome	1	1	1	1		
Sepsis	1	1			1	1
Upper respiratory tract infection	1	1			1	1
Urinary tract infection	1	1			1	1
Urosepsis	2	2			2	2
	15	15	2	2	13	13

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error	29	29	29	29
Poor quality product administered	35	35	35	35
Product administered at inappropriate site	1	1	1	1
Underdose	2	2	2	2
	67	67	67	67

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	1	1	1	1		
Blood pressure diastolic decreased	1	1	1	1		
C-reactive protein increased	1	1			1	1
Heart rate increased	1	1			1	1
Oxygen saturation decreased	2	2	2	2		
Pulse abnormal	1	1			1	1
Respiratory rate increased	1	1			1	1
	9	9	4	4	5	5

System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dehydration	1	1	1	1
	1	1	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	4	4	3	3	1	1
Fibromyalgia	1	1			1	1
Joint range of motion decreased	1	1	1	1		
Muscular weakness	1	1	1	1		
Myalgia	10	10	8	8	2	2
Neck pain	1	1	1	1		
Pain in extremity	11	11	11	11		
	29	29	25	25	4	4

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cerebrovascular accident	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dizziness	3	3	2	2	1	1
Dysstasia	1	1	1	1		
Facial paresis	1	1			1	1
Formication	1	1	1	1		
Headache	14	14	13	13	1	1
Hypoaesthesia	2	2	1	1	1	1
Ischaemic stroke	2	2			2	2
Loss of consciousness	1	1			1	1
Memory impairment	1	1			1	1
Migraine	2	2	2	2		
Paraesthesia	3	3	2	2	1	1
	33	33	22	22	11	11

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System Organ Class

**Product issues**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product colour issue	36	36	36	36
	36	36	36	36

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1	1	1		
Anxiety	1	1			1	1
Confusional state	1	1			1	1
Hallucination, visual	1	1			1	1
Insomnia	2	2	2	2		
Sleep talking	1	1			1	1
	7	7	3	3	4	4

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Acute kidney injury	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chronic obstructive pulmonary disease	2	2			2	2
Cough	3	3	1	1	2	2
Dyspnoea	7	7			7	7
Epistaxis	1	1	1	1		
Oropharyngeal pain	2	2	1	1	1	1
Oropharyngeal spasm	1	1			1	1
Pharyngeal swelling	1	1	1	1		
Productive cough	2	2			2	2
Pulmonary oedema	2	2			2	2
Respiratory distress	2	2			2	2
Rhinorrhoea	1	1	1	1		
Tachypnoea	1	1	1	1		
Throat irritation	1	1			1	1
Throat tightness	1	1			1	1
Upper respiratory tract congestion	1	1	1	1		
Wheezing	1	1	1	1		
	29	29	8	8	21	21

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis	1	1	1	1		
Erythema	1	1	1	1		
Pruritus	1	1			1	1
Skin ulcer	1	1			1	1
Urticaria	1	1	1	1		
	5	5	3	3	2	2

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	1	1			1	1
Circulatory collapse	1	1			1	1
Hypertension	1	1			1	1
Hypotension	2	2			2	2
Peripheral coldness	1	1	1	1		
	6	6	1	1	5	5

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Country Where Event Occurred  
**SWITZERLAND**

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	2	2	2	2
Anal haemorrhage	1	1	1	1
Gastric disorder	1	1	1	1
Nausea	1	1	1	1
	5	5	5	5

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chills	1	1	1	1		
Death	3	3			3	3
Fatigue	2	2	2	2		
Feeling cold	1	1	1	1		
General physical health deterioration	2	2			2	2
Malaise	1	1	1	1		
Pyrexia	1	1	1	1		
Vaccination site pain	3	3	3	3		
	15	15	10	10	5	5

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System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic reaction	1	1	1	1
	1	1	1	1

System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Pneumonia	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	2	2	1	1	1	1
C-reactive protein increased	1	1			1	1
Heart rate decreased	1	1			1	1
Heart rate increased	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
	6	6	2	2	4	4

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Back pain	1	1	1	1
Myalgia	1	1	1	1
Pain in extremity	1	1	1	1
	3	3	3	3

System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coma	1	1			1	1
Dizziness	1	1	1	1		
Dysgeusia	1	1	1	1		
Somnolence	1	1			1	1
	4	4	2	2	2	2

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Restlessness	1	1	1	1
	1	1	1	1

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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urethral pain	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Respiratory failure	1	1	1	1
Tachypnoea	1	1	1	1
	2	2	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Skin lesion	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**UNITED ARAB EMIRATES**

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypoacusis	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea	1	1	1	1		
Nausea	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue	1	1	1	1		
Pyrexia	2	2	2	2		
Vaccination site pain	2	2	2	2		
	7	7	5	5	2	2

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System Organ Class

**Infections and infestations**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
	1	1	1	1

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Off label use		1		1
Product use issue		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
	1	1	1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Depressed level of consciousness	1	1			1	1
Dizziness	1	1			1	1
Facial paralysis	1	1			1	1
Headache	2	2	1	1	1	1
Hypoaesthesia	1	1			1	1
	6	6	1	1	5	5

System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Depressed mood	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erectile dysfunction	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertension	2	2	1	1	1	1
	2	2	1	1	1	1

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Country Where Event Occurred

**UNITED KINGDOM**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eosinophilia	1	1	1	1		
Immune thrombocytopenia	1	1			1	1
Lymphadenitis	3	3	1	1	2	2
Lymphadenopathy	274	320	123	151	151	169
Lymphatic disorder	1	1	1	1		
Lymph node pain	61	74	31	39	30	35
Mast cell activation syndrome	1	1			1	1
Pancytopenia	1	1			1	1
Pseudolymphoma	1	1			1	1
Thrombocytopenia	5	5			5	5
Thrombocytosis	1	1			1	1
	350	409	157	193	193	216

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System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute cardiac event	1	1			1	1
Acute myocardial infarction	3	5			3	5
Angina pectoris	3	3			3	3
Arrhythmia	3	4			3	4
Arrhythmia supraventricular	2	2	1	1	1	1
Atrial f brillation	15	17			15	17
Bradycardia	9	10			9	10
Bundle branch block right	1	1	1	1		
Cardiac arrest	17	20			17	20
Cardiac disorder	1	1			1	1
Cardiac failure	2	2			2	2
Cardiac failure congestive	1	1			1	1
Cardiac flutter	3	3			3	3
Cardiopulmonary failure	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Coronary artery disease	2	2			2	2
Extrasystoles	3	4	2	2	1	2
Myocardial infarction	13	14			13	14
Myocardial ischaemia	1	1			1	1
Myocarditis	4	4			4	4
Palpitations	71	88	19	29	52	59
Pericarditis	2	2			2	2
Pulseless electrical activity	1	1			1	1
Right ventricular enlargement	1	1	1	1		
Sinus bradycardia		1				1
Sinus tachycardia	4	7	1	3	3	4
Supraventricular tachycardia	4	6	1	1	3	5
Tachycardia	80	104	17	33	63	71
Ventricular extrasystoles	3	3	1	1	2	2
Ventricular f brillation	2	3			2	3
	254	313	44	72	210	241

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System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling	1	1			1	1
Deafness	4	4			4	4
Ear congestion	1	1	1	1		
Ear discomfort	7	7	5	5	2	2
Ear disorder	1	1			1	1
Ear pain	29	33	13	14	16	19
Ear pruritus	2	2	1	1	1	1
Ear swelling		1				1
Hyperacusis	2	3		1	2	2
Hypoacusis	2	3	2	2		1
Middle ear inflammation	1	1			1	1
Motion sickness	3	4	3	4		
Sudden hearing loss	1	1			1	1
Tinnitus	18	26	8	12	10	14
Vertigo	43	49	8	11	35	38
Vertigo positional	2	2			2	2
	117	139	41	51	76	88

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	2	2	1	1	1	1
Age-related macular degeneration	1	1			1	1
Amblyopia	1	1	1	1		
Asthenopia	3	4	1	2	2	2
Blepharitis	1	1	1	1		
Blepharospasm	2	2			2	2
Blindness	2	2			2	2
Central vision loss	1	1			1	1
Conjunctival haemorrhage	3	4			3	4
Diplopia	6	8	3	5	3	3
Dry eye	3	4	1	2	2	2
Episcleritis	1	1	1	1		
Eye allergy	1	1			1	1
Eye disorder	9	10	3	4	6	6
Eye irritation	8	9	2	2	6	7
Eyelid exfoliation	1	1			1	1
Eyelid function disorder	1	1			1	1
Eyelid irritation	1	1	1	1		
Eyelid pain	1	1			1	1
Eyelid ptosis		1		1		
Eyelid rash	2	2			2	2
Eyelids pruritus	2	2	1	1	1	1
Eye movement disorder	3	3			3	3
Eye pain	47	52	14	17	33	35
Eye pruritus	16	18	4	5	12	13
Eye swelling	22	26	3	5	19	21
Foreign body sensation in eyes	2	2			2	2
Hypoesthesia eye	1	1			1	1
Iridocyclitis	2	2			2	2
Lacrimation increased	15	15	4	4	11	11
Maculopathy		1				1
Metamorphopsia	1	2			1	2

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mydriasis	1	1			1	1
Ocular discomfort	1	1	1	1		
Ocular hyperaemia	9	10	1	1	8	9
Oscillopsia	1	1	1	1		
Periorbital oedema	1	1			1	1
Periorbital swelling	3	5	2	4	1	1
Photophobia	21	28	5	7	16	21
Photopsia		1		1		
Pupillary reflex impaired	1	1			1	1
Pupils unequal	2	2			2	2
Swelling of eyelid	5	8	1	3	4	5
Vision blurred	48	55	18	22	30	33
Visual acuity reduced	1	1	1	1		
Visual brightness	1	1	1	1		
Visual impairment	16	17	3	3	13	14
Vitreous floaters	1	2	1	2		
	273	317	76	100	197	217

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions	1	1					1	1
Abdominal discomfort	17	20			4	7	13	13
Abdominal distension	7	9			3	4	4	5
Abdominal pain	52	63			18	27	34	36
Abdominal pain lower	5	5			2	2	3	3
Abdominal pain upper	61	74			21	29	40	45
Abdominal tenderness	3	4			1	2	2	2
Abnormal faeces		1				1		
Aerophagia	1	1					1	1
Anal haemorrhage		1						1
Anal incontinence	1	1					1	1
Aphthous ulcer	2	2					2	2
Breath odour	1	1			1	1		
Chapped lips	1	1			1	1		
Cheilitis	1	1					1	1
Colitis ulcerative	1	1					1	1
Constipation	4	4			1	1	3	3
Defaecation urgency	2	2					2	2
Diarrhoea	203	251			59	87	144	164
Diarrhoea haemorrhagic		1						1
Discoloured vomit	2	2			2	2		
Dry mouth	25	36			8	15	17	21
Dyspepsia	8	8			5	5	3	3
Dysphagia	20	21			5	5	15	16
Enlarged uvula	1	1			1	1		
Enteritis		1				1		
Eructation	5	5					5	5
Faeces discoloured	2	3			1	2	1	1
Faeces pale	1	2				1	1	1
Flatulence	1	1					1	1
Frequent bowel movements	2	5				2	2	3
Gastric disorder	2	2			1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastritis	2	3
Gastrointestinal disorder	1	1
Gastrointestinal pain	4	5
Gastroesophageal reflux disease	4	4
Gingival bleeding	3	3
Gingival blister	1	1
Gingival pain	6	7
Gingivitis ulcerative	1	1
Glossitis	1	1
Glossodynia	7	9
Haematemesis	7	8
Haematochezia	1	1
Hyperchlorhydria	1	1
Hypoaesthesia oral	32	42
Infantile vomiting	1	1
Irritable bowel syndrome	4	4
Lip blister	1	2
Lip discolouration	1	1
Lip disorder		2
Lip dry	2	3
Lip oedema	1	1
Lip pain	3	4
Lip pruritus	1	1
Lip swelling	29	44
Melaena	1	1
Mouth cyst	1	1
Mouth swelling	6	7
Mouth ulceration	12	16
Nausea	732	870
Odynophagia		1
Oedema mouth	2	2
Oesophageal pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	2
		1	1		
		1	1	3	4
		1	1	3	3
		1	1	2	2
		1	1		
		2	3	4	4
				1	1
		1	1		
		4	5	3	4
				7	8
				1	1
		1	1		
		17	23	15	19
		1	1		
		1	1	3	3
				1	2
				1	1
			2		
		1	2	1	1
				1	1
		1	2	2	2
		1	1		
		6	14	23	30
				1	1
		1	1		
		2	3	4	4
		5	9	7	7
3	3	231	327	501	543
					1
		1	1	1	1
		1	1		

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral blood blister	1	1
Oral discomfort	4	5
Oral mucosa erosion		1
Oral mucosal blistering	3	3
Oral mucosal eruption	1	1
Oral mucosal erythema	1	1
Oral pain	4	5
Oral papule	1	1
Oral pruritus	1	1
Paraesthesia oral	78	112
Parotid gland enlargement	1	1
Plicated tongue	1	1
Proctitis ulcerative	1	1
Rectal haemorrhage	2	2
Regurgitation	1	1
Retching	10	11
Salivary gland pain	1	1
Salivary hypersecretion	5	8
Small intestinal obstruction	1	1
Stiff tongue	1	1
Stomatitis	1	1
Submaxillary gland enlargement	1	1
Swollen tongue	41	49
Tongue discomfort	1	3
Tongue disorder	1	1
Tongue dry		1
Tongue eruption	1	1
Tongue erythema	1	1
Tongue movement disturbance	1	1
Tongue oedema	1	1
Tongue pruritus	1	1
Tongue ulceration	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1	3	4
			1		
		2	2	1	1
		1	1		
				1	1
		2	2	2	3
				1	1
		1	1		
		35	59	43	53
		1	1		
				1	1
				1	1
				2	2
				1	1
		3	4	7	7
				1	1
		2	5	3	3
				1	1
				1	1
		1	1		
		1	1		
		10	13	31	36
			2	1	1
				1	1
			1		
				1	1
		1	1		
				1	1
		1	1		
				2	2

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Toothache	5	5			2	2	3	3
Upper gastrointestinal haemorrhage	2	2					2	2
Vomiting	211	253	1	1	60	90	151	163
Vomiting projectile	3	3					3	3
	1,693	2,066	4	4	541	791	1152	1275

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adverse drug reaction	2	2					2	2
Alcohol interaction		1						1
Asthenia	124	138			48	54	76	84
Axillary pain	55	70			21	32	34	38
Chest discomfort	76	91			21	28	55	63
Chest pain	92	103			26	32	66	71
Chills	686	767	1	1	213	272	473	495
Chronic fatigue syndrome		1				1		
Clinical death	1	1					1	1
Condition aggravated	19	23			4	7	15	16
Crying	3	3			1	1	2	2
Death	54	54					54	54
Discomfort	18	19			10	10	8	9
Disease recurrence	10	10			2	2	8	8
Drug ineffective	226	246					226	246
Exercise tolerance decreased	1	1					1	1
Facial discomfort	2	3					2	3
Facial pain	16	17			5	5	11	12
Fatigue	976	1,137	5	5	328	434	648	703
Feeling abnormal	80	92	1	1	32	39	48	53
Feeling cold	96	106			40	46	56	60
Feeling drunk	6	9			2	2	4	7
Feeling hot	93	129			45	72	48	57
Feeling jittery		2				1		1
Feeling of body temperature change	31	39			12	19	19	20
Gait disturbance	20	23			7	9	13	14
Gait inability	8	8			2	2	6	6
General physical health deterioration	1	1					1	1
Glassy eyes	1	1					1	1
Hangover	5	5			2	2	3	3
Hunger	1	1			1	1		
Hyperpyrexia	2	2					2	2

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypothermia	7	7
Ill-defined disorder	1	1
Illness	57	63
Induration	1	1
Inflammation	13	13
Influenza like illness	182	199
Injected limb mobility decreased	1	1
Injection site erythema	1	1
Injection site pain	5	7
Injection site pruritus	1	1
Injection site warmth	1	1
Injury associated with device		1
Local reaction	5	6
Malaise	401	469
Mass	2	2
Multiple organ dysfunction syndrome	2	2
No adverse event	3	3
Nodule		1
Oedema	3	3
Oedema peripheral	2	2
Pain	391	443
Peripheral swelling	99	112
Pre-existing condition improved	1	2
Pyrexia	1,022	1,155
Secretion discharge	1	1
Sensation of foreign body	3	3
Serositis	1	1
Sudden death	7	7
Swelling	59	66
Swelling face	42	49
Symptom recurrence	1	1
Systemic inflammatory response syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	7
				1	1
		18	20	39	43
				1	1
		5	5	8	8
		74	85	108	114
				1	1
		1	1		
		3	4	2	3
		1	1		
		1	1		
			1		
		1	2	4	4
		134	174	267	295
		1	1	1	1
				2	2
		3	3		
			1		
		1	1	2	2
				2	2
		147	182	244	261
		29	39	70	73
		1	2		
3	3	294	374	728	781
				1	1
				3	3
				1	1
				7	7
		26	31	33	35
		6	8	36	41
		1	1		
				1	1

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Temperature regulation disorder	2	2
Tenderness	16	17
Therapeutic response unexpected	3	3
Thirst	15	16
Vaccination site bruising	20	21
Vaccination site discolouration	5	6
Vaccination site discomfort	13	15
Vaccination site erythema	109	137
Vaccination site haematoma	1	1
Vaccination site haemorrhage	3	4
Vaccination site hyperaesthesia	1	1
Vaccination site hypoaesthesia	6	9
Vaccination site induration	9	12
Vaccination site inflammation	12	16
Vaccination site joint movement impairment	7	8
Vaccination site joint pain	6	8
Vaccination site lymphadenopathy	2	2
Vaccination site macule	1	1
Vaccination site mass	22	28
Vaccination site movement impairment	11	16
Vaccination site oedema	2	3
Vaccination site pain	542	662
Vaccination site paraesthesia	8	10
Vaccination site pruritus	36	43
Vaccination site rash	20	26
Vaccination site reaction	11	14
Vaccination site swelling	122	153
Vaccination site ulcer	1	1
Vaccination site urticaria	3	4
Vaccination site vesicles	3	3
Vaccination site warmth	63	81
	6,096	7,053

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		9	10	7	7
		2	2	1	1
		7	8	8	8
1	1	8	8	12	13
		1	2	4	4
		7	9	6	6
		58	77	51	60
				1	1
			1	3	3
		1	1		
		1	4	5	5
		6	9	3	3
		5	8	7	8
		3	3	4	5
		2	3	4	5
				2	2
		1	1		
		9	14	13	14
		2	5	9	11
			1	2	2
4	4	239	328	303	334
		4	5	4	5
		23	28	13	15
		8	13	12	13
		3	6	8	8
		58	79	64	74
				1	1
		1	2	2	2
				3	3
		28	43	35	38
15	15	2055	2678	4041	4375

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System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bile duct stone	1	1	1	1
Hepatic artery embolism	1	1	1	1
Hepatic pain	1	1	1	1
Hepatitis	1	1	1	1
Jaundice	1	1	1	1
Liver injury	1	1	1	1
	6	6	6	6

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic oedema	1	1			1	1
Allergy to vaccine	12	19	4	10	8	9
Anaphylactic reaction	63	68			63	68
Anaphylactic shock	1	2			1	2
Anaphylactoid reaction	2	5			2	5
Drug hypersensitivity	3	3	1	1	2	2
Hypersensitivity	41	56	10	17	31	39
Immune-mediated adverse reaction		1		1		
Immune system disorder	1	1			1	1
Reaction to preservatives	1	1			1	1
Seasonal allergy	1	1	1	1		
Type IV hypersensitivity reaction	1	2			1	2
	127	160	16	30	111	130

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
African trypanosomiasis	1	1			1	1
Appendicitis	1	1			1	1
Asymptomatic COVID-19	2	2			2	2
Biliary sepsis	1	1			1	1
Breast abscess	1	1			1	1
Cellulitis	15	17			15	17
Cholecystitis infective	1	1			1	1
Clostridium difficile colitis	1	1			1	1
Conjunctivitis	4	4	1	1	3	3
Coronavirus infection		2				2
COVID-19	141	149			141	149
COVID-19 pneumonia	3	3			3	3
Cystitis	1	1			1	1
Ear infection	3	3	1	1	2	2
Eye infection	1	1			1	1
Folliculitis	1	2		1	1	1
Furuncle	1	1	1	1		
Gastroenteritis	1	2		1	1	1
Gastroenteritis viral	2	2	1	1	1	1
Genital herpes	1	1			1	1
Herpes virus infection		1				1
Herpes zoster	19	23	7	11	12	12
Herpes zoster oticus	1	1			1	1
Herpes zoster reactivation	1	1			1	1
Hordeolum	1	1			1	1
Infection	6	6			6	6
Influenza	44	48	15	19	29	29
Labyrinthitis	3	4	1	1	2	3
Localised infection	2	2			2	2
Lower respiratory tract infection	12	12			12	12
Mastitis	2	2			2	2
Myelitis	1	1			1	1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasopharyngitis	32	38
Oral candidiasis	2	2
Oral herpes	4	6
Parotitis	3	3
Pharyngitis	1	1
Pharyngitis streptococcal	2	2
Pneumonia	4	6
Post viral fatigue syndrome	2	2
Pustule	1	1
Pyelonephritis	1	1
Q fever	1	1
Rash pustular	1	1
Rhinitis	4	5
Sepsis	5	5
Severe acute respiratory syndrome	1	1
Sinusitis	2	2
Sputum purulent		1
Suspected COVID-19	77	81
Sweating fever	10	11
Tonsillitis	5	6
Tonsillitis bacterial	1	1
Urinary tract infection	5	5
Urinary tract infection bacterial	1	1
Urosepsis	1	1
Vaccination site abscess	1	1
Vaccination site cellulitis	6	8
Vaccination site infection	3	4
Vestibular neuronitis	1	2
Viral infection	1	1
Viral labyrinthitis	1	1
Viral pharyngitis	1	1
Viral rash	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
14	19	18	19
1	1	1	1
3	3	1	3
1	1	2	2
		1	1
		2	2
		4	6
		2	2
		1	1
		1	1
		1	1
		1	1
2	3	2	2
		5	5
		1	1
1	1	1	1
			1
1	1	76	80
		10	11
1	1	4	5
		1	1
		5	5
		1	1
		1	1
1	2	5	6
	1	3	3
		1	2
1	1		
1	1		
		1	1
1	1	2	2

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System Organ Class

**Infections and infestations**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral tonsillitis	1	1			1	1
Viral upper respiratory tract infection	1	1			1	1
Vulvovaginal candidiasis	2	2	1	1	1	1
	461	507	56	74	405	433

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Bite	1	1			1	1
Chillblains	1	1			1	1
Circumstance or information capable of leading to medication error	2	4	2	4		
Contraindicated product administered	2	2	1	1	1	1
Contusion	14	16	4	5	10	11
Expired product administered	1	2	1	2		
Exposure during pregnancy	3	3	3	3		
Exposure to SARS-CoV-2	1	1			1	1
Exposure via breast milk	4	4	4	4		
Eye contusion	2	2	1	1	1	1
Eye injury	1	1			1	1
Face crushing	1	1			1	1
Fall	25	25	6	6	19	19
Gastrointestinal stoma complication	1	1			1	1
Head injury	9	9	5	5	4	4
Heat illness	1	1			1	1
Heat oedema	1	1	1	1		
Heat stroke	1	1	1	1		
Inappropriate schedule of product administration	11	12	11	11		1
Incision site pain		1				1
Incorrect dose administered	1	1	1	1		
Incorrect route of product administration	17	27	17	27		
Injection related reaction	2	2	1	1	1	1
Injury corneal	1	1			1	1
Ligament sprain	1	1			1	1
Lower limb fracture	1	1			1	1
Maternal exposure during pregnancy	3	4	1	2	2	2
Maternal exposure timing unspecified	1	1	1	1		
Muscle strain	2	2			2	2
Occupational exposure to product		1		1		

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Occupational exposure to SARS-CoV-2	1	1	1	1		
Off label use	46	57	43	54	3	3
Overdose	4	6	4	6		
Poisoning	1	1			1	1
Poor quality product administered	3	9	3	9		
Post lumbar puncture syndrome	1	1			1	1
Postoperative ileus	1	1			1	1
Procedural nausea	1	1			1	1
Product administered at inappropriate site	1	1			1	1
Product administered to patient of inappropriate age	7	9	6	8	1	1
Product label confusion		1		1		
Product preparation error		3		3		
Product preparation issue	2	2	2	2		
Product use issue	39	50	36	47	3	3
Skin abrasion	1	1			1	1
Skin laceration	1	1			1	1
Stoma site discharge		1				1
Stoma site extravasation		1		1		
Stoma site haemorrhage		1				1
Superficial injury of eye	1	1			1	1
Synovial rupture	1	1	1	1		
Tendon injury	1	1			1	1
Underdose	1	5	1	5		
Upper limb fracture	1	1			1	1
Vaccination complication	3	4	1	2	2	2
Wrong product administered	1	1	1	1		
	230	293	161	219	69	74

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Alanine aminotransferase increased	4	4			1	1	3	3
Antibody test positive	1	1			1	1		
Anticoagulation drug level increased	1	1					1	1
Aspartate aminotransferase increased	1	1					1	1
Blood alkaline phosphatase increased	2	2			1	1	1	1
Blood creatine phosphokinase increased	2	2			1	1	1	1
Blood electrolytes increased	1	1			1	1		
Blood glucose decreased	3	3					3	3
Blood glucose increased	9	9			2	2	7	7
Blood ketone body present	1	1					1	1
Blood lactic acid increased	3	3			1	1	2	2
Blood pH increased	1	1			1	1		
Blood potassium abnormal	1	1					1	1
Blood pressure decreased	5	8			1	2	4	6
Blood pressure increased	32	44			18	25	14	19
Blood pressure orthostatic abnormal	1	1					1	1
Blood pressure orthostatic decreased		1						1
Blood pressure systolic decreased	1	1					1	1
Blood pressure systolic increased	2	3				1	2	2
Blood sodium decreased	1	1			1	1		
Blood test abnormal	1	2					1	2
Blood urea increased	1	1			1	1		
Blood urine present	2	2			2	2		
Body temperature	2	2					2	2
Body temperature abnormal	14	15			2	3	12	12
Body temperature decreased	3	3			1	1	2	2
Body temperature fluctuation	4	6			1	3	3	3
Body temperature increased	44	51	1	1	14	18	30	33
Coma scale abnormal	2	3					2	3
Cortisol decreased	1	1					1	1
C-reactive protein increased	2	2			1	1	1	1
Culture negative	1	1					1	1

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Electrocardiogram ST segment abnormal	1	1
Electrocardiogram ST segment elevation	1	1
Fibrin D dimer increased	1	1
Gamma-glutamyltransferase increased	1	1
Grip strength decreased	3	3
Haemoglobin decreased	2	2
Heart rate abnormal	3	3
Heart rate decreased	4	4
Heart rate increased	58	68
Heart rate irregular	3	3
Hepatic enzyme increased	1	1
Inflammatory marker increased	1	1
International normalised ratio increased	4	4
Intraocular pressure increased	1	1
Liver function test increased	2	2
Lymph node palpable	1	1
Oxygen saturation decreased	13	18
Pulse abnormal	1	1
Red blood cell sedimentation rate increased	1	1
Respiratory rate decreased	1	1
Respiratory rate increased	6	7
SARS-CoV-2 ant body test negative	2	2
SARS-CoV-2 ant body test positive	1	1
SARS-CoV-2 test false positive	1	1
SARS-CoV-2 test positive	11	17
Tri-iodothyronine decreased	1	1
Troponin increased	1	1
Urine output decreased	1	1
Weight decreased	1	1
White blood cell count decreased	1	1
	278	329

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	1
				1	1
		3	3		
		1	1	1	1
		1	1	2	2
		1	1	3	3
		20	26	38	42
				3	3
		1	1		
				1	1
				4	4
				1	1
		1	1	1	1
		1	1		
			1	13	17
				1	1
				1	1
			1	6	6
		2	2		
				1	1
		1	1		
				11	17
				1	1
				1	1
		1	1		
				1	1
		1	1	194	221
		1	1	84	108

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acidosis	2	2	1	1	1	1
Appetite disorder	1	1			1	1
Decreased appetite	103	113	27	30	76	83
Dehydration	15	16	7	8	8	8
Diabetes mellitus inadequate control	1	2			1	2
Diabetic complication	1	1			1	1
Diabetic ketoacidosis	2	3			2	3
Feeding disorder	6	6	5	5	1	1
Fluid intake reduced	2	2			2	2
Fluid retention		1		1		
Gout	2	2			2	2
Hyperglycaemia	6	8		1	6	7
Hypoglycaemia	6	8	1	2	5	6
Hyponatraemia	2	2			2	2
Hypophagia	2	2			2	2
Malnutrition	1	1			1	1
	152	170	41	48	111	122

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Ankylosing spondylitis	1	1
Arthralgia	488	548
Arthritis	8	9
Arthritis reactive	1	2
Arthropathy	1	1
Axillary mass	7	9
Back pain	100	110
Bone pain	23	27
Bone swelling	1	2
Costochondritis	2	2
Fibromyalgia	2	2
Flank pain	2	3
Groin pain	8	8
Inguinal mass	1	1
Jaw clicking	1	1
Joint effusion	3	3
Joint lock	1	1
Joint noise	1	1
Joint range of motion decreased	11	13
Joint stiffness	12	14
Joint swelling	16	19
Joint warmth		1
Limb discomfort	65	88
Limb mass	1	1
Mastication disorder	2	2
Mobility decreased	23	27
Muscle fatigue	10	15
Muscle rigidity	4	4
Muscle spasms	27	32
Muscle swelling	3	3
Muscle tightness	1	2
Muscle twitching	11	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
1	1	144	182	344	366
		1	2	7	7
				1	2
				1	1
		5	7	2	2
		34	43	66	67
		11	14	12	13
			1	1	1
				2	2
				2	2
		1	2	1	1
		5	5	3	3
				1	1
				1	1
				3	3
				1	1
				1	1
		3	4	8	9
		2	3	10	11
		3	5	13	14
			1		
		30	45	35	43
		1	1		
				2	2
		11	14	12	13
		1	3	9	12
				4	4
		10	13	17	19
		1	1	2	2
		1	1		1
		6	7	5	5

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscular weakness	51	60
Musculoskeletal chest pain	9	9
Musculoskeletal discomfort	7	7
Musculoskeletal disorder	3	3
Musculoskeletal pain	10	10
Musculoskeletal stiffness	63	72
Myalgia	692	802
Myofascial pain syndrome		1
Neck mass	3	3
Neck pain	103	125
Osteoarthritis	1	1
Pain in extremity	512	609
Pain in jaw	15	16
Periarthritis	2	2
Polymyalgia rheumatica	1	1
Posture abnormal	1	1
Psoriatic arthropathy	1	1
Rhabdomyolysis	3	3
Rheumatoid arthritis	2	2
Sacroiliitis	1	1
Sjogren's syndrome		1
Spinal disorder	1	1
Spinal pain	4	4
Symphysis	1	1
Synovial cyst	1	1
Synovitis	1	1
Systemic lupus erythematosus	1	1
Temporomandibular joint syndrome	2	2
Tendonitis	1	1
Torticollis	1	1
Trismus	1	1
	2,331	2,708

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		12	19	39	41
		2	2	7	7
		5	5	2	2
		1	1	2	2
		3	3	7	7
		21	25	42	47
3	3	210	284	482	518
			1		
		1	1	2	2
		38	55	65	70
		1	1		
3	3	201	270	311	339
		6	7	9	9
		1	1	1	1
				1	1
				1	1
				3	3
				2	2
				1	1
					1
		1	1		
		2	2	2	2
				1	1
		1	1		
				1	1
				1	1
		2	2		
				1	1
				1	1
				1	1
7	7	778	1035	1553	1673

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemia	1	1	1	1
Skin cancer	1	1	1	1
	2	2	2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Ageusia	24	29			7	11	17	18
Allodynia	1	1					1	1
Altered state of consciousness	1	1					1	1
Amnesia	1	1			1	1		
Anosmia	16	18			8	10	8	8
Anticholinergic syndrome	1	1					1	1
Aphasia	4	4					4	4
Aura	5	6			2	3	3	3
Balance disorder	19	23	1	1	4	5	15	18
Burning sensation	23	26			4	5	19	21
Cataplexy		1						1
Cerebellar infarction	1	2					1	2
Cerebellar stroke	1	1					1	1
Cerebral haemorrhage	2	2					2	2
Cerebral infarction	1	2					1	2
Cerebral venous sinus thrombosis	1	1					1	1
Cerebrovascular accident	18	20					18	20
Clumsiness	1	1					1	1
Cluster headache	7	7			1	1	6	6
Cognitive disorder	4	4					4	4
Consciousness fluctuating	1	1					1	1
Coordination abnormal	1	1			1	1		
Dementia	2	2					2	2
Depressed level of consciousness	4	4					4	4
Disturbance in attention	17	20			6	8	11	12
Dizziness	405	492	1	1	146	201	259	291
Dizziness exertional	1	1			1	1		
Dizziness postural	32	39			5	9	27	30
Drooling	1	1					1	1
Dysarthria	9	9					9	9
Dysgeusia	50	72			33	50	17	22
Dyskinesia	3	3			1	1	2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysstasia	7	7
Dystonia	1	1
Epilepsy	5	6
Exertional headache	1	1
Facial neuralgia	1	1
Facial paralysis	34	36
Facial paresis	4	6
Facial spasm	2	3
Formication	1	2
Generalised tonic-clonic seizure	4	6
Guillain-Barre syndrome	1	1
Haemorrhage intracranial	2	2
Haemorrhagic stroke	2	2
Hand-eye coordination impaired	1	1
Headache	1,348	1,559
Head discomfort	10	11
Hemiparaesthesia	1	1
Hemiparesis	8	10
Hyperaesthesia	9	9
Hypersomnia	12	14
Hypertonia	1	1
Hypoaesthesia	74	95
Hypokinesia	3	3
Hyporeflexia	2	2
Hyporesponsive to stimuli	1	1
Hyposmia	4	4
Hypotonia	1	1
Idiopathic intracranial hypertension	1	1
Incoherent	1	1
Ischaemic stroke	5	7
Lacunar infarction	2	2
Lacunar stroke	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3	4	4
				1	1
				5	6
		1	1		
		1	1		
				34	36
			2	4	4
		2	3		
				1	2
				4	6
				1	1
				2	2
				2	2
				1	1
5	5	450	587	898	972
		3	4	7	7
				1	1
				8	10
		4	4	5	5
		3	5	9	9
				1	1
		22	38	52	57
		1	1	2	2
				2	2
				1	1
		2	2	2	2
				1	1
				1	1
				5	7
				2	2
				1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lethargy	142	159
Locked-in syndrome	1	1
Loss of consciousness	32	33
Medication overuse headache	1	1
Memory impairment	4	5
Mental impairment	3	4
Migraine	111	119
Migraine with aura	6	7
Mononeuropathy	1	1
Monoparesis	2	2
Monoplegia	4	4
Movement disorder	8	8
Multiple sclerosis	2	2
Multiple sclerosis relapse	2	2
Muscle contractions involuntary	2	2
Muscle tone disorder	1	1
Myoclonus	1	1
Narcolepsy	1	1
Neuralgia	5	6
Neuropathy peripheral	2	2
Optic neuritis	1	1
Paraesthesia	131	162
Paralysis	7	7
Parosmia	5	5
Partial seizures	1	1
Peripheral sensory neuropathy	1	1
Peroneal nerve palsy	1	1
Petit mal epilepsy	2	2
Poor quality sleep	10	11
Posterior revers ble encephalopathy syndrome	1	1
Presyncope	39	48
Primary cough headache	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		48	57	94	102
				1	1
				32	33
		1	2	3	3
				3	4
		35	40	76	79
		2	3	4	4
				1	1
		1	1	1	1
				4	4
		2	2	6	6
				2	2
				2	2
		1	1	1	1
				1	1
		1	1		
				1	1
		1	1	4	5
				2	2
				1	1
		58	83	73	79
				7	7
		2	2	3	3
				1	1
				1	1
				2	2
		3	4	7	7
				1	1
		20	24	19	24
				2	2

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Primary headache associated with sexual activity	1	1					1	1
Radiculopathy	1	1					1	1
Restless legs syndrome	4	4			1	1	3	3
Retinal migraine	1	1					1	1
Sciatica	2	2					2	2
Sedation	1	1			1	1		
Seizure	19	19					19	19
Sensory disturbance	8	10			6	7	2	3
Sensory loss	1	1					1	1
Serotonin syndrome	1	1					1	1
Sinus headache	10	11				1	10	10
Sleep deficit	1	1					1	1
Slow response to stimuli	1	1					1	1
Somnolence	62	71			23	28	39	43
Speech disorder	4	4					4	4
Stiff leg syndrome	1	1					1	1
Subarachnoid haemorrhage	1	1					1	1
Syncope	86	99					86	99
Taste disorder	13	14			8	9	5	5
Tension headache	23	24			5	6	18	18
Thunderclap headache	1	1					1	1
Transient ischaemic attack	5	6					5	6
Tremor	99	115			26	33	73	82
Trigeminal neuralgia	1	1					1	1
Tunnel vision	1	1					1	1
Unresponsive to stimuli	14	16					14	16
Vestibular migraine	1	1					1	1
Visual field defect	2	2			1	1	1	1
Writer's cramp	1	1					1	1
	3,105	3,609	7	7	958	1266	2147	2343

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Abortion spontaneous	2	2	2	2
Morning sickness	1	1	1	1
	3	3	3	3

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Liquid product physical issue		2		2
Product packaging quantity issue		4		4
Product temperature excursion issue	3	3	3	3
	3	9	3	9

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal dreams	9	12	5	8	4	4
Agitation	11	11	4	4	7	7
Anger	1	1			1	1
Anxiety	26	37	8	15	18	22
Apathy	2	2			2	2
Bradyphrenia	1	1			1	1
Communication disorder	1	1			1	1
Confusional state	38	42	8	9	30	33
Decreased interest	2	2	1	1	1	1
Delirium	15	15			15	15
Delusion	1	1			1	1
Depersonalisation/derealisation disorder	2	2	1	1	1	1
Depressed mood	2	3		1	2	2
Depression	3	4			3	4
Derealisation	1	1			1	1
Disorganised speech	1	1	1	1		
Disorientation	9	13		3	9	10
Dissociation	1	2	1	2		
Eating disorder	1	1			1	1
Emotional distress	1	1	1	1		
Enuresis	3	3	1	1	2	2
Euphoric mood	1	1			1	1
Fear	2	3	1	1	1	2
Fear of injection	1	1	1	1		
Frustration tolerance decreased	1	1	1	1		
Hallucination	19	19			19	19
Hallucination, olfactory		1				1
Hallucination, tactile	1	1			1	1
Hallucination, visual	5	5			5	5
Indifference	1	1			1	1
Initial insomnia	2	2	1	1	1	1
Insomnia	77	84	34	39	43	45

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Intentional self-injury	1	1			1	1
Irritability	4	4	1	1	3	3
Mental disorder		1		1		
Mental fatigue	7	7	3	3	4	4
Middle insomnia	7	7	4	4	3	3
Mood altered	3	3	2	2	1	1
Negative thoughts	1	1			1	1
Nervousness	7	9	3	3	4	6
Nightmare	6	8	3	5	3	3
Obsessive-compulsive symptom	1	1			1	1
Panic attack	3	3			3	3
Panic disorder	1	1			1	1
Paranoia	1	1			1	1
Phonophobia	1	1	1	1		
Psychotic behaviour	1	1			1	1
Restlessness	11	18	7	10	4	8
Sleep attacks	2	2			2	2
Sleep disorder	29	33	15	19	14	14
Sleep disorder due to a general medical condition	4	4	1	1	3	3
Sleep disorder due to general medical condition, insomnia type	3	3	2	2	1	1
Sleep terror	1	1			1	1
Somatic symptom disorder		1				1
Stress	2	2	2	2		
Tearfulness	1	1			1	1
Tension	1	1			1	1
Thinking abnormal	1	1			1	1
Vomiting psychogenic	1	1			1	1
	341	392	113	144	228	248

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System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	5	5			5	5
Bladder discomfort	1	1	1	1		
Bladder pain	1	1			1	1
Chromaturia	3	3			3	3
Costovertebral angle tenderness	1	1	1	1		
Dysuria	1	1	1	1		
Haematuria		1		1		
Haemorrhage urinary tract	1	1			1	1
Hypertonic bladder		1		1		
Incontinence	2	2			2	2
Micturition disorder	1	1			1	1
Nephrotic syndrome	1	1			1	1
Nocturia	1	1	1	1		
Pollakiuria	2	2	1	1	1	1
Polyuria	1	1	1	1		
Renal failure	2	2			2	2
Renal pain	10	10	5	5	5	5
Urinary incontinence	5	5	1	1	4	4
Urinary retention	5	5			5	5
Urinary tract disorder	1	1			1	1
	44	46	12	14	32	32

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System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast discomfort	1	1	1	1		
Breast mass	1	1			1	1
Breast pain	11	12	4	5	7	7
Breast swelling	3	3	3	3		
Dysmenorrhoea	2	3	1	2	1	1
Erectile dysfunction	1	1			1	1
Menopausal symptoms	2	2	2	2		
Menorrhagia	3	5		2	3	3
Menstruation irregular	1	2		1	1	1
Metrorrhagia		1		1		
Nipple pain	2	3	1	2	1	1
Nipple swelling	1	2	1	2		
Penile swelling	1	1			1	1
Polymenorrhoea	2	2	1	1	1	1
Prostatomegaly	1	1	1	1		
Scrotal erythema		1				1
Scrotal exfoliation		1				1
Scrotal pain	1	2	1	1		1
Scrotal swelling		1				1
Vaginal haemorrhage	4	4			4	4
Vulvovaginal pruritus	1	1	1	1		
	38	50	17	25	21	25

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute pulmonary oedema	1	1			1	1
Acute respiratory failure	2	2			2	2
Allergic cough	2	2			2	2
Aphonia	2	4			2	4
Aspiration	1	1			1	1
Asthma	17	20	5	6	12	14
Bronchospasm	3	3			3	3
Catarrh		1		1		
Choking	1	1			1	1
Cough	124	139	41	51	83	88
Dry throat	8	10	1	3	7	7
Dysphonia	10	13	3	3	7	10
Dyspnoea	174	206	40	53	134	153
Dyspnoea exertional	7	10	2	5	5	5
Epistaxis	16	21	6	8	10	13
Haemoptysis	1	2			1	2
Hypersensitivity pneumonitis	1	1			1	1
Hyperventilation	1	1			1	1
Hypopnoea	2	2			2	2
Hypoxia	4	4			4	4
Increased upper airway secretion	2	3		1	2	2
Increased viscosity of upper respiratory secretion	2	2	1	1	1	1
Intranasal hypoaesthesia	1	1			1	1
Lung consolidation	1	1			1	1
Lung opacity	1	1			1	1
Nasal congestion	11	13	6	8	5	5
Nasal discharge discolouration	1	1	1	1		
Nasal discomfort	2	3	1	2	1	1
Nasal dryness	1	1			1	1
Nasal obstruction	1	1			1	1
Nasal odour	1	1	1	1		

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasal oedema	1	1
Nasal pruritus	1	1
Obstructive airways disorder	1	1
Oropharyngeal blistering	3	3
Oropharyngeal discomfort	5	5
Oropharyngeal pain	120	142
Orthopnoea	1	1
Painful respiration	3	5
Paranasal sinus inflammation	1	1
Pharyngeal disorder	1	1
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia	1	3
Pharyngeal inflammation	4	4
Pharyngeal oedema	4	4
Pharyngeal paraesthesia	4	5
Pharyngeal swelling	20	22
Pharyngeal ulceration	1	1
Pleural effusion	1	1
Pleurisy	2	2
Pleuritic pain	3	3
Pneumonia aspiration	3	3
Pneumonitis	1	1
Productive cough	7	8
Pulmonary embolism	1	1
Pulmonary oedema	2	2
Pulmonary pain	1	3
Pulmonary thrombosis	1	1
Rales	1	1
Respiration abnormal	1	3
Respiratory arrest	3	3
Respiratory disorder	3	4
Respiratory distress	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
		1	1
		3	3
1	1	4	4
51	68	69	74
1	1		
1	2	2	3
		1	1
		1	1
	1	1	2
		4	4
		4	4
1	1	3	4
8	9	12	13
		1	1
		1	1
		2	2
		3	3
		3	3
		1	1
2	2	5	6
		1	1
		2	2
	1	1	2
		1	1
		1	1
	1	1	2
		3	3
	1	3	3
		1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract irritation	1	1	1	1		
Rhinitis allergic	1	1			1	1
Rhinorrhoea	24	26	15	16	9	10
Sinonasal obstruction	1	1			1	1
Sinus congestion	3	3	2	2	1	1
Sinus disorder	1	1			1	1
Sinus pain	11	12	4	4	7	8
Sneezing	18	19	11	12	7	7
Snoring	1	1			1	1
Stridor	1	1			1	1
Tachypnoea	6	6	1	1	5	5
Throat clearing	2	2			2	2
Throat irritation	11	16	4	6	7	10
Throat tightness	32	39	6	8	26	31
Tonsillar hypertrophy	3	4	1	1	2	3
Tonsillar inflammation	1	1	1	1		
Upper-airway cough syndrome	1	1	1	1		
Upper respiratory tract congestion	1	1			1	1
Vocal cord disorder	1	1			1	1
Wheezing	23	32	5	11	18	21
	747	879	227	298	520	581

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecia	1	1	1	1		
Angioedema	17	21			17	21
Blister	8	8	5	5	3	3
Cold sweat	42	54	16	19	26	35
Dermatitis	6	6	4	4	2	2
Dermatitis allergic	8	15	3	7	5	8
Dermatitis bullous	1	1			1	1
Drug eruption	3	3			3	3
Dry skin	7	7	7	7		
Eczema	5	5	2	2	3	3
Erythema	97	121	45	63	52	58
Erythema multiforme	2	2			2	2
Fixed eruption	1	1	1	1		
Haemorrhage subcutaneous	1	1			1	1
Hair colour changes	1	1	1	1		
Hyperhidrosis	111	128	35	48	76	80
Itching scar	1	1			1	1
Livedo reticularis	1	2		1	1	1
Mechanical urticaria	1	1	1	1		
Miliaria	2	4	1	1	1	3
Nail discolouration	2	2			2	2
Night sweats	36	38	16	18	20	20
Pain of skin	10	12	2	2	8	10
Papule	3	4		1	3	3
Peau d'orange	1	1	1	1		
Petechiae	4	5		1	4	4
Photosensitivity reaction		1				1
Piloerection	2	3	1	1	1	2
Pruritus	153	194	69	95	84	99
Psoriasis	1	1			1	1
Purpura	3	3	2	2	1	1
Rash	149	180	68	88	81	92

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash erythematous	44	63	19	31	25	32
Rash macular	32	41	20	27	12	14
Rash maculo-papular	2	3	1	1	1	2
Rash morbilliform	1	1			1	1
Rash papular	8	14	3	8	5	6
Rash pruritic	43	49	15	17	28	32
Rash vesicular	4	4	1	1	3	3
Sensitive skin	5	5	1	1	4	4
Skin burning sensation	14	14	3	3	11	11
Skin discolouration	8	8	3	3	5	5
Skin disorder	1	1	1	1		
Skin erosion	2	2	1	1	1	1
Skin exfoliation	7	7	1	1	6	6
Skin induration	1	1	1	1		
Skin irritation	4	4	2	2	2	2
Skin lesion	2	2	2	2		
Skin mass	2	3	1	2	1	1
Skin reaction	1	2		1	1	1
Skin sensitisation	2	2			2	2
Skin swelling	2	3	1	2	1	1
Skin tightness	5	6	2	2	3	4
Skin ulcer	1	1			1	1
Skin warm	19	22	8	8	11	14
Skin weeping	1	1			1	1
Stevens-Johnson syndrome	1	1			1	1
Toxic epidermal necrolysis	1	1			1	1
Toxic skin eruption	1	1			1	1
Urticaria	67	85	27	42	40	43
Vasculitic rash	1	1			1	1
	962	1,175	394	527	568	648

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System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	2	2			2	2
Immobile	1	1			1	1
Impaired driving ability	2	2	1	1	1	1
Loss of personal independence in daily activities	9	10	2	2	7	8
	14	15	3	3	11	12

System Organ Class

**SOC Not Yet Coded**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
	14	16	14	16
	14	16	14	16

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthma prophylaxis	1	1			1	1
Limb immobilisation	1	1	1	1		
Weight loss diet	1	1			1	1
	3	3	1	1	2	2

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm rupture	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Circulatory collapse	17	18			17	18
Cyanosis	5	5	1	1	4	4
Deep vein thrombosis	5	5			5	5
Flushing	35	54	14	27	21	27
Haematoma	2	2	1	1	1	1
Haemorrhage	1	1			1	1
Hot flush	37	49	15	22	22	27
Hypertension	46	56	14	19	32	37
Hypertensive crisis	1	1			1	1
Hypotension	33	40	8	11	25	29
Infarction	1	1			1	1
Lymphoedema	5	5			5	5
Neurogenic shock	4	4			4	4
Orthostatic hypotension	2	2			2	2
Pallor	22	33	8	12	14	21
Peripheral circulatory failure	1	2			1	2
Peripheral coldness	23	28	9	11	14	17
Peripheral ischaemia	1	1			1	1
Poor peripheral circulation	1	1	1	1		
Raynaud's phenomenon	1	1			1	1
Superficial vein prominence	1	1	1	1		
Thrombosis	4	4			4	4
Varicose vein	1	1	1	1		
Vasculitis	1	1			1	1
Vasodilatation	2	2			2	2
Vein disorder	1	1			1	1
Vein rupture	1	1			1	1
Vena cava thrombosis	1	1			1	1
	257	323	73	107	184	216

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Country Where Event Occurred

**UNITED STATES**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood disorder	1	1	1	1		
Coagulopathy	1	1			1	1
Eosinophilia	1	1	1	1		
Febrile neutropenia	1	1			1	1
Haemolytic anaemia	1	1			1	1
Immune thrombocytopenia	2	3			2	3
Leukocytosis	3	3	2	2	1	1
Lymphadenitis	6	8	6	8		
Lymphadenopathy	327	399	308	374	19	25
Lymph node pain	71	88	67	84	4	4
Pancytopenia	1	1			1	1
Thrombocytopenia	4	4			4	4
Thrombotic thrombocytopenic purpura		1				1
	419	512	385	470	34	42

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System Organ Class

**Cardiac disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	3	3			3	3
Arrhythmia	3	4			3	4
Arteriospasm coronary	1	1			1	1
Atrial fibrillation	7	7	1	1	6	6
Bradycardia	1	1			1	1
Cardiac arrest	7	7			7	7
Cardiac discomfort		1		1		
Cardiac disorder	3	6	2	5	1	1
Cardiac flutter	2	3			2	3
Cardiac valve sclerosis	1	1			1	1
Cardio-respiratory arrest	2	2			2	2
Dilatation ventricular	1	1			1	1
Extrasystoles	1	2	1	2		
Myocardial infarction	6	9			6	9
Myocarditis	1	1			1	1
Nodal rhythm	1	1	1	1		
Palpitations	91	145	71	110	20	35
Pericardial effusion	1	1			1	1
Pericarditis	4	5			4	5
Postural orthostatic tachycardia syndrome	1	1	1	1		
Right ventricular dysfunction	1	1			1	1
Sinus tachycardia	5	5	2	2	3	3
Supraventricular extrasystoles	1	1			1	1
Supraventricular tachycardia	3	5	2	2	1	3
Tachycardia	90	150	61	104	29	46
Ventricular extrasystoles	1	6	1	4		2
Ventricular fibrillation	1	1			1	1
Ventricular tachycardia	1	2			1	2
	240	373	143	233	97	140

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System Organ Class

**Congenital, familial and genetic disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Von Willebrand's disease		1		1
		1		1

System Organ Class

**Ear and labyrinth disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Auricular swelling	1	1	1	1		
Deafness	9	12			9	12
Deafness neurosensory	3	5			3	5
Deafness unilateral	1	3			1	3
Ear congestion	2	2	1	1	1	1
Ear discomfort	13	20	13	19		1
Ear disorder	4	4	4	4		
Ear pain	35	49	34	47	1	2
Ear pruritus	4	4	4	4		
Ear swelling	2	5	2	5		
Hyperacusis	3	5	3	4		1
Hypoacusis	12	15	12	15		
Motion sickness	2	3	2	3		
Paraesthesia ear		1		1		
Sudden hearing loss	2	2			2	2
Tinnitus	44	62	35	49	9	13
Vertigo	48	64	48	61		3
Vertigo positional	1	2		1	1	1
	186	259	159	215	27	44

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System Organ Class

**Endocrine disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autoimmune thyroiditis	1	1			1	1
Hypothyroidism	2	2			2	2
Thyroid disorder	2	2	2	2		
	5	5	2	2	3	3

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sensation in eye	4	5	4	5		
Asthenopia	7	9	6	8	1	1
Blepharochalasis	1	1	1	1		
Blepharospasm	3	4	3	4		
Blindness	3	4			3	4
Blindness transient		1				1
Chalazion	1	1	1	1		
Conjunctival haemorrhage	1	1			1	1
Conjunctival irritation	1	1	1	1		
Conjunctival oedema	1	1	1	1		
Conjunctivitis allergic	2	2	2	2		
Corneal oedema	1	1	1	1		
Diplopia	4	4	3	3	1	1
Dry eye	3	3	3	3		
Episcleritis	2	2	2	2		
Erythema of eyelid	4	5	4	5		
Eye allergy	1	1	1	1		
Eye discharge	1	3	1	3		
Eye disorder	12	16	9	12	3	4
Eye haemorrhage	4	6			4	6
Eye inflammation	3	4	1	2	2	2
Eye irritation	15	19	15	18		1
Eyelid disorder	1	2	1	2		
Eyelid function disorder		1		1		
Eyelid irritation	1	1	1	1		
Eyelid oedema	2	2	2	2		
Eyelid pain	2	2	2	2		
Eyelid ptosis	1	2	1	1		1
Eyelid sensory disorder	1	1	1	1		
Eyelids pruritus	2	4	1	3	1	1
Eye movement disorder	1	2	1	1		1
Eye oedema	4	4	4	4		

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System Organ Class

Eye disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye pain	33	45	28	40	5	5
Eye paraesthesia	1	1			1	1
Eye pruritus	11	18	9	15	2	3
Eye swelling	33	46	29	42	4	4
Glare	1	1	1	1		
Glaucoma	2	2			2	2
Hypoaesthesia eye	2	2	2	2		
Lacrimation increased	7	9	6	8	1	1
Mydriasis	1	1	1	1		
Myopia	1	1	1	1		
Ocular discomfort	7	9	4	6	3	3
Ocular hyperaemia	14	20	14	20		
Periorbital discomfort		1		1		
Periorbital oedema		1		1		
Periorbital swelling	6	13	6	11		2
Photophobia	13	19	12	18	1	1
Photopsia	4	4	3	3	1	1
Pupillary disorder	1	1	1	1		
Scleritis	1	1			1	1
Swelling of eyelid	14	21	14	21		
Vision blurred	43	57	36	46	7	11
Visual impairment	13	19	12	17	1	2
	297	407	252	346	45	61

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	41	55	39	53	2	2
Abdominal distension	8	12	7	11	1	1
Abdominal pain	51	68	49	63	2	5
Abdominal pain lower	2	7	2	5		2
Abdominal pain upper	60	73	56	69	4	4
Abdominal rigidity	1	2	1	1		1
Abnormal faeces	1	1	1	1		
Anal incontinence	1	1	1	1		
Aphthous ulcer	3	3	3	3		
Aptyalism		1		1		
Bowel movement irregularity	2	2	2	2		
Breath odour	2	2	2	2		
Chapped lips	2	2	2	2		
Cheilitis		1		1		
Colitis ulcerative	1	1			1	1
Constipation	3	4	3	4		
Defaecation urgency		1		1		
Dental paraesthesia		2		2		
Diarrhoea	245	328	237	317	8	11
Diarrhoea haemorrhagic		1				1
Dry mouth	22	40	19	36	3	4
Dyspepsia	15	20	15	20		
Dysphagia	31	40	15	22	16	18
Enlarged uvula	3	4	1	1	2	3
Eructation	1	1	1	1		
Faeces discoloured	1	1	1	1		
Faeces soft	1	1	1	1		
Flatulence	6	8	6	8		
Food poisoning		1		1		
Frequent bowel movements	3	3	3	3		
Gastric disorder	1	2	1	2		
Gastritis	2	3	2	3		

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gastrointestinal disorder	12	17
Gastrointestinal pain	6	7
Gastrointestinal sounds abnormal	2	2
Gastroesophageal reflux disease	3	3
Gastroesophageal sphincter insufficiency	1	1
Gingival bleeding	2	4
Gingival blister	1	1
Gingival discolouration		1
Gingival discomfort		1
Gingival disorder	1	1
Gingival erythema	2	2
Gingival pain	4	6
Gingival swelling	6	6
Glossitis	2	3
Glossodynia	4	6
Haematochezia	6	7
Haemorrhoids	1	1
Hyperaesthesia teeth	2	2
Hypoaesthesia oral	59	86
Infantile vomiting	1	2
Infrequent bowel movements	1	1
Intestinal obstruction		1
Irritable bowel syndrome	1	1
Lip blister	2	3
Lip disorder	2	3
Lip dry	1	1
Lip erythema	1	3
Lip exfoliation	1	1
Lip oedema	2	4
Lip pain	1	3
Lip pruritus	4	6
Lip swelling	43	60

Spontaneous			
Nonserious		Serious	
I	C	I	C
11	16	1	1
6	7		
2	2		
3	3		
		1	1
2	4		
1	1		
			1
			1
1	1		
2	2		
4	4		2
6	6		
2	3		
4	6		
		6	7
1	1		
2	2		
47	71	12	15
1	2		
1	1		
			1
1	1		
2	3		
2	3		
1	1		
1	3		
1	1		
2	3		1
1	2		1
4	5		1
32	42	11	18

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System Organ Class

**Gastrointestinal disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Mouth swelling	3	8
Mouth ulceration	1	2
Mucous stools		1
Nausea	730	996
Noninfective gingivitis	1	1
Odynophagia	5	5
Oesophageal pain	1	1
Oral discomfort	3	8
Oral disorder	3	6
Oral dysaesthesia	1	1
Oral mucosal blistering	2	4
Oral mucosal eruption	2	5
Oral mucosal erythema	1	2
Oral pain	4	8
Oral pruritus	4	7
Palatal disorder	1	1
Palatal swelling	2	3
Pancreatitis		1
Pancreatitis acute	1	1
Paraesthesia oral	70	114
Rectal haemorrhage	1	1
Retching	9	11
Salivary gland pain	1	1
Salivary hypersecretion	2	2
Small intestinal obstruction		1
Stiff tongue		1
Stomatitis	10	11
Strawberry tongue		1
Swollen tongue	29	45
Tongue blistering	1	1
Tongue coated		1
Tongue discolouration	2	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	5	1	3
1	2		
	1		
691	940	39	56
1	1		
4	4	1	1
1	1		
3	7		1
3	6		
		1	1
2	4		
2	5		
1	2		
4	7		1
4	7		
1	1		
2	2		1
			1
		1	1
58	96	12	18
		1	1
8	10	1	1
1	1		
2	2		
			1
			1
9	10	1	1
	1		
16	25	13	20
1	1		
	1		
2	3		

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System Organ Class

**Gastrointestinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue discomfort	7	11	6	10	1	1
Tongue disorder	4	9	2	7	2	2
Tongue dry		1		1		
Tongue erythema	3	3	3	3		
Tongue haematoma		1		1		
Tongue haemorrhage	1	1	1	1		
Tongue movement disturbance	1	1			1	1
Tongue oedema	1	1			1	1
Tongue pruritus	6	8	6	7		1
Tongue ulceration	2	2	2	2		
Toothache	8	14	8	14		
Uvulitis	1	1	1	1		
Vomiting	198	277	188	261	10	16
Vomiting projectile	1	2	1	2		
	1,806	2,523	1650	2289	156	234

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Asthenia	240	315	219	289	21	26
Axillary pain	45	53	44	52	1	1
Chest discomfort	100	147	69	106	31	41
Chest pain	80	110	57	80	23	30
Chills	1,160	1,512	1119	1457	41	55
Condition aggravated	37	49	33	41	4	8
Crying	10	12	9	11	1	1
Cyst	2	2	2	2		
Death	29	30			29	30
Discomfort	36	47	34	45	2	2
Disease progression	1	1	1	1		
Disease recurrence	19	25	17	23	2	2
Drug ineffective	563	727	3	3	560	724
Drug interaction	7	7	7	7		
Enanthema		1		1		
Energy increased	2	2	2	2		
Extensive swelling of vaccinated limb		1		1		
Face oedema		2		1		1
Facial discomfort		2		2		
Facial pain	19	24	17	21	2	3
Fatigue	1,091	1,491	1060	1452	31	39
Feeling abnormal	189	255	179	239	10	16
Feeling cold	71	93	68	89	3	4
Feeling drunk	7	7	6	6	1	1
Feeling hot	119	175	106	155	13	20
Feeling jittery	9	12	8	10	1	2
Feeling of body temperature change	14	19	13	18	1	1
Gait disturbance	37	47	31	40	6	7
Gait inability	13	15	11	12	2	3
General physical health deterioration	1	1			1	1
Glassy eyes	1	2	1	2		

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System Organ Class

General disorders and administration site conditions

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hangover	4	5
Hunger	3	5
Hyperpyrexia		1
Hyperthermia	1	1
Hypothermia	1	1
Illness	72	95
Induration	2	3
Inflammation	8	14
Inflammatory pain	1	1
Influenza like illness	117	152
Inhibitory drug interaction	1	1
Injected limb mobility decreased	2	2
Injection site erythema	3	3
Injection site extravasation	1	2
Injection site hypoaesthesia		1
Injection site joint movement impairment	1	1
Injection site pain	10	16
Injection site rash	2	3
Injection site swelling	3	3
Injection site urticaria		1
Irritability postvaccinal	1	1
Localised oedema	1	2
Local reaction		1
Malaise	353	494
Mass	5	5
Mucosal disorder	2	2
Multiple organ dysfunction syndrome	1	1
No adverse event	4	4
Nodule	1	1
Oedema	4	5
Oedema peripheral	7	8
Pain	965	1,248

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	5		
3	5		
			1
1	1		
		1	1
68	91	4	4
1	2	1	1
8	13		1
1	1		
113	147	4	5
1	1		
2	2		
3	3		
1	2		
	1		
		1	1
9	15	1	1
2	3		
3	3		
	1		
1	1		
1	2		
	1		
330	468	23	26
5	5		
2	2		
		1	1
4	4		
1	1		
3	4	1	1
6	7	1	1
925	1198	40	50

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System Organ Class

**General disorders and administration site conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Peripheral swelling	119	155
Pre-existing condition improved	1	1
Pyrexia	1,220	1,581
Screaming	2	2
Secretion discharge		1
Sensation of foreign body	15	24
Sluggishness	6	7
Sudden death	1	1
Swelling	92	115
Swelling face	58	87
Temperature intolerance	1	1
Tenderness	12	18
Therapeutic response unexpected	6	7
Thirst	15	17
Ulcer	1	1
Vaccination site bruising	19	25
Vaccination site coldness		2
Vaccination site discharge	3	3
Vaccination site discolouration	8	8
Vaccination site discomfort	10	19
Vaccination site erythema	171	224
Vaccination site extravasation	3	3
Vaccination site haemorrhage	7	15
Vaccination site hyperaesthesia	1	1
Vaccination site hypersensitivity	2	2
Vaccination site hypoaesthesia	10	14
Vaccination site induration	18	28
Vaccination site inflammation	8	9
Vaccination site injury	1	1
Vaccination site irritation	2	2
Vaccination site joint movement impairment	6	6
Vaccination site joint pain	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
117	150	2	5
1	1		
1166	1507	54	74
1	1	1	1
	1		
11	16	4	8
6	7		
		1	1
83	103	9	12
49	73	9	14
1	1		
12	18		
6	7		
15	17		
1	1		
18	24	1	1
	2		
3	3		
8	8		
9	18	1	1
167	219	4	5
3	3		
7	15		
1	1		
2	2		
10	14		
17	27	1	1
8	8		1
1	1		
2	2		
5	5	1	1
2	2	1	1

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System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site lymphadenopathy	5	5	5	5		
Vaccination site macule	2	3	2	3		
Vaccination site mass	35	37	32	34	3	3
Vaccination site movement impairment	18	30	18	30		
Vaccination site nodule	8	10	8	10		
Vaccination site oedema		1		1		
Vaccination site pain	740	1,102	726	1086	14	16
Vaccination site pallor	1	1	1	1		
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	9	18	7	15	2	3
Vaccination site pruritus	76	96	73	93	3	3
Vaccination site rash	22	33	22	33		
Vaccination site reaction	12	14	12	14		
Vaccination site scab	2	2	2	2		
Vaccination site swelling	149	192	146	188	3	4
Vaccination site ulcer	1	1	1	1		
Vaccination site urticaria	14	21	14	21		
Vaccination site vesicles	6	8	6	8		
Vaccination site warmth	75	89	73	87	2	2
Vessel puncture site haemorrhage		1		1		
Vessel puncture site injury		1		1		
	8,476	11,319	7496	10050	980	1269

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System Organ Class

**Hepatobiliary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis	1	1			1	1
Gallbladder disorder	1	2		1	1	1
Hepatic pain		1		1		
Jaundice	2	2	2	2		
Liver injury	1	1			1	1
	5	7	2	4	3	3

System Organ Class

**Immune system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	18	36	13	25	5	11
Anaphylactic reaction	57	86			57	86
Anaphylactic shock	1	3			1	3
Anaphylactoid reaction	1	3			1	3
Autoimmune disorder	1	4			1	4
Contrast media allergy	1	1	1	1		
Drug hypersensitivity	9	11	9	10		1
Food allergy		1		1		
Hypersensitivity	61	91	48	67	13	24
Immune system disorder		2				2
Immunodeficiency	1	2			1	2
Reaction to excipient	3	3	2	2	1	1
Rubber sensitivity	1	1	1	1		
Seasonal allergy	3	3	3	3		
Sensitisation	1	1	1	1		
Serum sickness		1				1
Type IV hypersensitivity reaction	2	2	2	2		
	160	251	80	113	80	138

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acarodermatitis	1	1	1	1		
Appendicitis	4	6			4	6
Asymptomatic COVID-19	1	5			1	5
Bronchitis	3	5	3	4		1
Cellulitis	3	4			3	4
Conjunctivitis	3	4	3	4		
Conjunctivitis viral	1	1	1	1		
COVID-19	375	467	2	3	373	464
COVID-19 pneumonia	2	2			2	2
Cystitis	1	1			1	1
Ear infection	1	2	1	2		
Escherichia infection	1	1			1	1
Eye infection		1		1		
Fungal infection	3	3	3	3		
Furuncle	1	1	1	1		
Gastroenteritis viral		1				1
Gastrointestinal viral infection	1	1	1	1		
Herpes simplex	2	3	2	3		
Herpes virus infection	4	5	4	5		
Herpes zoster	32	38	31	37	1	1
Hordeolum	1	4	1	4		
Infection	2	3	2	3		
Infection parasitic	1	1	1	1		
Influenza	22	32	21	30	1	2
Kidney infection	1	1			1	1
Labyrinthitis		1				1
Laryngitis	1	2	1	2		
Localised infection	1	1	1	1		
Lower respiratory tract infection	1	1			1	1
Lymph gland infection	1	1	1	1		
Mastitis		1				1
Meningitis		1				1

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Meningitis viral	1	1			1	1
Nasopharyngitis	42	58	40	56	2	2
Oral candidiasis	1	2	1	2		
Oral herpes	10	16	9	15	1	1
Oral viral infection		1		1		
Orchitis		1		1		
Pertussis		1				1
Pharyngitis		1		1		
Pharyngitis streptococcal		1		1		
Pneumonia	7	8			7	8
Pustule	2	3	2	2		1
Rash pustular		1		1		
Respiratory tract infection	1	1			1	1
Rhinitis	2	3	2	3		
Rhinovirus infection	1	1	1	1		
Sepsis	2	2			2	2
Sinusitis	9	17	8	16	1	1
Staphylococcal infection	1	1			1	1
Staphylococcal skin infection		1				1
Streptococcal infection		1				1
Suspected COVID-19	27	35	4	6	23	29
Tonsillitis	1	1	1	1		
Tooth infection	1	1	1	1		
Tuberculosis	2	2			2	2
Upper respiratory tract infection	2	2	2	2		
Urinary tract infection	7	9	6	8	1	1
Vaccination site cellulitis	3	4	2	2	1	2
Vaccination site infection	4	4	4	4		
Vaginal infection		1		1		
Varicella		1		1		
Varicella zoster virus infection		1		1		
Viral infection	1	1	1	1		

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System Organ Class

Infections and infestations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Viral rash		1		1		
Vulvovaginal mycotic infection	1	1	1	1		
	598	786	166	238	432	548

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental exposure to product	10	15	9	14	1	1
Accidental overdose	8	25	8	24		1
Accidental underdose	1	2	1	2		
Animal bite	1	1	1	1		
Arthropod bite	4	4	4	4		
Booster dose missed	2	2	2	2		
Burn oral cavity	1	1			1	1
Chillblains	1	1	1	1		
Circumstance or information capable of leading to device use error	1	1	1	1		
Circumstance or information capable of leading to medication error	38	47	38	47		
Contraindicated product administered	1	1	1	1		
Contusion	15	20	15	20		
Dental restoration failure	2	2	2	2		
Epicondylitis	2	2	2	2		
Expired product administered	1	1	1	1		
Exposure during pregnancy	12	15	11	14	1	1
Exposure to SARS-CoV-2	36	43	25	32	11	11
Exposure via breast milk	41	71	41	71		
Exposure via eye contact	1	2	1	2		
Exposure via skin contact	10	13	9	12	1	1
Eye contusion	4	4	4	4		
Face injury	3	4	3	3		1
Fall	15	21	10	14	5	7
Foreign body aspiration		1				1
Fracture		1				1
Frostbite	1	1	1	1		
Head injury	5	6	3	4	2	2
Inappropriate schedule of product administration	267	273	267	273		
Incision site haemorrhage	1	1			1	1
Incomplete course of vaccination	8	8	8	8		

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System Organ Class

**Injury, poisoning and procedural complications**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Incorrect dose administered	10	13
Incorrect route of product administration	43	64
Injury	1	1
Intentional product misuse	1	1
Joint dislocation	1	2
Ligament injury	2	2
Ligament sprain	1	1
Limb injury	4	5
Lip injury	2	2
Maternal exposure during breast feeding	1	1
Maternal exposure during pregnancy	48	71
Maternal exposure timing unspecified	1	1
Muscle strain	1	3
Nasal injury	2	2
Neck injury		1
Nerve injury		1
Occupational exposure to product	1	1
Occupational exposure to SARS-CoV-2	5	6
Off label use	188	242
Overdose	33	50
Poor quality product administered	91	192
Post procedural haemorrhage	1	1
Procedural pain	2	3
Product administered at inappropriate site	23	35
Product administered to patient of inappropriate age	4	5
Product administration error	11	11
Product confusion	1	1
Product dose omission issue	2	2
Product preparation error	64	86
Product preparation issue	48	64
Product prescribing error	2	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
9	12	1	1
40	61	3	3
1	1		
1	1		
		1	2
2	2		
1	1		
4	5		
1	1	1	1
1	1		
47	70	1	1
1	1		
1	3		
2	2		
	1		
	1		
1	1		
4	5	1	1
187	241	1	1
33	50		
91	192		
		1	1
1	2	1	1
22	34	1	1
4	5		
11	11		
1	1		
2	2		
64	85		1
48	63		1
2	5		

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System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	179	241	177	239	2	2
Scar	1	1	1	1		
Scratch	3	4	1	2	2	2
Skin injury	1	2	1	2		
Skin laceration	2	3	2	3		
Sunburn	2	2	2	2		
Suture related complication	1	1			1	1
Tongue injury	1	1	1	1		
Underdose	70	108	70	108		
Vaccination complication	2	2	2	2		
Wound	2	2	2	2		
Wound haemorrhage	1	1			1	1
Wrong product administered	5	6	5	6		
Wrong technique in product usage process	23	47	22	46	1	1
	1,379	1,885	1337	1834	42	51

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System Organ Class

Investigations

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

		Spontaneous			
		Nonserious		Serious	
		I	C	I	C
Alanine aminotransferase increased	1			1	1
Aspartate aminotransferase increased	1	1	1		
Bilirubin urine present	1	1	1		
Blood count abnormal			1		
Blood creatinine increased	1	1	1		
Blood glucose abnormal	2	2	2		
Blood glucose decreased	3	2	3	1	1
Blood glucose fluctuation	1	1	1		
Blood glucose increased	11	9	10	2	2
Blood iron decreased	1	1	1		
Blood potassium decreased	3	2	2	1	1
Blood pressure abnormal	1	1	3		
Blood pressure decreased	6	4	8	2	3
Blood pressure diastolic decreased	1	1	1		
Blood pressure diastolic increased	1	1	2		1
Blood pressure increased	59	34	59	25	38
Blood pressure systolic increased	5	2	2	3	4
Blood sodium decreased	1	1	1		
Blood testosterone decreased	1	1	1		
Blood thyroid stimulating hormone increased	2	2	2		
Blood urine present	3	3	4		
Body height decreased	5	5	6		
Body temperature abnormal	6	6	8		
Body temperature decreased	6	6	6		1
Body temperature fluctuation	1	1	1		
Body temperature increased	31	31	46		
Capillary nail refill test abnormal			1		
Coronavirus test positive	1			1	1
C-reactive protein increased	5	4	4	1	1
Crystal urine	1	1	1		
Ejection fraction abnormal			1		
Electrocardiogram abnormal	3	3	3		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Electrocardiogram QT prolonged		1
Eosinophil count increased	2	2
Epinephrine increased		1
Fibrin D dimer increased	2	3
Gastric pH decreased	1	1
Grip strength decreased	1	2
Haematocrit decreased	1	1
Haemoglobin decreased	2	2
Haemoglobin increased	1	1
Heart rate abnormal	2	3
Heart rate decreased	2	7
Heart rate increased	155	245
Heart rate irregular	5	8
Hepatic enzyme increased	1	1
Influenza B virus test positive	1	1
International normalised ratio decreased	1	1
International normalised ratio increased	3	3
Intraocular pressure increased	1	1
Lipids increased		1
Liver function test abnormal	1	1
Lymph node palpable	1	1
Monocyte count increased	1	1
Myocardial necrosis marker increased	1	2
Neutrophil count increased	1	1
Orthostatic heart rate response increased	1	1
Oxygen consumption	1	1
Oxygen saturation decreased	13	14
Platelet count decreased	2	3
Platelet count increased	5	5
PO2 decreased	2	2
Pulse abnormal	7	9
Red blood cell count decreased	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
		2	2
	1		
1	2	1	1
1	1		
1	2		
1	1		
1	1	1	1
1	1		
2	3		
2	5		2
121	195	34	50
5	7		1
1	1		
1	1		
2	2	1	1
1	1		
	1		
		1	1
1	1		
		1	2
		1	1
1	1		
1	1		
8	9	5	5
	1	2	2
3	3	2	2
1	1	1	1
5	7	2	2
1	1		

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System Organ Class

Investigations

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Red blood cell sedimentation rate increased	2	2	2	2		
Red blood cells urine positive	1	1	1	1		
Respiratory rate decreased		1				1
Respiratory rate increased	3	6	1	3	2	3
SARS-CoV-1 test positive	1	1			1	1
SARS-CoV-2 ant body test negative	9	9	9	9		
SARS-CoV-2 ant body test positive	2	6	2	5		1
SARS-CoV-2 test false positive	1	1	1	1		
SARS-CoV-2 test positive	168	234	3	4	165	230
Streptococcus test positive		1		1		
Troponin increased	2	2			2	2
Tryptase increased	1	1	1	1		
Urine output increased	1	1	1	1		
Weight decreased	13	16	10	13	3	3
Weight increased	2	4	2	4		
White blood cell count increased	3	4			3	4
	591	854	324	480	267	374

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System Organ Class

**Metabolism and nutrition disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Decreased appetite	69	90	65	84	4	6
Dehydration	16	23	13	19	3	4
Diabetes mellitus	4	5			4	5
Diet refusal	1	1			1	1
Feeding disorder	7	9	6	8	1	1
Fluid imbalance	1	1			1	1
Fluid intake reduced	1	1	1	1		
Food aversion	1	1	1	1		
Gout	5	5	5	5		
Hyperglycaemia	3	3	1	1	2	2
Hypocalcaemia	1	1			1	1
Hypoglycaemia	3	4	3	4		
Hypokalaemia	1	1			1	1
Hypomagnesaemia	1	1			1	1
Hypophagia	2	2	2	2		
Increased appetite	2	2	2	2		
Malnutrition		1		1		
Oligodipsia	1	1			1	1
Overweight	1	1	1	1		
Polydipsia	2	2	2	2		
Poor feeding infant		1		1		
Tetany	1	2			1	2
	123	158	102	132	21	26

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	488	632	468	606	20	26
Arthritis	17	18	16	17	1	1
Arthropathy	3	5	3	5		
Axillary mass	6	10	5	8	1	2
Back pain	138	178	129	166	9	12
Bone pain	29	37	25	33	4	4
Bone swelling	2	4	2	4		
Costochondritis	1	1			1	1
Extremity contracture	1	1	1	1		
Facet joint syndrome	1	1	1	1		
Facial asymmetry		1		1		
Fibromyalgia	1	1			1	1
Flank pain	3	3	3	3		
Groin pain	3	3	3	3		
Immune-mediated arthritis		1				1
Intervertebral disc protrusion	1	1	1	1		
Joint effusion	1	1	1	1		
Joint instability	1	2			1	2
Joint noise	1	1	1	1		
Joint range of motion decreased	14	22	11	19	3	3
Joint stiffness	10	12	10	11		1
Joint swelling	17	27	14	24	3	3
Limb discomfort	43	63	39	57	4	6
Limb mass	2	2	1	1	1	1
Mixed connective tissue disease	1	1			1	1
Mobility decreased	14	22	12	19	2	3
Muscle atrophy	1	1	1	1		
Muscle discomfort	4	5	4	5		
Muscle disorder	2	2	2	2		
Muscle fatigue	4	6	4	6		
Muscle spasms	64	77	56	69	8	8
Muscle swelling	2	2	2	2		

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle tightness	27	35	26	33	1	2
Muscle twitching	14	16	13	15	1	1
Muscular weakness	49	63	39	51	10	12
Musculoskeletal chest pain	11	19	11	19		
Musculoskeletal discomfort	16	20	15	19	1	1
Musculoskeletal disorder	5	6	3	4	2	2
Musculoskeletal pain	6	9	5	7	1	2
Musculoskeletal stiffness	61	73	58	69	3	4
Myalgia	594	798	571	768	23	30
Myopathy	1	1	1	1		
Myositis	2	2			2	2
Neck mass	5	5	5	5		
Neck pain	134	164	129	156	5	8
Nuchal rigidity	1	2	1	2		
Osteochondritis	1	1	1	1		
Pain in extremity	701	929	688	910	13	19
Pain in jaw	23	33	21	31	2	2
Periarthritis	2	2	1	1	1	1
Polymyalgia rheumatica	1	1			1	1
Psoriatic arthropathy	1	1			1	1
Rheumatoid arthritis	1	2			1	2
Sinus tarsi syndrome	1	1	1	1		
Soft tissue swelling		1		1		
Spinal pain	7	10	7	10		
Systemic lupus erythematosus	1	1			1	1
Systemic sclerosis		1				1
Tendonitis	2	3	1	2	1	1
Tendon pain	2	2	2	2		
Tenosynovitis		1		1		
Trismus	3	3	3	3		
Undifferentiated connective tissue disease		1				1
	2,547	3,349	2417	3179	130	170

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear neoplasm	1	1	1	1		
Lung neoplasm malignant	1	1			1	1
Neoplasm skin	1	1	1	1		
	3	3	2	2	1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Acoustic neuritis		1				1	
Acute disseminated encephalomyelitis	1	1			1	1	
Ageusia	42	65	37	57	5	8	
Allodynia	1	1	1	1			
Amnesia	5	6	3	4	2	2	
Anaesthesia		2		2			
Anosmia	42	65	36	55	6	10	
Aphasia	5	8	2	5	3	3	
Ataxia		1				1	
Aura	1	1	1	1			
Autonomic nervous system imbalance	1	1			1	1	
Balance disorder	21	29	19	25	2	4	
Basal ganglia haemorrhage	1	2			1	2	
Brachial plexopathy	1	1			1	1	
Bradykinesia		1		1			
Brain injury	2	2			2	2	
Brain oedema	2	2			2	2	
Burning sensation	41	57	36	49	5	8	
Central nervous system lesion	1	1	1	1			
Cerebral disorder		1		1			
Cerebral haemorrhage	3	3			3	3	
Cerebrovascular accident	13	16			13	16	
Cluster headache	1	1	1	1			
Cognitive disorder	2	5	2	4		1	
Coma	1	1			1	1	
Coordination abnormal	2	2	1	1	1	1	
Demyelinating polyneuropathy	1	1			1	1	
Depressed level of consciousness	1	2			1	2	
Disturbance in attention	15	24	14	20	1	4	
Dizziness	489	742	438	657	51	85	
Dizziness exertional	2	2	2	2			
Dizziness postural	10	12	8	10	2	2	

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drooling	1	1	1	1		
Dysaesthesia		1		1		
Dysarthria	4	8	2	6	2	2
Dysgeusia	71	107	69	104	2	3
Dyskinesia	3	5	2	3	1	2
Dyslexia		1		1		
Dysstasia	9	10	6	6	3	4
Dystonia	1	1			1	1
Encephalopathy	1	1			1	1
Facial nerve disorder	1	1	1	1		
Facial paralysis	50	67		1	50	66
Facial paresis	5	5	2	2	3	3
Febrile convulsion	1	1			1	1
Fine motor skill dysfunction	3	4	3	4		
Formication	3	3	3	3		
Freezing phenomenon		1		1		
Guillain-Barre syndrome	2	3			2	3
Haemorrhage intracranial	1	1			1	1
Haemorrhagic stroke	1	1			1	1
Hand-eye coordination impaired	1	1			1	1
Headache	1,525	2,045	1458	1956	67	89
Head discomfort	22	31	21	29	1	2
Head titubation	1	1	1	1		
Hemiparesis	2	3			2	3
Hemiplegia	1	1			1	1
Hyperaesthesia	12	16	11	15	1	1
Hypersomnia	22	30	20	28	2	2
Hypertonia		1		1		
Hypoaesthesia	179	259	148	218	31	41
Hypogeusia	3	5	3	5		
Hypokinesia	5	6	5	6		
Hyposmia	1	4	1	4		

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System Organ Class

**Nervous system disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hypotonia	2	2
Incoherent	1	1
Infant irritability	1	3
Irregular sleep wake rhythm disorder		1
Lethargy	50	64
Loss of consciousness	31	39
Loss of proprioception	1	1
Memory impairment	9	12
Meningism	1	1
Mental impairment	9	14
Migraine	82	100
Migraine with aura	1	1
Mononeuropathy	1	1
Motor dysfunction	3	3
Movement disorder	19	21
Muscle contractions involuntary	1	1
Myelitis transverse	1	1
Nerve compression	6	6
Nervous system disorder	1	1
Neuralgia	22	24
Neuritis	1	1
Neurological symptom	1	1
Neuropathy peripheral	11	12
Noninfective encephalitis	1	1
Nystagmus	2	2
Occipital neuralgia	1	1
Optic neuritis	1	1
Paraesthesia	199	301
Paraesthesia mucosal		1
Paralysis	5	5
Parosmia	10	17
Peroneal nerve palsy	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
		1	1
1	3		
	1		
49	62	1	2
		31	39
		1	1
6	8	3	4
1	1		
		9	14
76	93	6	7
1	1		
		1	1
1	1	2	2
19	21		
		1	1
		1	1
6	6		
		1	1
21	23	1	1
1	1		
		1	1
		11	12
		1	1
1	1	1	1
1	1		
		1	1
169	259	30	42
	1		
		5	5
10	16		1
	1	1	1

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System Organ Class

**Nervous system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Polyneuropathy	2	2			2	2
Poor quality sleep	13	20	13	20		
Postictal state		1		1		
Presyncope	30	45	23	34	7	11
Psychomotor hyperactivity	2	2	1	1	1	1
Reduced facial expression		1		1		
Restless legs syndrome	2	2	2	2		
Sciatica	1	1	1	1		
Sedation	1	2	1	2		
Seizure	6	9			6	9
Sensory disturbance	4	6	4	6		
Sensory loss	5	6	5	6		
Serotonin syndrome	1	1			1	1
Sinus headache	4	7	4	7		
Sleep paralysis	1	1	1	1		
Slow response to stimuli		1		1		
Somnolence	65	92	59	86	6	6
Speech disorder	15	20	13	18	2	2
Syncope	26	39			26	39
Taste disorder	11	22	10	21	1	1
Tension headache	4	5	4	5		
Transient global amnesia	1	1	1	1		
Transient ischaemic attack	3	4			3	4
Tremor	97	129	82	109	15	20
Trigeminal nerve disorder		1		1		
Trigeminal neuralgia	2	2	1	1	1	1
Trigeminal neuritis	1	1	1	1		
Tunnel vision	2	4			2	4
Unresponsive to stimuli	3	3			3	3
Visual field defect	1	1	1	1		
	3,416	4,757	2951	4123	465	634

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortion spontaneous	6	6			6	6
Premature rupture of membranes	1	1			1	1
Uterine contractions during pregnancy	1	1	1	1		
	8	8	1	1	7	7

System Organ Class

**Product issues**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device breakage	1	1			1	1
Liquid product physical issue	5	5	5	5		
Needle issue	3	6	3	6		
Product complaint		1		1		
Product formulation issue		1				1
Product leakage	5	9	5	9		
Product packaging quantity issue		4		4		
Product temperature excursion issue	15	105	15	105		
Syringe issue		1		1		
	29	133	28	131	1	2

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System Organ Class

Psychiatric disorders

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1			1	1
Abnormal dreams	8	10	8	10		
Aggression	2	2	2	2		
Agitation	3	7	3	7		
Anger	4	4	4	4		
Anxiety	44	65	40	59	4	6
Communication disorder		1		1		
Confusional state	19	24	17	21	2	3
Delirium	3	4			3	4
Delusional perception	2	2	1	1	1	1
Depersonalisation/derealisation disorder	1	1	1	1		
Depressed mood	6	8	5	7	1	1
Depression	3	3	1	1	2	2
Disorientation	6	8	5	7	1	1
Dissociation	2	2	1	1	1	1
Dysphemia		1		1		
Eating disorder	6	10	5	8	1	2
Emotional disorder	3	5	3	5		
Emotional distress	1	1			1	1
Euphoric mood	1	1	1	1		
Fear	6	10	6	9		1
Frustration tolerance decreased	1	2	1	2		
Hallucination	1	2			1	2
Hallucination, auditory	2	2			2	2
Hallucination, visual	2	2			2	2
Hydrophobia	1	1	1	1		
Hypervigilance	1	1	1	1		
Illness anxiety disorder	1	1	1	1		
Impulsive behaviour	1	1	1	1		
Initial insomnia	2	3	2	3		
Insomnia	84	103	81	100	3	3
Intrusive thoughts	1	1	1	1		

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System Organ Class

**Psychiatric disorders**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Irritability	8	9
Laziness	1	2
Mania	1	1
Mental disorder	3	4
Mental fatigue	1	1
Middle insomnia	14	16
Mutism	1	1
Nervousness	18	32
Nightmare	6	7
Panic attack	3	7
Panic reaction	4	5
Paranoia	1	2
Post-traumatic stress disorder	1	2
Pressure of speech	1	1
Psychiatric symptom	1	1
Restlessness	12	14
Sitophobia	1	1
Sleep disorder	18	22
Sleep disorder due to a general medical condition	2	3
Sleep disorder due to general medical condition, insomnia type	1	2
Sleep talking	1	1
Somatic symptom disorder	1	1
Staring		1
Stress	6	8
Substance abuse	1	1
Tachyphrenia	4	4
Tearfulness	1	1
Tension	1	1
Terminal insomnia	2	3
Thinking abnormal	4	6

Spontaneous			
Nonserious		Serious	
I	C	I	C
7	8	1	1
1	2		
		1	1
2	3	1	1
1	1		
14	15		1
		1	1
18	31		1
6	7		
2	5	1	2
4	4		1
1	2		
1	2		
		1	1
1	1		
9	11	3	3
1	1		
17	20	1	2
2	3		
1	2		
1	1		
1	1		
			1
6	8		
		1	1
4	4		
1	1		
1	1		
2	3		
4	6		

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System Organ Class

**Psychiatric disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tic	1	1	1	1		
	338	450	301	400	37	50

System Organ Class

**Renal and urinary disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Bladder discomfort	1	1	1	1		
Chromaturia	5	6	5	6		
Costovertebral angle tenderness	1	1	1	1		
Dysuria	3	4	3	4		
Haematuria		1				1
Incontinence	1	2	1	1		1
Micturition urgency	1	1	1	1		
Nephrolithiasis	1	1			1	1
Nocturia	1	1	1	1		
Pollakiuria	8	9	8	9		
Polyuria	3	3	3	3		
Renal disorder	2	2	2	2		
Renal impairment	1	1			1	1
Renal pain	7	8	7	8		
Urge incontinence		1		1		
Urinary incontinence	1	2	1	2		
Urinary retention	1	1			1	1
	38	46	34	40	4	6

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System Organ Class

**Reproductive system and breast disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adnexa uteri pain	1	1	1	1		
Breast discomfort	2	2	2	2		
Breast mass	1	1	1	1		
Breast milk discolouration	1	1	1	1		
Breast pain	9	9	9	9		
Breast swelling	2	3	2	3		
Breast tenderness	2	3	2	2		1
Dysmenorrhoea	3	4	3	4		
Menorrhagia	1	1	1	1		
Menstrual disorder	8	9	8	9		
Menstruation irregular	8	8	8	8		
Metrorrhagia	3	4	3	4		
Nipple pain	2	3	2	3		
Nipple swelling		2		2		
Pelvic pain	2	2	2	2		
Penile haemorrhage	1	1			1	1
Pruritus genital	1	1			1	1
Suppressed lactation	1	1	1	1		
Uterine haemorrhage	1	1			1	1
Vaginal haemorrhage	6	7	2	3	4	4
Vulvovaginal pruritus	1	1			1	1
Vulvovaginal rash	1	1			1	1
Vulvovaginal swelling	1	1			1	1
	58	67	48	56	10	11

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aphonia	1	2	1	2		
Asthma	9	11	7	9	2	2
Bronchospasm	3	4	2	3	1	1
Choking	3	3			3	3
Choking sensation	2	2			2	2
Cough	164	241	143	208	21	33
Dry throat	16	24	13	19	3	5
Dysphonia	16	26	9	14	7	12
Dyspnoea	210	287	141	189	69	98
Dyspnoea exertional	7	10	5	8	2	2
Epistaxis	18	22	17	21	1	1
Grunting	1	1			1	1
Haemoptysis	7	7	5	5	2	2
Hiccups	2	3	2	3		
Hyperventilation	5	9	3	5	2	4
Hypopnoea	3	3	2	2	1	1
Hypoxia		2				2
Increased bronchial secretion		1		1		
Increased upper airway secretion	3	4	3	3		1
Intranasal paraesthesia	1	2	1	2		
Laryngeal oedema	1	2			1	2
Laryngeal pain	1	1	1	1		
Laryngospasm	2	2			2	2
Lower respiratory tract congestion		1		1		
Lung disorder	2	2	2	2		
Lung infiltration		1				1
Nasal congestion	81	126	74	117	7	9
Nasal discomfort	3	6	3	5		1
Nasal disorder		1		1		
Nasal dryness	2	3	1	2	1	1
Nasal oedema	5	7	5	6		1
Obstructive airways disorder	1	2	1	1		1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Organising pneumonia		1
Oropharyngeal discomfort	7	15
Oropharyngeal pain	127	197
Oropharyngeal swelling	1	1
Orthopnoea	1	1
Painful respiration	2	3
Paranasal sinus discomfort	10	12
Paranasal sinus hypersecretion	2	2
Pharyngeal disorder	3	3
Pharyngeal erythema	5	5
Pharyngeal hypoaesthesia	5	9
Pharyngeal inflammation	3	3
Pharyngeal oedema	2	2
Pharyngeal paraesthesia	9	18
Pharyngeal swelling	40	64
Pleural effusion	2	2
Pleurisy	1	1
Pleuritic pain	1	2
Pneumonitis	1	1
Productive cough	9	12
Pulmonary congestion	3	4
Pulmonary embolism	2	3
Pulmonary oedema		1
Pulmonary pain	2	3
Respiration abnormal	1	1
Respiratory arrest	2	2
Respiratory disorder	1	1
Respiratory distress	6	8
Respiratory failure	1	1
Respiratory symptom		1
Respiratory tract congestion	8	10
Rhinalgia	5	6

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
6	10	1	5
118	183	9	14
		1	1
1	1		
2	3		
10	12		
2	2		
3	3		
4	4	1	1
2	5	3	4
3	3		
		2	2
3	12	6	6
23	37	17	27
1	1	1	1
		1	1
1	2		
1	1		
8	11	1	1
		3	4
		2	3
			1
2	3		
1	1		
		2	2
1	1		
		6	8
		1	1
			1
8	10		
5	6		

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rhinorrhoea	79	105	73	99	6	6
Sinus congestion	12	16	11	15	1	1
Sinus disorder	8	11	8	11		
Sinus pain	6	7	6	7		
Sneezing	21	29	21	29		
Snoring	1	2		1	1	1
Sputum discoloured	3	3	2	2	1	1
Status asthmaticus	1	1			1	1
Stridor	3	4			3	4
Suffocation feeling		1		1		
Tachypnoea	2	5	1	2	1	3
Throat clearing	1	2	1	1		1
Throat irritation	53	88	40	70	13	18
Throat tightness	52	84	27	43	25	41
Tonsillar erythema	1	1	1	1		
Tonsillar hypertrophy	2	3	2	3		
Tonsillolith	1	1	1	1		
Tracheomalacia		1				1
Upper-airway cough syndrome	6	11	6	11		
Upper airway obstruction	1	1			1	1
Upper respiratory tract congestion	12	21	11	20	1	1
Wheezing	17	27	9	15	8	12
	1,113	1,637	866	1273	247	364

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acne	3	4	3	4		
Alopecia	3	3	3	3		
Angioedema	5	12			5	12
Blister	12	18	12	18		
Circumoral swelling	1	1	1	1		
Cold sweat	24	35	20	31	4	4
Dermatitis	5	5	5	5		
Dermatitis allergic	4	4	3	3	1	1
Dermatitis contact	4	4	4	4		
Dermatitis exfoliative	1	1			1	1
Drug eruption		1		1		
Dry skin	2	3	2	3		
Ecchymosis	1	1	1	1		
Eczema		2		2		
Erythema	102	146	89	128	13	18
Hidradenitis	1	2	1	2		
Hyperhidrosis	129	180	120	166	9	14
Livedo reticularis	2	3	1	1	1	2
Macule	1	1	1	1		
Mechanical urticaria		1		1		
Night sweats	34	44	31	39	3	5
Pain of skin	9	12	9	12		
Palmar erythema	3	4	2	3	1	1
Papule	1	2	1	2		
Petechiae	9	9	8	8	1	1
Photosensitivity reaction	4	7	4	7		
Piloerection	3	5	2	4	1	1
Plantar erythema	1	1	1	1		
Pruritus	213	316	190	285	23	31
Psoriasis		1		1		
Purpura	1	1	1	1		
Rash	201	290	177	251	24	39

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System Organ Class

**Skin and subcutaneous tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash erythematous	33	49	28	39	5	10
Rash macular	26	37	24	33	2	4
Rash maculo-papular	7	9	7	9		
Rash papular	16	19	16	19		
Rash pruritic	38	53	36	50	2	3
Rash vesicular	8	8	7	7	1	1
Rosacea	1	1	1	1		
Scab		1		1		
Sensitive skin	7	7	7	7		
Skin burning sensation	11	13	11	13		
Skin discolouration	12	17	11	14	1	3
Skin disorder	10	14	10	13		1
Skin exfoliation	4	4	3	3	1	1
Skin indentation	1	1	1	1		
Skin irritation	7	8	7	8		
Skin lesion	2	2	2	2		
Skin mass	1	1	1	1		
Skin odour abnormal	1	1	1	1		
Skin reaction	3	4	2	3	1	1
Skin swelling	4	4	4	4		
Skin tightness	1	3		2	1	1
Skin warm	2	2	2	2		
Stevens-Johnson syndrome	1	1			1	1
Urticaria	176	246	138	200	38	46
	1,151	1,624	1011	1422	140	202

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System Organ Class

**Social circumstances**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bedridden	7	7	6	6	1	1
Contraindication to vaccination	2	2	2	2		
Exercise lack of	1	1	1	1		
Impaired driving ability	2	3	2	3		
Impaired work ability	5	7	5	7		
Loss of personal independence in daily activities	22	27	20	24	2	3
	39	47	36	43	3	4

System Organ Class

**Surgical and medical procedures**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Serious	
			I	C
Spinal fusion surgery	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure fluctuation	2	3	1	2	1	1
Circulatory collapse	3	3			3	3
Cyanosis	5	6	3	4	2	2
Deep vein thrombosis	6	6			6	6
Diastolic hypotension		1				1
Flushing	83	160	59	120	24	40
Giant cell arteritis	1	1	1	1		
Haemorrhage	3	5			3	5
Hot flush	37	55	33	49	4	6
Hyperaemia		1		1		
Hypertension	44	71	26	43	18	28
Hypertensive crisis	1	2			1	2
Hypertensive emergency	1	3			1	3
Hypotension	15	17	9	11	6	6
Labile hypertension	1	1	1	1		
Lymphoedema	6	8	6	8		
Microembolism	1	1			1	1
Orthostatic hypotension	1	1			1	1
Pallor	13	19	11	15	2	4
Peripheral coldness	14	29	14	28		1
Peripheral vascular disorder	1	1	1	1		
Phlebitis	1	1	1	1		
Poor peripheral circulation	1	2		1	1	1
Raynaud's phenomenon	1	2	1	2		
Shock symptom	1	2			1	2
Superficial vein prominence	1	1	1	1		
Thrombosis	4	4			4	4
Varicose vein	1	1	1	1		
Vascular pain	1	1	1	1		
Vasodilatation		1		1		
Vein discolouration	1	1	1	1		
	250	410	171	293	79	117

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Country Where Event Occurred  
**UNITED STATES MINOR OUTLYING ISLA**

System Organ Class

**Blood and lymphatic system disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphadenopathy	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Discomfort	1	1	1	1
Vaccination site pain		1		1
	1	2	1	2

System Organ Class

**Injury, poisoning and procedural complications**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration	1	1	1	1
	1	1	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint range of motion decreased	1	1	1	1
	1	1	1	1

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**APPENDIX 2.5.2: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Age Group by Preferred Term per Country**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval) / 18,061 (Cumulative)

Total Number of Adverse Events (PT): 51,740 (Interval) / 63,975 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AFGHANISTAN**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Erythema		1		1		
Facial paralysis		1				1
Feeling of body temperature change		1		1		
Muscle tightness		1		1		
Paraesthesia		1		1		
Pruritus		1		1		
Rash		1		1		
Swelling face		1		1		
		9		8		1

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Country Where Event Occurred

**ANDORRA**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administered to patient of inappropriate age	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**AUSTRIA**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Burning sensation	1	1	1	1		
Diarrhoea	1	1	1	1		
Fatigue	2	2	2	2		
Feeling drunk	1	1	1	1		
Hangover	1	1	1	1		
Headache	1	1	1	1		
Malaise	1	1	1	1		
Migraine	2	2	2	2		
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Poor quality product administered	1	1	1	1		
Product preparation error	1	1	1	1		
Pruritus	1	1	1	1		
Vaccination site pain	3	3	3	3		
Vaccination site pruritus	1	1	1	1		
	20	20	19	19	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	1	1	1	1
Cardiovascular disorder	1	1	1	1
Diarrhoea	1	1	1	1
Fatigue	1	1	1	1
Nausea	1	1	1	1
Vomiting	1	1	1	1
	6	6	6	6

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	1	1			1	1
Influenza	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
	3	3	1	1	2	2

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	2	2			2	2
Death	3	3			3	3
Fatigue	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Myocardial infarction	1	1			1	1
Nausea	2	2	2	2		
Pulmonary embolism	1	1			1	1
Rales	1	1			1	1
Respiratory depression	1	1			1	1
Somnolence	1	1			1	1
Urinary retention	1	1			1	1
Vaginal discharge	1	1	1	1		
Vomiting	2	2	2	2		
Wrong technique in product usage process	1	1	1	1		
	19	19	7	7	12	12

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
Pruritus	1	1	1	1
Urticaria	1	1	1	1
Vaccination site pain	2	2	2	2
	5	5	5	5

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Country Where Event Occurred

**BAHRAIN**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**BELGIUM**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site erythema	1	1	1	1
Vaccination site warmth	1	1	1	1
	2	2	2	2

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Pain in extremity	1	1	1	1
Palpitations	1	1	1	1
Sensory disturbance	1	1	1	1
Swollen tongue	1	1	1	1
Vaccination site pain	1	1	1	1
Vaccination site swelling	1	1	1	1
	8	8	8	8

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiovascular disorder	2	2			2	2
Fatigue	1	1	1	1		
Malaise	1	1	1	1		
Nausea	1	1	1	1		
Pulmonary embolism	1	1			1	1
Sudden death	1	1			1	1
	7	7	3	3	4	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute kidney injury	1	1			1	1
Acute respiratory failure	1	1			1	1
Agitation	2	2			2	2
Amnesia	1	1			1	1
Blood lactic acid increased	1	1			1	1
Bradycardia	1	1			1	1
Cardiovascular disorder	2	2			2	2
Confusional state	2	2			2	2
Death	1	1			1	1
Depressed level of consciousness	1	1			1	1
Disorientation	1	1			1	1
Dyspnoea	1	1			1	1
Eye movement disorder	1	1			1	1
Fatigue	1	1	1	1		
General physical health deterioration	1	1			1	1
Haemorrhage intracranial	1	1			1	1
Hypoglycaemia	1	1			1	1
Hypotension	1	1			1	1
Hypovolaemic shock	1	1			1	1
Intestinal dilatation	1	1			1	1
Intestinal ischaemia	2	2			2	2
Leukocytosis	1	1			1	1
Liver function test abnormal	1	1			1	1
Lung infiltration	1	1			1	1
Malaise	4	4	1	1	3	3
Metabolic acidosis	1	1			1	1
Nervous system disorder	1	1			1	1
Neutropenia	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Patient elopement	1	1			1	1
Pneumonitis	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Presyncope	2	2			2	2
Pyrexia	1	1			1	1
Renal disorder	1	1			1	1
Respiratory disorder	2	2			2	2
Sepsis	1	1			1	1
Septic shock	1	1			1	1
Staring	1	1			1	1
Sudden death	1	1			1	1
Tachycardia	1	1			1	1
Tachypnoea	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
	53	53	4	4	49	49

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	5	5			5	5
Dizziness	1	1	1	1		
Drug ineffective	5	5			5	5
Exposure via skin contact	1	1	1	1		
Fatigue	2	2	2	2		
Headache	1	1	1	1		
Illness	1	1	1	1		
Memory impairment	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Occupational exposure to product	1	1	1	1		
Pain in extremity	1	1	1	1		
Poor quality sleep	1	1	1	1		
Vaccination site pain	1	1	1	1		
	22	22	12	12	10	10

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Country Where Event Occurred

**BERMUDA**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**BULGARIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Erythema	1	1	1	1		
Nausea	1	1	1	1		
Palpitations	1	1	1	1		
Swelling	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site swelling	1	1	1	1		
	11	11	9	9	2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	2	2	2	2
Asthenia	2	2	2	2
Body temperature increased	2	2	2	2
Chills	1	2	1	2
Diarrhoea	1	1	1	1
Fatigue	1	1	1	1
Headache	3	3	3	3
Hyperhidrosis		1		1
Lymphadenopathy	1	1	1	1
Lymph node pain	1	1	1	1
Myalgia	2	2	2	2
Neck pain	1	1	1	1
Pain	1	1	1	1
Pain in extremity		1		1
Pyrexia	2	2	2	2
Swelling	1	1	1	1
Vaccination site pain	4	4	4	4
Vaccination site swelling	1	1	1	1
Vomiting	1	1	1	1
	27	30	27	30

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia	1	1	1	1
Rash	1	1	1	1
Rash erythematous	1	1	1	1
Rash pruritic	1	1	1	1
Vaccination site erythema	1	1	1	1
	5	5	5	5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure diastolic decreased	1	1	1	1		
Body temperature increased	1	1	1	1		
Chills	1	1			1	1
COVID-19	1	1			1	1
Diarrhoea	1	1	1	1		
Dizziness	2	2	1	1	1	1
Dizziness postural	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	1	1			1	1
Headache	2	2	1	1	1	1
Head discomfort	1	1			1	1
Hyperhidrosis	1	1			1	1
Myalgia	2	2	2	2		
Nausea	2	2	1	1	1	1
Pallor	1	1	1	1		
Paraesthesia	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Peripheral coldness	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vertigo	1	1			1	1
	28	28	18	18	10	10

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		1		1		
COVID-19	1	2			1	2
Drug ineffective	1	2			1	2
Lymphadenopathy	2	2	2	2		
	4	8	2	4	2	4

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Country Where Event Occurred

**CANADA**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	4	4	4	4
	4	4	4	4

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Arthralgia	3	3	3	3		
Asthenia	2	3	2	3		
Buttock injury	1	1	1	1		
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	1	1	1	1		
Decreased appetite	2	2	2	2		
Diarrhoea	2	2	2	2		
Distract bility	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	1	1	1	1		
Dyspnoea	1	1	1	1		
Erythema	1	1	1	1		
Exposure during pregnancy	2	2	2	2		
Eye pain	1	1	1	1		
Fatigue	5	5	5	5		
Feeling abnormal	2	2	2	2		
Genital blister	1	1	1	1		
Headache	6	7	6	7		
Herpes zoster	1	1	1	1		
Hot flush	1	1	1	1		
Impaired work ability	1	1	1	1		
Insomnia	1	1	1	1		
Lip swelling	1	1	1	1		
Localised infection	1	1	1	1		
Lung disorder	1	1			1	1
Lymphadenopathy		1		1		
Malaise	1	1	1	1		
Maternal exposure during pregnancy	2	2	2	2		
Migraine	1	1	1	1		
Muscle spasms	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle twitching	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	4	4	4	4		
Nausea	6	7	6	7		
Neck pain	1	1	1	1		
Odynophagia		1		1		
Off label use	4	4	4	4		
Oropharyngeal pain	1	2	1	2		
Overdose	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	5	5	5	5		
Palpitations	1	1	1	1		
Paraesthesia	1	1	1	1		
Product use issue	3	3	3	3		
Pruritus	1	1	1	1		
Pulmonary pain	1	1			1	1
Pyrexia	3	4	3	4		
Rash	1	1	1	1		
Rash pustular	1	1	1	1		
Swelling		1		1		
Swollen tongue		1		1		
Tachycardia	1	1	1	1		
Taste disorder	1	1	1	1		
Type IV hypersensitivity reaction	1	1	1	1		
Vaccination site pain	4	4	4	4		
Vaccination site rash	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vomiting	2	2	2	2		
	97	106	93	102	4	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Administration site pain	1	1	1	1		
Affect lability	1	1	1	1		
Anaphylactic reaction	1	1	1	1		
Angioedema	1	1			1	1
Anxiety	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Arthralgia	5	5	4	4	1	1
Asthenia	1	1	1	1		
Body temperature increased	1	1	1	1		
Chills	5	7	5	7		
Depression	1	1	1	1		
Diarrhoea	4	5	4	5		
Dizziness	4	4	4	4		
Drug ineffective	2	2			2	2
Dysphagia	2	2	2	2		
Ear discomfort	1	1	1	1		
Eczema	1	1	1	1		
Erythema	1	1			1	1
Eye swelling	1	1	1	1		
Face oedema	1	1			1	1
Facial paralysis		1				1
Fatigue	9	10	8	9	1	1
Fear	1	1	1	1		
Feeling abnormal	1	2	1	2		
Feeling cold	2	2	1	1	1	1
Feeling hot	1	1	1	1		
Fibromyalgia	1	1	1	1		
Fluid retention		1		1		
Flushing	1	1			1	1
Gastroesophageal reflux disease	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Headache	11	13
Heart rate increased		1
Hyperhidrosis	1	1
Hypersensitivity	2	2
Hypertension	2	2
Hypoaesthesia	2	2
Hypotension	1	1
Illness	1	1
Influenza like illness	2	2
Joint swelling	1	1
Lethargy	1	1
Leukoplakia	1	1
Lymphadenopathy	4	4
Malaise	1	1
Maternal exposure during pregnancy	5	5
Metrorrhagia	1	1
Muscular weakness	1	1
Myalgia	9	9
Nasal congestion	1	1
Nasopharyngitis	1	1
Nausea	1	2
Neck pain	1	1
Off label use	6	6
Oropharyngeal pain	1	1
Overdose	1	1
Pain	3	5
Pain in extremity	5	8
Paraesthesia	4	6
Paraesthesia oral	2	4
Petechiae	1	1
Pharyngeal swelling	2	2
Presyncope	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
11	13		
	1		
1	1		
1	1	1	1
1	1	1	1
1	1	1	1
		1	1
1	1		
2	2		
1	1		
1	1		
1	1		
4	4		
1	1		
5	5		
1	1		
1	1		
8	8	1	1
1	1		
1	1		
1	2		
1	1		
6	6		
1	1		
1	1		
3	5		
5	8		
3	4	1	2
2	3		1
1	1		
1	1	1	1
	1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product administered at inappropriate site	1	1	1	1		
Product use issue	5	5	5	5		
Pruritus	2	2	1	1	1	1
Pyrexia	10	11	10	11		
Rash	1	1			1	1
Rash macular	1	1	1	1		
Rheumatoid arthritis	1	1			1	1
SARS-CoV-2 test positive	2	2			2	2
Sinus pain	1	1	1	1		
Skin burning sensation	1	1	1	1		
Skin lesion	1	1	1	1		
Sneezing	1	1	1	1		
Stress	1	1	1	1		
Swelling	1	1			1	1
Swollen tongue	2	2	1	1	1	1
Syncope	1	1			1	1
Tachycardia	3	3	2	2	1	1
Tachypnoea	1	1	1	1		
Thirst		1		1		
Throat irritation	1	1	1	1		
Tongue disorder	1	1			1	1
Urticaria	3	4	3	4		
Vaccination site pain	5	5	4	4	1	1
Vomiting	1	1	1	1		
Vulval disorder	1	1			1	1
	179	203	150	171	29	32

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Arthralgia	3	3	3	3		
Blood pressure fluctuation	1	1	1	1		
Chills	1	1	1	1		
Cold sweat	1	1	1	1		
Diarrhoea		1		1		
Disease recurrence	1	1	1	1		
Dizziness	1	1	1	1		
Dysgeusia		1		1		
Dysphagia		1		1		
Fatigue	3	3	3	3		
Headache	7	7	7	7		
Heart rate increased	1	1	1	1		
Herpes zoster	1	1	1	1		
Hyperaesthesia	1	1	1	1		
Hypertension		1		1		
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Joint swelling	1	1			1	1
Lip swelling	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	3	3	3	3		
Nausea	2	2	2	2		
Oral mucosal blistering	1	1	1	1		
Overdose	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Pain of skin	1	1	1	1		
Paraesthesia oral		1		1		
Peripheral swelling	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	2	2	2	2		
Pyrexia	3	3	3	3		
Rash	2	2	2	2		
Tachycardia	1	1			1	1
Tongue pruritus		1		1		
Tremor	2	2	2	2		
Vaccination site induration	1	1	1	1		
Vaccination site pain	4	4	4	4		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vision blurred	1	1	1	1		
Visual impairment	1	1	1	1		
Vomiting	1	1	1	1		
	61	67	58	64	3	3

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	1	1	1	1
Abdominal pain upper	1	1	1	1
Back pain	1	1	1	1
Eye pruritus	1	1	1	1
Fatigue	1	2	1	2
Gastroenteritis	1	1	1	1
Headache	2	2	2	2
Hypersomnia		1		1
Hypoaesthesia	1	1	1	1
Nausea	1	1	1	1
Pain	1	1	1	1
Pain in extremity	1	1	1	1
Pharyngeal hypoaesthesia	1	1	1	1
Pruritus	1	1	1	1
	14	16	14	16

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\* I=Interval, C=Cumulative  
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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Agitation	1	1	1	1		
Cellulitis	1	1			1	1
COVID-19	1	1			1	1
Deafness	1	1			1	1
Decreased appetite	1	1	1	1		
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Herpes zoster	1	1	1	1		
Lethargy	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Rash macular	1	1	1	1		
Skin lesion	1	1	1	1		
Somnolence	1	1	1	1		
Varicella	1	1	1	1		
Vital functions abnormal	1	1			1	1
Vomiting	1	1	1	1		
	17	17	12	12	5	5

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine		1		1		
Chills	1	1	1	1		
COVID-19	3	3			3	3
Diarrhoea	1	1	1	1		
Drug ineffective	4	4			4	4
Exposure during pregnancy	2	2	2	2		
Exposure via breast milk	2	2	2	2		
Fatigue	2	2	2	2		
Headache	2	2	2	2		
Hypersensitivity	2	2	2	2		
Inappropriate schedule of product administration	1	1	1	1		
Incomplete course of vaccination	1	1	1	1		
Malaise	2	2	2	2		
Maternal exposure during pregnancy	4	4	4	4		
Maternal exposure timing unspecified	2	2	2	2		
Musculoskeletal stiffness	1	1	1	1		
Off label use	7	7	7	7		
Overdose	3	3	3	3		
Pain in extremity	2	2	2	2		
Product preparation issue	10	10	10	10		
Product use issue	7	7	7	7		
SARS-CoV-2 test positive	1	1			1	1
Syncope		1				1
Underdose	4	4	4	4		
Vaccination site pain		1		1		
	64	67	56	58	8	9

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Country Where Event Occurred

**CHILE**

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Arthralgia	2	2	1	1	1	1
Arthritis	1	1			1	1
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Chills	2	2	1	1	1	1
Diarrhoea	2	2	2	2		
Disease recurrence	1	1	1	1		
Dyspnoea	1	1			1	1
Eye pruritus	1	1			1	1
Eye swelling	1	1	1	1		
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Headache	4	4	3	3	1	1
Hyperhidrosis	1	1	1	1		
Joint swelling	2	2	1	1	1	1
Lymphadenopathy	2	2	1	1	1	1
Lymph node pain	2	2	2	2		
Muscle spasms	1	1	1	1		
Myalgia	1	1			1	1
Nasal congestion	1	1	1	1		
Ocular hyperaemia	1	1			1	1
Off label use	1	1	1	1		
Pain in extremity	2	2	2	2		
Photophobia	1	1			1	1
Product use issue	1	1	1	1		
Pyrexia	3	3	2	2	1	1
Sensory loss	1	1	1	1		
Swelling face	1	1	1	1		
Vaccination site pain	1	1			1	1
	42	42	28	28	14	14

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abdominal pain upper	1	1	1	1
Nausea	1	1	1	1
Pancreatitis	1	1	1	1
Urine analysis abnormal	1	1	1	1
	4	4	4	4

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	2	2	2	2		
Crying		1				1
Dermatitis allergic		4		4		
Diarrhoea	2	2	2	2		
Dizziness		1		1		
Dry mouth		1				1
Erythema	1	1	1	1		
Fatigue		1		1		
Headache	2	3	2	3		
Hypersensitivity	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Lymphadenopathy	1	2	1	2		
Malaise	1	2	1	2		
Maternal exposure timing unspecified	1	1	1	1		
Myalgia	1	2	1	2		
Nausea		1		1		
Off label use	1	1	1	1		
Pain		1		1		
Paraesthesia		1				1
Peripheral swelling	1	1	1	1		
Polydipsia	1	1	1	1		
Product use issue	1	1	1	1		
Pyrexia		1		1		
Vaccination site pain	1	2	1	2		
	18	35	18	32		3

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Country Where Event Occurred

**COLOMBIA**

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Candida infection	1	1	1	1
Gingivitis	1	1	1	1
Hypersensitivity	1	1	1	1
Leukocytosis	1	1	1	1
Mouth swelling	1	1	1	1
Stomatitis	1	1	1	1
	6	6	6	6

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Country Where Event Occurred

**COSTA RICA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
Lymph node pain	1	1	1	1
Pain in extremity	1	1	1	1
	3	3	3	3

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper	1	1	1	1
Asthenia	1	1	1	1
Energy increased	1	1	1	1
Euphoric mood	1	1	1	1
Fatigue	1	1	1	1
Headache	3	3	3	3
Heart rate irregular	1	1	1	1
Insomnia	1	1	1	1
Pain in extremity	1	1	1	1
Pruritus	1	1	1	1
Rash	1	1	1	1
Red blood cell sedimentation rate increased	1	1	1	1
Sleep disorder	1	1	1	1
Tachycardia	1	1	1	1
Vaccination site pain	1	1	1	1
Vasculitis	1	1	1	1
	18	18	18	18

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hepatic enzyme increased	1	1	1	1
Joint range of motion decreased	1	1	1	1
Malaise	1	1	1	1
Mobility decreased	1	1	1	1
Myalgia	1	1	1	1
Pyrexia	1	1	1	1
Splenomegaly	1	1	1	1
	7	7	7	7

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	2	2	2	2
Eye allergy	1	1	1	1
Eye inflammation	1	1	1	1
Feeling abnormal	1	1	1	1
Feeling hot	1	1	1	1
Headache	2	2	2	2
Limb discomfort	1	1	1	1
Malaise	1	1	1	1
Myalgia	1	1	1	1
Pain	1	1	1	1
Pyrexia	2	2	2	2
Vaccination site pain	2	2	2	2
	16	16	16	16

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Country Where Event Occurred

**CROATIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	1	1	1	1		
Dysgeusia	1	1			1	1
Eye pain	1	1	1	1		
Fatigue		1		1		
Feeling cold	1	1	1	1		
Headache	1	1	1	1		
Myalgia		1		1		
Neck pain	1	1	1	1		
Pain in extremity		1		1		
Pharyngeal paraesthesia	1	1			1	1
Pyrexia	1	2	1	2		
Tongue oedema	1	1			1	1
Tremor	1	1			1	1
Vaccination site pain	4	5	4	5		
Vaccination site swelling	1	1	1	1		
	15	20	11	16	4	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Body temperature increased		1		1		
Burning sensation	1	1			1	1
Chills	2	2	2	2		
Erythema	1	1			1	1
Eyelid ptosis	1	1			1	1
Facial paresis	1	1			1	1
Fatigue	2	3	2	3		
Headache	4	5	3	4	1	1
Hypoaesthesia oral	1	1			1	1
Lip disorder	1	1			1	1
Malaise	1	1	1	1		
Myalgia		1		1		
Pain	1	1	1	1		
Paraesthesia	1	1			1	1
Peripheral swelling	1	1	1	1		
Pruritus	1	1			1	1
Pyrexia	3	4	3	4		
Rash	1	1			1	1
Rash erythematous	1	1			1	1
Type I hypersensitivity	1	1			1	1
Vaccination site oedema	1	1			1	1
Vaccination site pain	1	2		1	1	1
	28	34	14	20	14	14

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Body temperature increased	1	1	1	1		
Bronchospasm	1	1			1	1
Dyspnoea	1	1			1	1
Erythema	1	1	1	1		
Headache	1	1	1	1		
Multi-organ disorder	1	1			1	1
Pyrexia	2	2	2	2		
Rash	1	1	1	1		
Respiratory tract oedema	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Tachypnoea	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	1	1	1	1		
Wheezing	1	1			1	1
	19	19	8	8	11	11

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
Headache	1	1	1	1
Vaccination site pain	1	1	1	1
	3	3	3	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergy to chemicals	1	1	1	1
Feeling hot	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**CYPRUS**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	1	1	1		
Eyelid ptosis	1	1	1	1		
Facial paresis	1	1	1	1		
Headache	2	2	2	2		
Hypersensitivity	1	1	1	1		
Hypoaesthesia	1	1			1	1
Pyrexia	1	1	1	1		
	8	8	7	7	1	1

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cervix oedema	1	1	1	1		
Facial paralysis	1	1			1	1
Hypertension	1	1			1	1
Hypoaesthesia eye	1	1			1	1
Hypoaesthesia oral	1	1			1	1
Rash	1	1	1	1		
Tachyarrhythmia	1	1			1	1
Tachycardia	1	1			1	1
	8	8	2	2	6	6

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood pressure increased	1	1	1	1
Lymphadenopathy	1	1	1	1
	2	2	2	2

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Myocardial infarction		1		1
		1		1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
Dysgeusia	1	1	1	1
Migraine	1	1	1	1
Swollen tongue	1	1	1	1
Vaccination site pain	2	2	2	2
	6	6	6	6

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Country Where Event Occurred

**CZECH REPUBLIC**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Chills	1	1	1	1		
Circulatory collapse	1	1			1	1
COVID-19	1	1			1	1
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Fatigue	2	2	2	2		
Headache	3	3	3	3		
Nausea	1	1	1	1		
Pain	1	1	1	1		
Pyrexia	2	2	2	2		
Rhinorrhoea	1	1	1	1		
Somnolence	1	1	1	1		
	17	17	13	13	4	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2			2	2
Anaphylactic reaction	1	1			1	1
Angioedema	1	1			1	1
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Asthma	1	1			1	1
Blood pressure increased	1	1			1	1
Chills	1	1			1	1
Dizziness	2	2	1	1	1	1
Dyspnoea	3	3	1	1	2	2
Erythema	2	2	2	2		
Fatigue	3	3	3	3		
Headache	2	2	2	2		
Hypertension	1	1	1	1		
Hyperventilation	1	1	1	1		
Hypoesthesia	1	1	1	1		
Joint stiffness	1	1	1	1		
Lip swelling	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Mobility decreased	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Nausea	3	3	2	2	1	1
Pain in extremity	2	2	2	2		
Paraesthesia	2	2	1	1	1	1
Peripheral swelling	1	1			1	1
Photophobia	1	1	1	1		
Pruritus	1	1	1	1		
Rash	1	1	1	1		
Somnolence	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Swelling	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Tachypnoea	1	1			1	1
Throat tightness	1	1			1	1
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vertigo	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	1	1			1	1
	54	54	34	34	20	20

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Body temperature increased	1	1	1	1		
Cough	1	1	1	1		
Drug ineffective	1	1			1	1
Facial paresis	1	1			1	1
Fatigue	2	2	2	2		
Hypersensitivity	1	1			1	1
Myalgia	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Pyrexia	1	1	1	1		
Rhinitis	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Swollen tongue	1	1			1	1
	15	15	9	9	6	6

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Back pain	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue	2	2	2	2		
Hypersensitivity	1	1	1	1		
Musculoskeletal chest pain	1	1	1	1		
Myalgia	1	1	1	1		
Pyrexia	1	1	1	1		
Vaccination site pain	1	1	1	1		
	10	10	8	8	2	2

\* I=Interval, C=Cumulative

\* AE=Adverse Event

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Country Where Event Occurred

**DENMARK**

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Arthralgia	1	1	1	1		
Axillary pain	1	1	1	1		
Chills	2	2	2	2		
Diarrhoea	1	1	1	1		
Dizziness	3	3	1	1	2	2
Dyspnoea	1	1			1	1
Eye pain	1	1	1	1		
Fatigue	2	2	2	2		
Flushing	1	1			1	1
Headache	7	7	7	7		
Hot flush	1	1	1	1		
Hypersensitivity	2	2			2	2
Influenza like illness	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	3	3	1	1	2	2
Migraine	1	1	1	1		
Myalgia	7	7	7	7		
Nausea	2	2	1	1	1	1
Obstructive airways disorder	1	1			1	1
Odynophagia	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Palpitations	2	2			2	2
Presyncope	1	1			1	1
Pruritus	1	1	1	1		
Pyrexia	9	9	9	9		
Rash	1	1			1	1
Rash erythematous	1	1			1	1
Rash pruritic	1	1			1	1
Stridor	1	1			1	1
Swelling face	2	2			2	2
Tachycardia	1	1			1	1

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Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
3	3	1	1
13	13		
2	2		
		1	1
4	4	1	1
		1	1
90	90	64	64
		26	26

Urticaria  
 Vaccination site erythema  
 Vaccination site pain  
 Vaccination site pruritus  
 Vaccination site rash  
 Vaccination site swelling  
 Vision blurred

1  
4  
13  
2  
1  
5  
1  
90

1  
4  
13  
2  
1  
5  
1  
90

64  
64  
26  
26

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Anaphylactic reaction	4	4			4	4
Arthralgia	6	6	6	6		
Asthenia	2	2	1	1	1	1
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	2	2			2	2
Body temperature increased	1	1	1	1		
Chest discomfort	3	3	1	1	2	2
Chills	6	6	4	4	2	2
Cold sweat	1	1	1	1		
Derealisation	1	1	1	1		
Diarrhoea	3	3	3	3		
Discomfort	2	2			2	2
Disturbance in attention	2	2	1	1	1	1
Dizziness	12	12	8	8	4	4
Dry eye	1	1	1	1		
Dysaesthesia	1	1	1	1		
Dysgeusia	1	1	1	1		
Dysphonia	1	1			1	1
Dyspnoea	3	3			3	3
Dyspnoea at rest	1	1			1	1
Erythema	1	1			1	1
Eye pain	2	2	2	2		
Eye pruritus	1	1	1	1		
Facial pain	1	1	1	1		
Fatigue	7	7	6	6	1	1
Feeling drunk	1	1	1	1		
Feeling hot	4	4	3	3	1	1
Flushing	1	1			1	1
Gastroesophageal reflux disease	1	1	1	1		
Headache	21	21	19	19	2	2
Heart rate increased	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyperhidrosis	1	1
Hypersensitivity	2	2
Hyperventilation	1	1
Influenza like illness	1	1
Insomnia	1	1
Lymphadenopathy	1	1
Lymph node pain	1	1
Malaise	11	11
Muscle discomfort	1	1
Muscle fatigue	1	1
Myalgia	8	8
Nasal obstruction	1	1
Nausea	9	9
Neck pain	1	1
Oropharyngeal discomfort	1	1
Oropharyngeal pain	1	1
Pain	2	2
Pain in extremity	5	5
Pallor	5	5
Palpitations	5	5
Paraesthesia	4	4
Pharyngeal swelling	2	2
Presyncope	5	5
Pruritus	2	2
Pyrexia	13	13
Rash	4	4
Rash erythematous	3	3
Respiratory failure	1	1
Restlessness	2	2
Sinus tachycardia	1	1
Swelling face	2	2
Swollen tongue	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		2	2
		1	1
1	1		
1	1		
1	1		
7	7	4	4
1	1		
1	1		
8	8		
1	1		
6	6	3	3
1	1		
1	1		
1	1	1	1
5	5		
2	2	3	3
3	3	2	2
2	2	2	2
		2	2
1	1	4	4
2	2		
11	11	2	2
1	1	3	3
2	2	1	1
		1	1
2	2		
1	1		
		2	2
		1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	1	1			1	1
Tachycardia	1	1			1	1
Throat irritation	1	1	1	1		
Tremor	2	2			2	2
Urinary incontinence	1	1			1	1
Urticaria	2	2	1	1	1	1
Vaccination site erythema	2	2	2	2		
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site pain	23	23	22	22	1	1
Vaccination site swelling	3	3	3	3		
Vaccination site warmth	2	2	2	2		
Visual impairment	1	1	1	1		
Vomiting	3	3	2	2	1	1
	241	241	168	168	73	73

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Anxiety	1	1			1	1
Arthralgia	2	2	2	2		
Asthenia	1	1			1	1
Body temperature increased	1	1	1	1		
Chest discomfort	1	1			1	1
Chills	4	4	3	3	1	1
Cough	1	1			1	1
Dermatitis allergic	1	1			1	1
Diarrhoea	1	1	1	1		
Dizziness	6	6	2	2	4	4
Dizziness postural	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia	1	1			1	1
Dyspnoea	2	2			2	2
Erythema	1	1			1	1
Fatigue	4	4	2	2	2	2
Feeling hot	3	3			3	3
Flushing	2	2	2	2		
Glossodynia	1	1	1	1		
Headache	7	7	5	5	2	2
Heart rate increased	1	1	1	1		
Hypersensitivity	1	1			1	1
Hypertension	1	1	1	1		
Influenza like illness	1	1	1	1		
Loss of consciousness	1	1			1	1
Malaise	7	7	5	5	2	2
Myalgia	4	4	3	3	1	1
Nasopharyngitis	1	1	1	1		
Nausea	5	5	2	2	3	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal pain	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	2	2	2	2		
Palpitations	2	2	2	2		
Paraesthesia	2	2			2	2
Paraesthesia oral	1	1			1	1
Pharyngeal swelling	2	2			2	2
Presyncope	2	2	1	1	1	1
Pruritus	1	1			1	1
Pyrexia	7	7	6	6	1	1
Rash erythematous	1	1			1	1
Restlessness	1	1	1	1		
Sensory disturbance	1	1	1	1		
Swollen tongue	2	2			2	2
Syncope	1	1			1	1
Tachycardia	1	1	1	1		
Throat tightness	2	2	1	1	1	1
Urticaria	1	1			1	1
Vaccination site irritation	1	1			1	1
Vaccination site pain	3	3	2	2	1	1
Vomiting	1	1			1	1
	104	104	53	53	51	51

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Bronchospasm	1	1			1	1
Cardiac arrest	1	1			1	1
Chronic obstructive pulmonary disease	1	1			1	1
Cough	1	1			1	1
Discomfort	1	1			1	1
Dizziness	1	1			1	1
Dyspnoea	1	1			1	1
Foaming at mouth	1	1	1	1		
General physical health deterioration	1	1			1	1
Headache	1	1			1	1
Heart rate increased	1	1			1	1
Hyperhidrosis	1	1	1	1		
Hypotension	1	1			1	1
Malaise	2	2	1	1	1	1
Nausea	2	2	1	1	1	1
Oxygen saturation decreased	1	1			1	1
Pallor	1	1	1	1		
Presyncope	1	1			1	1
Prolonged expiration	1	1			1	1
Pyrexia	1	1			1	1
Tachypnoea	1	1			1	1
Vertigo	1	1			1	1
	25	25	5	5	20	20

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression	1	1			1	1
Angioedema	1	1			1	1
Aspiration	1	1			1	1
Asthenia	1	1	1	1		
Bacteraemia	1	1			1	1
Blood pressure systolic increased	1	1	1	1		
Coma	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	1	1			1	1
COVID-19	1	1			1	1
Death	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Drug interaction	1	1			1	1
Dyspnoea	2	2	1	1	1	1
Fatigue	1	1			1	1
Fluid intake reduced	1	1	1	1		
Flushing	1	1			1	1
General physical health deterioration	2	2			2	2
Headache	1	1			1	1
Hemiparesis	1	1			1	1
Hypertension	1	1			1	1
Hypophagia	1	1	1	1		
Hypotension	1	1			1	1
Incorrect route of product administration	2	2	2	2		
Malaise	2	2	1	1	1	1
Mobility decreased	1	1			1	1
Nausea	1	1	1	1		
Pneumonia	1	1			1	1
Pneumonia aspiration	1	1			1	1
Pulmonary oedema	1	1			1	1

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Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	1	1			1	1
Rales	1	1			1	1
Rash pruritic	1	1	1	1		
Respiratory arrest	1	1			1	1
Respiratory failure	1	1			1	1
Sepsis	1	1			1	1
Severe acute respiratory syndrome	1	1			1	1
Skin lesion	1	1	1	1		
Somnolence	1	1			1	1
Sudden death	1	1			1	1
Swelling face	1	1	1	1		
Thinking abnormal	1	1			1	1
Vomiting	3	3	1	1	2	2
	51	51	14	14	37	37

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
Product administration error	1	1	1	1
Underdose	1	1	1	1
	3	3	3	3

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Country Where Event Occurred

**ESTONIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Maternal exposure during pregnancy	2	2	2	2
Paraesthesia	1	1	1	1
Vaccination site pain	1	1	1	1
	4	4	4	4

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asymptomatic COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Facial nerve disorder	1	1	1	1		
Feeling hot	1	1	1	1		
Fracture	1	1			1	1
Headache	1	1	1	1		
Hypoaesthesia	2	2	2	2		
Malaise	1	1	1	1		
Maternal exposure during pregnancy	2	2	2	2		
Myalgia	1	1	1	1		
Off label use	1	1	1	1		
Paraesthesia	2	2	2	2		
Product use issue	1	1	1	1		
Syringe issue	1	1	1	1		
Tachycardia	1	1	1	1		
Underdose	1	1	1	1		
	19	19	16	16	3	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	1	1	1	1
Hypertension	1	1	1	1
Immunisation anxiety related reaction	2	2	2	2
Palpitations	1	1	1	1
Restlessness	1	1	1	1
	6	6	6	6

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Country Where Event Occurred

**FINLAND**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest discomfort	1	1			1	1
Cough	1	1			1	1
Dyspnoea	1	1			1	1
Headache	1	1			1	1
Heart rate increased	1	1			1	1
Hypokalaemia	1	1			1	1
Malaise	1	1			1	1
Migraine	1	1			1	1
Nausea	1	1			1	1
Paraesthesia	1	1			1	1
Pharyngeal oedema	1	1			1	1
Pharyngeal swelling	1	1			1	1
Tremor	1	1			1	1
Vaccination site haematoma	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vaccination site warmth	1	1	1	1		
	17	17	4	4	13	13

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	1	1			1	1
Aneurysm	1	1			1	1
Axillary pain	1	1	1	1		
Chest discomfort	1	1			1	1
C-reactive protein increased	1	1	1	1		
Derealisation	1	1	1	1		
Dizziness	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Erythema	2	2	1	1	1	1
Extrasystoles	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	1	1			1	1
Heart rate increased	1	1			1	1
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypokalaemia	1	1			1	1
Lymphadenopathy	2	2	2	2		
Malaise	2	2	2	2		
Nausea	1	1	1	1		
Nodule	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Presyncope	1	1	1	1		
Rash	1	1			1	1
Rash erythematous	1	1	1	1		
Seizure	1	1			1	1
Subarachnoid haemorrhage	1	1			1	1
Syncope	1	1			1	1
Tachycardia	1	1	1	1		
Type IV hypersensitivity reaction	1	1	1	1		
Urticaria	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	1	1	1		
Vaccination site plaque	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vomiting	1	1			1	1
	40	40	26	26	14	14

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	2			2	2
Back pain	1	1	1	1		
Erythema	1	1			1	1
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Gait disturbance	1	1	1	1		
Hypotension	1	1			1	1
Irritability postvaccinal	1	1	1	1		
Malaise	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	2	2	2	2		
Nuchal rigidity	1	1	1	1		
Pain in extremity	1	1	1	1		
Pyrexia	2	2	2	2		
Somnolence	1	1	1	1		
Throat irritation	1	1			1	1
Vaccination site pain	1	1	1	1		
	20	20	15	15	5	5

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death	1	1	1	1
Fatigue	1	1	1	1
	2	2	2	2

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Lymphadenopathy	1	1	1	1
Tenderness	1	1	1	1
	3	3	3	3

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Country Where Event Occurred

**FRANCE**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	2	2	2	2
	2	2	2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	1	1			1	1
Dysphagia	1	1			1	1
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1			1	1
Hypertensive crisis	1	1			1	1
Injection site pain	1	1	1	1		
Myalgia	1	1	1	1		
Neck pain	1	1	1	1		
Ocular discomfort	1	1	1	1		
Oropharyngeal discomfort	1	1			1	1
Otitis externa	1	1	1	1		
Overdose	1	1	1	1		
Pain	1	1	1	1		
Paraesthesia	1	1	1	1		
Product preparation issue	1	1	1	1		
Suspected COVID-19	1	1			1	1
Urticaria	1	1			1	1
Vaccination site induration	1	1	1	1		
Vaccination site pain	2	2	2	2		
	22	22	15	15	7	7

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Aortic dissection	2	2			2	2
Cardio-respiratory arrest	1	1			1	1
Chills	1	1	1	1		
COVID-19	2	2			2	2
Death	1	1			1	1
Drug ineffective	2	2			2	2
Dysphagia	1	1			1	1
Erythema	1	1	1	1		
Formication	1	1			1	1
Headache	1	1	1	1		
Hot flush	1	1	1	1		
Hypertension	2	2	2	2		
Insomnia	2	2	2	2		
Lip oedema	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	3	3	2	2	1	1
Nasal congestion	1	1	1	1		
Nausea	1	1	1	1		
Overdose	4	4	4	4		
Pain in extremity	1	1	1	1		
Palpitations	1	1	1	1		
Papule	1	1	1	1		
Product preparation issue	5	5	5	5		
Pruritus	1	1	1	1		
Pyrexia	1	1	1	1		
Tachycardia	1	1	1	1		
Underdose	1	1	1	1		
Vaccination complication	1	1	1	1		
Vaccination site pain	2	2	2	2		
	46	46	33	33	13	13

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Aphthous ulcer	1	1	1	1		
Asthenia	1	1	1	1		
Blood uric acid increased	1	1	1	1		
Bronchial obstruction	1	1			1	1
Constipation	1	1	1	1		
COVID-19	1	1			1	1
C-reactive protein increased	1	1	1	1		
Death	6	6			6	6
Dizziness	2	2	1	1	1	1
Drug ineffective	1	1			1	1
Dyspnoea	2	2			2	2
Erythema	1	1	1	1		
Glycosylated haemoglobin increased	1	1	1	1		
Headache	1	1	1	1		
Incorrect route of product administration	2	2	2	2		
Increased bronchial secretion	1	1			1	1
Malaise	2	2	1	1	1	1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	1	1	1	1		
Nausea	3	3	3	3		
Off label use	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	4	4	3	3	1	1
Rash erythematous	1	1	1	1		
Rash maculo-papular	1	1	1	1		
Sudden death	2	2			2	2
Tachycardia	1	1	1	1		
Tongue haematoma	2	2	2	2		
Vaccination site erythema	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term

Vaccination site pruritus

Interval Total #  
Spontaneous AE

1

49

Cumulative Total #  
Spontaneous AE

1

49

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
31	31	18	18

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Anaphylactic shock	1	1			1	1
Anxiety	2	2			2	2
Arrhythmia	1	1			1	1
Arrhythmia supraventricular	1	1			1	1
Atrial f brillation	2	2			2	2
Blood pressure systolic increased	1	1			1	1
Bronchitis	1	1			1	1
Cardiac arrest	1	1			1	1
Cardiac failure	2	2			2	2
Cardio-respiratory arrest	1	1			1	1
Cerebrovascular accident	2	2			2	2
Chest pain	1	1			1	1
Cognitive disorder	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	1	1			1	1
C-reactive protein increased	1	1			1	1
Death	3	3			3	3
Depressed level of consciousness	1	1			1	1
Diarrhoea	2	2			2	2
Dysarthria	1	1			1	1
Dyspnoea	1	1			1	1
Fall	1	1			1	1
Fear	1	1			1	1
Haemoptysis	1	1			1	1
Haemorrhagic stroke	1	1			1	1
Hyperleukocytosis	1	1			1	1
Hypertonia	1	1			1	1
Hypotension	1	1			1	1
Inappropriate schedule of product administration	2	2	2	2		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Injection site erythema	1	1	1	1		
International normalised ratio abnormal	1	1			1	1
Ischaemic stroke	1	1			1	1
Loss of consciousness	1	1			1	1
Lymphopenia	1	1	1	1		
Malaise	3	3			3	3
Nausea	2	2			2	2
Oedema peripheral	1	1			1	1
Overdose	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Petit mal epilepsy	1	1			1	1
Productive cough	1	1			1	1
Product preparation error	1	1	1	1		
Pruritus	1	1	1	1		
Rales	1	1			1	1
Renal failure	1	1			1	1
Sudden death	4	4			4	4
Tachycardia	1	1			1	1
Thrombocytopenia	1	1			1	1
Urticaria	1	1			1	1
Vomiting	2	2			2	2
	68	68	7	7	61	61

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accidental overdose	1	1	1	1		
Arthralgia	2	2	2	2		
Chills	1	1	1	1		
Coronavirus test positive	1	1	1	1		
Cough	1	1	1	1		
COVID-19	4	4			4	4
Drug ineffective	6	6	1	1	5	5
Eyelid irritation	1	1	1	1		
Fatigue	3	3	3	3		
Headache	1	1	1	1		
Herpes zoster	1	1	1	1		
Intercepted product preparation error	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Needle issue	1	1	1	1		
Occupational exposure to product	1	1	1	1		
Pain in extremity	1	1	1	1		
Poor quality product administered	2	2	2	2		
Product administered at inappropriate site	1	1	1	1		
Product preparation issue	11	11	11	11		
Product temperature excursion issue	1	1	1	1		
Pyrexia	1	1	1	1		
Suspected COVID-19	1	1			1	1
Underdose	12	12	12	12		
Vaccination site pain	2	2	2	2		
Wrong technique in product usage process	2	2	2	2		
	60	60	50	50	10	10

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Country Where Event Occurred

**GERMANY**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cough	1	1	1	1
Exposure via breast milk	1	1	1	1
Fatigue	1	1	1	1
Off label use	1	1	1	1
Oropharyngeal pain	1	1	1	1
Rash macular	1	1	1	1
Rhinorrhoea	1	1	1	1
	7	7	7	7

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain lower	2	2	2	2		
Abnormal faeces	1	1	1	1		
Abscess	1	1			1	1
Acne	1	1	1	1		
Acute myocardial infarction	1	1			1	1
Anaphylactic reaction	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	3	3	3	3		
Asthenia	9	9	9	9		
Asthma	1	1	1	1		
Back pain	2	2	2	2		
Blood pressure decreased	1	1	1	1		
Blood pressure increased	1	1	1	1		
Burning sensation	1	1			1	1
Chills	9	9	9	9		
Coronavirus infection	1	1	1	1		
Cough	1	1	1	1		
COVID-19	2	2			2	2
Diarrhoea	5	5	5	5		
Disease recurrence	1	1	1	1		
Dizziness	10	10	7	7	3	3
Drug ineffective	3	3			3	3
Dyspnoea	4	4	2	2	2	2
Ear pain	1	1	1	1		
Epistaxis	1	1	1	1		
Erythema	1	1	1	1		
Fatigue	21	21	21	21		
Feeling cold	4	4	3	3	1	1
Flatulence	1	1	1	1		
Flushing	1	1			1	1
Genital herpes	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematoma	1	1
Haemoptysis	1	1
Headache	20	20
Hyperhidrosis	3	3
Hypersensitivity	1	1
Hypertension	2	2
Hypoaesthesia	4	4
Hypotension	2	2
Incorrect route of product administration	3	3
Influenza like illness	4	4
Limb discomfort	3	3
Local reaction	2	2
Lymphadenopathy	1	1
Lymph node pain	2	2
Malaise	2	2
Maternal exposure during pregnancy	1	1
Mobility decreased	1	1
Movement disorder	1	1
Muscle twitching	1	1
Muscular weakness	3	3
Musculoskeletal stiffness	1	1
Myalgia	6	6
Nasopharyngitis	1	1
Nausea	6	6
Neck pain	2	2
Neuralgic amyotrophy	1	1
Oedema	1	1
Off label use	1	1
Oropharyngeal pain	2	2
Otitis media	1	1
Pain	4	4
Pain in extremity	10	10

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
20	20		
3	3		
		1	1
1	1	1	1
4	4		
		2	2
3	3		
4	4		
3	3		
2	2		
1	1		
2	2		
2	2		
1	1		
1	1		
1	1		
3	3		
1	1		
6	6		
1	1		
6	6		
2	2		
		1	1
		1	1
1	1		
2	2		
1	1		
4	4		
10	10		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Palpitations	4	4
Paraesthesia	1	1
Peripheral swelling	1	1
Peripheral vascular disorder	1	1
Presyncope	1	1
Product use issue	1	1
Pruritus	4	4
Pulmonary embolism	1	1
Pyrexia	3	3
Rash	2	2
Rash pruritic	1	1
Respiratory distress	1	1
SARS-CoV-2 test positive	1	1
Sensation of foreign body	1	1
Sensory loss	1	1
Sinusitis	1	1
Sinus tachycardia	1	1
Swelling	3	3
Swelling face	1	1
Syncope	2	2
Tachycardia	3	3
Tremor	2	2
Vaccination site erythema	2	2
Vaccination site haematoma	1	1
Vaccination site movement impairment	1	1
Vaccination site pain	28	28
Vaccination site paraesthesia	1	1
Vaccination site pruritus	1	1
Vaccination site swelling	8	8
Vaccination site warmth	1	1
Vertigo	2	2
Vomiting	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3	1	1
1	1		
		1	1
1	1		
1	1		
1	1		
2	2	2	2
		1	1
3	3		
		2	2
1	1		
		1	1
		1	1
		1	1
1	1		
		1	1
2	2	1	1
		1	1
2	2	2	2
3	3		
		2	2
2	2		
1	1		
1	1		
8	8		
1	1		
2	2		
1	1		

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Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
230	230	41	41

271

271

230

230

41

41

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal pain	3	3
Abdominal pain upper	2	2
Abnormal faeces	4	4
Accidental overdose	3	8
Ageusia	1	1
Agitation		1
Anaphylactic reaction	6	7
Anaphylactoid reaction	1	1
Angioedema	2	2
Arrhythmia	1	1
Arthralgia	7	7
Asthenia	10	14
Atypical pneumonia	1	1
Back pain	1	1
Bladder discomfort	1	1
Bladder pain	1	1
Blood pressure fluctuation	1	1
Blood pressure increased	1	1
Body temperature increased	6	6
Bone pain	1	1
Cardiovascular disorder	1	1
Cardiovascular insufficiency	1	1
Chest discomfort	2	2
Chills	15	16
Circulatory collapse	1	1
Cold sweat	1	1
Cough	3	4
Deafness	1	1
Dermatitis allergic	1	1
Diabetes mellitus		1
Diarrhoea	10	10
Diplopia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
		2	2		
		4	4		
		2	6	1	2
		1	1		
			1		
				6	7
				1	1
				2	2
				1	1
		7	7		
		8	11	2	3
				1	1
		1	1		
		1	1		
		1	1		
		1	1		
		6	6		
		1	1		
		1	1		
				1	1
		2	2		
		15	16		
				1	1
				1	1
		3	4		
				1	1
		1	1		
					1
		10	10		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Disturbance in attention	1	1
Dizziness	16	18
Drug ineffective	2	2
Dry eye	1	1
Dry mouth	1	1
Dysaesthesia	1	1
Dyspepsia	1	1
Dysphagia	1	1
Dysphonia	2	2
Dyspnoea	7	8
Epilepsy	1	1
Episcleritis	1	1
Epistaxis	2	2
Erythema	4	4
Eye irritation	1	1
Eye pruritus	1	1
Eye swelling	1	1
Face oedema	1	1
Fatigue	39	42
Feeling cold	1	1
Feeling hot	1	1
Flushing	4	5
Haematuria	1	1
Headache	35	40
Heart rate increased	1	2
Herpes zoster	1	1
Hordeolum	1	1
Hot flush	1	1
Hunger	1	1
Hyperhidrosis	1	1
Hypersensitivity	4	4
Hypertension	4	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		14	15	2	3
				2	2
		1	1		
		1	1		
				1	1
		1	1		
				1	1
		2	2		
		5	5	2	3
				1	1
		1	1		
		2	2		
		4	4		
		1	1		
		1	1		
		1	1		
				1	1
1	1	39	41		1
		1	1		
		1	1		
		2	2	2	3
		1	1		
1	1	32	36	3	4
			1	1	1
		1	1		
		1	1		
		1	1		
		1	1		
		2	2	2	2
			1	4	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypotension	3	3
Hypotonia	1	1
Illness	1	1
Incorrect route of product administration	2	2
Influenza like illness	10	10
Laryngeal oedema	2	2
Limb discomfort	1	1
Livedo reticularis	1	1
Local reaction	1	1
Loss of consciousness	1	1
Lymphadenopathy	4	4
Lymph node pain	1	1
Malaise	3	4
Mobility decreased	1	1
Movement disorder	1	1
Muscle tightness	1	1
Muscular weakness	2	2
Myalgia	17	17
Nasopharyngitis	2	2
Nausea	11	12
Neck pain	5	5
Neuralgia	1	1
Off label use	1	1
Oral mucosa erosion	1	1
Orthostatic intolerance	1	1
Pain	3	4
Pain in extremity	26	27
Palpitations	9	10
Paraesthesia	4	4
Paraesthesia oral	2	2
Performance status decreased		1
Peripheral vascular disorder	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	2
		1	1		
		1	1		
		2	2		
		10	10		
				2	2
		1	1		
		1	1		
		1	1		
				1	1
		4	4		
		1	1		
1	1	3	3		1
		1	1		
		1	1		
		2	2		
1	1	17	17		
		2	2		
		10	11	1	1
		5	5		
		1	1		
		1	1		
				1	1
		2	2	1	2
		25	26	1	1
		8	9	1	1
		4	4		
		2	2		
			1		
		1	1	2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal hypoaesthesia	1	1
Pharyngeal swelling	1	1
Photosensitivity reaction	1	1
Pollakiuria	1	1
Poor quality sleep	1	1
Product use issue	1	1
Protein urine present	1	1
Pruritus	3	3
Pruritus allergic	1	1
Psychological factor affecting medical condition	1	1
Pyrexia	22	23
Rash	7	7
Rash maculo-papular	1	1
Rash pruritic	1	1
Renal pain	1	1
Respiratory distress	4	4
Respiratory symptom	1	1
Retching	1	1
Rhinalgia	1	1
Rhinitis		1
Rhinorrhoea	1	1
SARS-CoV-2 test positive	2	2
Scratch	1	1
Sensation of foreign body	1	1
Sensory disturbance	3	3
Sleep disorder	1	1
Sneezing	1	1
Somnolence	1	1
Suspected COVID-19	1	1
Swelling	1	2
Tachyarrhythmia	1	1
Tachycardia	8	9

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		1	1		
		1	1		
		1	1		
		1	1		
		3	3		
		1	1		
				1	1
1	1	22	23		
		5	5	2	2
		1	1		
		1	1		
		1	1		
				4	4
		1	1		
				1	1
		1	1		
				2	2
		1	1		
				1	1
		3	3		
		1	1		
		1	1		
		1	1		
				1	1
		1	2		
				1	1
		4	4	4	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Tachypnoea	1	1			1	1		
Tension headache	1	1					1	1
Thirst	1	1			1	1		
Throat irritation	2	2			2	2		
Throat tightness	2	2			2	2		
Tremor	4	4			4	4		
Urticaria	2	2			1	1	1	1
Vaccination site dermatitis	1	1			1	1		
Vaccination site discomfort	2	2			2	2		
Vaccination site erythema	6	6			6	6		
Vaccination site hyperaesthesia	1	1			1	1		
Vaccination site induration	3	3			3	3		
Vaccination site joint movement impairment	1	1			1	1		
Vaccination site movement impairment	2	2			2	2		
Vaccination site pain	45	45			45	45		
Vaccination site pruritus	3	3			3	3		
Vaccination site reaction	2	2			2	2		
Vaccination site swelling	6	6			6	6		
Vaccination site warmth	5	5			5	5		
Vertigo	1	1			1	1		
Vision blurred	1	1					1	1
Visual impairment	2	2			1	1	1	1
Vomiting	2	2			2	2		
Weight bearing difficulty	1	1					1	1
	522	560	5	5	447	473	75	87

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Accidental overdose	2	5	2	5		
Acute myocardial infarction	2	2			2	2
Acute respiratory failure	1	1			1	1
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angina pectoris	1	1			1	1
Anxiety		1		1		
Arrhythmia	1	1	1	1		
Arthralgia	5	5	5	5		
Asthenia	4	7	4	7		
Asthma	1	1			1	1
Body temperature increased	1	1	1	1		
Bronchial disorder	1	1	1	1		
Cardiovascular disorder	1	1	1	1		
Chest discomfort		1		1		
Chills	3	3	3	3		
Circulatory collapse	1	1			1	1
Condition aggravated	1	1			1	1
COVID-19	6	6			6	6
Cyanosis	1	1			1	1
Death	1	1			1	1
Decreased appetite	1	1	1	1		
Depressed level of consciousness	1	1			1	1
Diarrhoea	2	2	2	2		
Dizziness	9	11	9	11		
Drug ineffective	6	6			6	6
Drug interaction	1	1	1	1		
Dysphagia	2	2			2	2
Dyspnoea	1	2		1	1	1
Dyspnoea exertional	1	1			1	1
Dysstasia	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema	2	2
Eye haemorrhage	1	1
Eye irritation	1	1
Facial paralysis		1
Fatigue	12	13
Feeling hot	1	1
Gait disturbance	1	1
General physical health deterioration	2	2
Headache	15	18
Herpes zoster	1	1
Huntington's disease	3	3
Hyperhidrosis	2	3
Hypersensitivity	1	1
Hypertension	2	2
Hypoaesthesia	2	2
Hypoaesthesia oral	1	1
Hypotension	1	1
Induration	1	1
Infective exacerbation of chronic obstructive airways disease	1	1
Influenza like illness	3	3
Injection site pain	1	1
Insomnia	1	1
Language disorder	1	1
Leukopenia		1
Limb discomfort	1	2
Lip oedema	1	1
Lip swelling	1	1
Local reaction	1	1
Loss of consciousness	1	1
Malaise	2	2
Mesenteric vein thrombosis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
		1	1
1	1		
			1
12	13		
1	1		
1	1		
		2	2
15	18		
1	1		
		3	3
2	3		
		1	1
2	2		
2	2		
1	1		
		1	1
1	1		
		1	1
3	3		
1	1		
1	1		
		1	1
			1
1	2		
1	1		
		1	1
1	1		
2	2		
		1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Middle insomnia	1	1
Migraine		1
Movement disorder		1
Musculoskeletal disorder	1	1
Myalgia	7	7
Nasal congestion	1	1
Nasopharyngitis	1	1
Nausea	2	3
Neck pain	1	1
Off label use	1	1
Oropharyngeal pain	1	1
Oxygen saturation decreased	1	1
Pain	5	5
Pain in extremity	4	4
Palpitations	1	2
Paraesthesia	4	4
Paraesthesia oral	1	1
Pharyngeal swelling	1	1
Pneumonia aspiration	2	2
Product administered at inappropriate site	1	1
Product use issue	1	1
Pruritus	2	2
Psoriasis	1	1
Pyrexia	5	5
Respiratory tract infection	1	1
Restlessness	2	2
Rhinitis	1	1
Rhinorrhoea	2	2
Seizure	3	4
Sense of oppression	1	1
Skin discolouration	1	1
Somnolence	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	1		
	1		
		1	1
7	7		
1	1		
1	1		
2	3		
1	1		
1	1		
		1	1
4	4	1	1
4	4		
1	2		
4	4		
1	1		
		1	1
		2	2
		1	1
1	1		
2	2		
1	1		
2	2		
1	1	2	3
1	1		
1	1		
1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	1	1			1	1
Status epilepticus	1	1			1	1
Swelling	2	2	2	2		
Swollen tongue	1	1	1	1		
Syncope	1	1			1	1
Tachycardia	2	2	1	1	1	1
Throat tightness	1	1			1	1
Tongue disorder	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema		1		1		
Vaccination site hyperaesthesia		1		1		
Vaccination site pain	9	13	9	13		
Vaccination site swelling	2	5	2	5		
Vomiting	1	1	1	1		
	205	238	150	180	55	58

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	1	1			1	1
Asthenia	1	1			1	1
Bedridden	1	1			1	1
Blister	1	1	1	1		
Body temperature increased	1	1	1	1		
Cerebrovascular accident	1	1			1	1
Chills	2	2	2	2		
COVID-19	4	4			4	4
COVID-19 pneumonia	1	1			1	1
Death	3	3			3	3
Diarrhoea	2	2	1	1	1	1
Dizziness	2	2	1	1	1	1
Drug ineffective	6	6			6	6
Dysgeusia	1	1	1	1		
Eye pruritus	1	1			1	1
Eye swelling	1	1			1	1
Fatigue	4	4	3	3	1	1
Feeling hot	1	1	1	1		
Gait disturbance	1	1	1	1		
Headache	2	2	2	2		
Herpes zoster	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hyperpyrexia	1	1			1	1
Hypersensitivity	2	2			2	2
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypotonia	1	1			1	1
Injection site discomfort	1	1	1	1		
Irregular breathing	1	1			1	1
Lacrimation increased	1	1	1	1		
Malaise	2	2			2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Multiple organ dysfunction syndrome	1	1			1	1
Myalgia	1	1	1	1		
Pain in extremity	4	4	4	4		
Paresis		1		1		
Pulmonary sepsis	1	1			1	1
Pyrexia	2	2	1	1	1	1
Rash	1	1			1	1
Respiratory distress	2	2			2	2
Rhinorrhoea	2	2	1	1	1	1
Rhonchi	1	1			1	1
Rosacea	1	1			1	1
Sneezing	1	1	1	1		
Sudden death	3	3			3	3
Suspected COVID-19	1	1			1	1
Swelling face	1	1			1	1
Tremor	1	1	1	1		
Unresponsive to stimuli	1	1			1	1
Vaccination site irritation	1	1	1	1		
Vaccination site pain	6	6	6	6		
Vomiting	3	3	2	2	1	1
	85	86	38	39	47	47

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower	1	1	1	1		
Acute kidney injury	4	4			4	4
Acute myocardial infarction	3	3			3	3
Allergic oedema	1	1	1	1		
Anaphylactic shock	2	2			2	2
Apathy	2	2			2	2
Arrhythmia	1	1			1	1
Arthralgia	2	2	2	2		
Asthenia	2	2	1	1	1	1
Atrial f brillation	1	1			1	1
Blood pressure decreased	1	1			1	1
Blood urine present	1	1			1	1
Body temperature increased	3	3	1	1	2	2
Bradycardia	2	2			2	2
Bronchitis	1	1			1	1
Bronchospasm	1	1	1	1		
Cardiac arrest	1	1			1	1
Cardiac failure	6	6			6	6
Cardiac failure congestive	1	1			1	1
Cardiac fibrillation	1	1			1	1
Cardiogenic shock	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chronic kidney disease	1	1			1	1
Circulatory collapse	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	1	1	1	1		
Constipation	1	1	1	1		
Cough	2	2	2	2		
COVID-19	15	15			15	15
COVID-19 pneumonia	3	3			3	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Crepitations	1	1			1	1
Death	23	23			23	23
Decreased appetite	1	1			1	1
Dementia	1	1			1	1
Dementia of the Alzheimer's type, with delirium	1	1			1	1
Dermatitis allergic	1	1	1	1		
Diarrhoea	1	1	1	1		
Diet refusal	2	2			2	2
Disorientation	1	1	1	1		
Disturbance in attention	2	2	1	1	1	1
Dizziness postural	1	1	1	1		
Drug ineffective	20	20			20	20
Dry skin	1	1	1	1		
Dyspnoea	4	4	1	1	3	3
Epilepsy	1	2			1	2
Erythema	1	1	1	1		
Facial paralysis	1	1			1	1
Fall	4	4			4	4
Fatigue	3	3	2	2	1	1
Febrile infection	2	2			2	2
Feeling cold	1	1	1	1		
Femoral neck fracture	1	1			1	1
Flatulence	1	1	1	1		
Food refusal	2	2			2	2
General physical condition abnormal	1	1			1	1
General physical health deterioration	8	8	1	1	7	7
Headache	3	3	2	2	1	1
Head injury	1	1			1	1
Hemiparesis	1	1			1	1
Hypercalcaemia	1	1			1	1
Hyperpyrexia	1	1			1	1
Hypersensitivity	3	3			3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		23	23
		1	1
		1	1
		1	1
1	1		
1	1		
		2	2
1	1		
1	1	1	1
1	1		
		20	20
1	1		
1	1	3	3
		1	2
1	1		
		1	1
		4	4
2	2	1	1
		2	2
1	1		
		1	1
1	1		
		2	2
		1	1
1	1	7	7
2	2	1	1
		1	1
		1	1
		1	1
		3	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersomnia	1	1
Hypertension	1	1
Hypoaesthesia	1	1
Incorrect route of product administration	2	2
Influenza like illness	1	1
Ischaemic stroke	1	1
Jaw clicking	1	1
Limb discomfort	1	1
Local reaction	1	1
Lymphadenopathy	1	1
Malaise	2	2
Mobility decreased	1	1
Motor dysfunction	1	1
Movement disorder	1	1
Multimorbidity	1	1
Muscle swelling	1	1
Myalgia	1	1
Myocardial infarction	1	1
Nausea	5	5
Oxygen saturation decreased	3	3
Pain in extremity	1	1
Pathogen resistance	1	1
Peripheral vascular disorder	2	2
Personality change	1	1
Pharyngeal inflammation	1	1
Pharyngeal swelling	1	1
Pneumonia	4	4
Pneumonia aspiration	1	1
Poor quality sleep	1	1
Product administered at inappropriate site	1	1
Product preparation issue	1	1
Pruritus	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
		1	1
2	2		
		1	1
		1	1
1	1		
1	1		
1	1		
1	1	1	1
		1	1
		1	1
		1	1
1	1		
1	1		
		1	1
2	2	3	3
		3	3
1	1		
		1	1
		2	2
		1	1
1	1		
		1	1
1	1	3	3
		1	1
		1	1
1	1		
1	1		
		1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulmonary embolism	2	2			2	2
Pyrexia	9	9	4	4	5	5
Rash	4	4	1	1	3	3
Rash macular	1	1			1	1
Rash pruritic	1	1	1	1		
Reaction to excipient	1	1	1	1		
Renal failure	2	2			2	2
Respiratory distress	2	2	1	1	1	1
Respiratory failure	2	2			2	2
Respiratory tract infection	1	1			1	1
Rhinalgia	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Rhonchi	1	1			1	1
SARS-CoV-2 ant body test positive	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
Seizure	1	1			1	1
Sepsis	1	1			1	1
Septic shock	1	1			1	1
Sneezing	1	1	1	1		
Somnolence	2	2	1	1	1	1
Staphylococcal sepsis	1	1			1	1
Stridor	1	1			1	1
Sudden cardiac death	1	1			1	1
Sudden death	4	4			4	4
Swollen tongue	2	2			2	2
Syncope	1	1			1	1
Tachyarrhythmia	2	2			2	2
Tachycardia	2	2			2	2
Throat tightness	1	1			1	1
Transient ischaemic attack	1	1			1	1
Unresponsive to stimuli	1	1			1	1
Urticaria	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	2	2	1	1	1	1
Vaccination site rash	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Ventricular fibrillation	2	2			2	2
Vomiting	5	5	1	1	4	4
	272	273	59	59	213	214

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Ageusia	1	1	1	1		
Angina pectoris	1	1			1	1
Anosmia	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	3	3	3	3		
Asthenopia	1	1	1	1		
Blood glucose fluctuation	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	1	1			1	1
Burning sensation	1	1	1	1		
Cardiovascular disorder	3	3	3	3		
Chest discomfort	1	1	1	1		
Chills	8	8	7	7	1	1
Circulatory collapse	1	1			1	1
Circumstance or information capable of leading to medication error	1	1	1	1		
Coronavirus infection	1	1			1	1
Cough		1				1
COVID-19	49	49			49	49
Cranial nerve disorder	1	1	1	1		
Death	5	5			5	5
Diarrhoea	2	2	2	2		
Disturbance in attention	2	2	2	2		
Dizziness	11	11	11	11		
Drug ineffective	76	76			76	76
Dysgeusia	1	1	1	1		
Dysphagia	1	1			1	1
Dyspnoea	1	1			1	1
Ear pain	2	2	2	2		
Eczema	1	1	1	1		

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
1	1		
1	1		
1	1		
35	35		
2	2		
1	1		
1	1		
35	35		
1	1		
1	1		
3	3		
3	4	2	3
1	1		
		1	1
1	1		
3	3		
1	1		
1	1		
1	1		
1	1		
1	1		
1	1		
1	1		
1	1		
6	6		
1	1		
4	5		1
13	13		
1	1		
1	1		
23	23		
2	2		
10	10		

Erythema	2	2
Exposure during pregnancy	1	1
Eye pain	1	1
Facial pain	1	1
Fatigue	35	35
Feeling cold	2	2
Feeling hot	1	1
Feeling of body temperature change	1	1
Headache	35	35
Head discomfort	1	1
Hyperaesthesia	1	1
Hypersensitivity	3	3
Hypertension	3	4
Hypoaesthesia	1	1
Hypotension	1	1
Illness	1	1
Inappropriate schedule of product administration	3	3
Incorrect dose administered	1	1
Incorrect route of product administration	1	1
Increased upper airway secretion	1	1
Influenza like illness	1	1
Limb discomfort	1	1
Lip swelling	1	1
Lymphadenopathy	6	6
Lymph node pain	1	1
Malaise	4	5
Maternal exposure during pregnancy	13	13
Mobility decreased	1	1
Muscular weakness	1	1
Myalgia	23	23
Nasopharyngitis	2	2
Nausea	10	10

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
4	4		
3	3		
3	3		
18	18		
1	1		
1	1		
1	1		
2	2		
1	1		
1	1		
2	2		
5	5		
1	1		
9	10		
3	3		
2	2		
3	3		
3	3		
32	32		
1	1		
1	1		
1	1		
1	1		
4	4		
1	1		
1	1		
1	1		
2	2		
1	1		
9	9		

Neck pain	1	1
Occupational exposure to product	1	1
Off label use	4	4
Oropharyngeal pain	3	3
Pain	3	3
Pain in extremity	18	18
Palpitations	1	1
Paraesthesia	1	1
Peripheral embolism	1	1
Peripheral swelling	2	2
Poor quality product administered	1	1
Product leakage	1	1
Product preparation error	2	2
Product use issue	5	5
Pruritus	1	1
Pyrexia	9	10
Rash	3	3
Rhinorrhoea	2	2
SARS-CoV-2 ant body test positive	3	3
SARS-CoV-2 test false positive	3	3
SARS-CoV-2 test positive	32	32
Sensation of foreign body	1	1
Sleep disorder	1	1
Somnolence	1	1
Sudden hearing loss	1	1
Suspected COVID-19	4	4
Swelling face	1	1
Tachycardia	1	1
Taste disorder	1	1
Throat irritation	2	2
Tongue discomfort	1	1
Underdose	9	9

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site bruising	2	2	2	2		
Vaccination site erythema	1	1	1	1		
Vaccination site haematoma	1	1	1	1		
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site movement impairment	3	3	3	3		
Vaccination site pain	80	80	80	80		
Vaccination site swelling	3	3	3	3		
Vertigo	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	3	3	3	3		
Wrong technique in product usage process	1	1	1	1		
	558	562	383	383	175	179

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Country Where Event Occurred

**GREECE**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Pain in extremity	1	1	1	1
Pyrexia	1	1	1	1
Rash	1	1	1	1
Tachycardia	1	1	1	1
Throat irritation	1	1	1	1
	6	6	6	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction	1	2			1	2
Angioedema	2	2			2	2
Arthralgia	1	1	1	1		
Atrial fibrillation	1	1			1	1
Blood pressure decreased	2	2	2	2		
Blood pressure diastolic increased	1	1	1	1		
Bronchospasm	2	2			2	2
Burning sensation	2	2	2	2		
Chest pain	2	2	1	1	1	1
Chills	3	3	2	2	1	1
Cough	3	3			3	3
Cyanosis	1	1	1	1		
Defaecation urgency		1				1
Diarrhoea	2	2	1	1	1	1
Diastolic hypertension	1	1			1	1
Discomfort	1	1	1	1		
Dizziness	7	7	5	5	2	2
Drug interaction	1	1			1	1
Dry mouth	2	2	2	2		
Dry throat	1	1	1	1		
Dysgeusia	4	4	2	2	2	2
Dysphagia	4	4	2	2	2	2
Dysphonia	3	3			3	3
Dyspnoea	2	2			2	2
Erythema		1				1
Eye oedema	1	1			1	1
Fatigue	3	3	2	2	1	1
Feeling hot	1	1			1	1
Flatulence		1				1
Flushing	2	3	1	1	1	2
Gait disturbance	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Gastrointestinal hypermotility		1				1	
Headache	6	6	5	5	1	1	
Hyperhidrosis	2	2	2	2			
Hypersensitivity	4	4	2	2	2	2	
Hypertension	2	2	1	1	1	1	
Hypertensive emergency	1	1			1	1	
Hypoaesthesia	4	4	3	3	1	1	
Hypoaesthesia oral	4	4	1	1	3	3	
Injection site pain	1	1	1	1			
Joint range of motion decreased	1	1	1	1			
Laryngeal oedema	1	1			1	1	
Mucosal dryness		1					1
Muscular weakness	1	1	1	1			
Myalgia	2	2	1	1	1	1	
Nausea	4	4	3	3	1	1	
Pain	1	1	1	1			
Pain in extremity	3	3	3	3			
Palpitations	1	1	1	1			
Poor quality sleep	1	1	1	1			
Presyncope	3	3	1	1	2	2	
Pruritus	2	2	1	1	1	1	
Pyrexia	4	4	3	3	1	1	
Rash	5	5	4	4	1	1	
Seizure	1	1			1	1	
Skin burning sensation	1	1	1	1			
Somnolence	1	1	1	1			
Tachycardia	4	5	2	2	2	3	
Tremor	1	2			1	2	
Vaccination site pain	5	5	5	5			
Vomiting	2	2	2	2			
	126	135	76	76	50	59	

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Anaphylactic shock	3	3			3	3
Anxiety	1	1	1	1		
Asthenia	1	1	1	1		
Cardiac arrest	1	1			1	1
Cardiac valve disease	1	1			1	1
Chest pain	1	1			1	1
Condition aggravated	1	1			1	1
Dizziness	3	3	2	2	1	1
Dyspnoea	1	1			1	1
Erythema	1	1	1	1		
Fall	1	1			1	1
Fatigue	1	1			1	1
Gait disturbance	1	1	1	1		
Headache	2	2	2	2		
Hyperhidrosis	1	1			1	1
Hypertensive crisis	1	1			1	1
Hypoaesthesia	1	1	1	1		
Leukocytosis	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	1	1	1	1		
Myalgia	1	1	1	1		
Nasal congestion	1	1	1	1		
Nausea	1	1			1	1
Oral herpes	1	1	1	1		
Orthostatic hypotension	1	1	1	1		
Pneumonia	1	1			1	1
Pruritus	1	1	1	1		
Pyrexia	5	5	4	4	1	1
Rash	1	1	1	1		
Respiratory tract infection	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rheumatoid arthritis	1	1			1	1
Rhinitis allergic	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Tachycardia	1	1			1	1
Throat irritation	1	1	1	1		
Tongue ulceration	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	6	6	6	6		
	54	54	31	31	23	23

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Headache	1	1	1	1
	2	2	2	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Acute respiratory failure	1	1			1	1
Auscultation	1	1	1	1		
Blood pressure inadequately controlled	1	1	1	1		
Cardiac arrest	2	2			2	2
Cardiac disorder	1	1			1	1
Dysphoria	1	1			1	1
Dyspnoea	2	2	1	1	1	1
Nausea	1	1	1	1		
Sudden death	2	2			2	2
Tachypnoea	1	1	1	1		
Vomiting	1	1	1	1		
	15	15	7	7	8	8

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactoid reaction	1	1			1	1
Asthenia	3	3	3	3		
Blister	1	1	1	1		
Blood pressure increased	2	2	1	1	1	1
Chills	1	1	1	1		
COVID-19	1	1			1	1
Deafness unilateral	1	1			1	1
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Dysgeusia	1	1	1	1		
Dyspnoea	1	1	1	1		
Eyelid ptosis	1	1			1	1
Fatigue	2	2	2	2		
Feeling cold	1	1	1	1		
Gastrointestinal disorder	2	2	2	2		
Headache	3	3	3	3		
Hypersensitivity	5	5	4	4	1	1
Hypertension	2	2	2	2		
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	3	3	3	3		
Hypotension	1	1	1	1		
Incomplete course of vaccination	1	1	1	1		
Injury	1	1	1	1		
Limb discomfort	1	1	1	1		
Liquid product physical issue	3	3	3	3		
Local reaction	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Maternal exposure during pregnancy	1	1	1	1		
Migraine	1	1	1	1		
Muscle spasms	1	1	1	1		
No adverse event	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	1	1	1	1		
Pain in extremity	2	2	2	2		
Palpitations	1	1	1	1		
Poor quality product administered	3	3	3	3		
Product quality issue	1	1	1	1		
Pulmonary thrombosis	1	1			1	1
Pyrexia	2	2	2	2		
Rash	1	1	1	1		
Rash pruritic	1	1	1	1		
Tachycardia	3	3	3	3		
Therapeutic response unexpected	1	1	1	1		
Tinnitus	2	2	2	2		
Vaccination site discomfort		1		1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site warmth	1	1	1	1		
Vomiting	1	1	1	1		
	72	73	64	65	8	8

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Country Where Event Occurred

**HUNGARY**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	1	1	1	1
	1	1	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Chest pain	1	1	1	1		
Confusional state	1	1	1	1		
Dizziness	2	2	2	2		
Ear discomfort	1	1	1	1		
Ear pain	1	1	1	1		
Ear pruritus	1	1	1	1		
Erythema	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	2	2	1	1	1	1
Hypoaesthesia	2	2	2	2		
Hypoaesthesia oral	1	1	1	1		
Hypoglycaemia	1	1	1	1		
Infertility	1	1			1	1
Lymphadenopathy	1	1			1	1
Malaise	2	2	1	1	1	1
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	3	3	3	3		
Palpitations	1	1	1	1		
Panic attack	1	1	1	1		
Pyrexia	2	2	1	1	1	1
Rash	1	1	1	1		
Tremor	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site pain	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vaginal discharge	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vision blurred	1	1	1	1		
Vomiting	1	1	1	1		
	42	42	37	37	5	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	2	2		
Anosmia	1	1	1	1		
Asthenia	5	6	5	6		
Axillary pain	1	1	1	1		
Back pain	1	1	1	1		
Blister	1	1	1	1		
Blood glucose increased		1		1		
Blood pressure increased		1				1
Body temperature increased	1	1	1	1		
Chills	3	4	3	4		
COVID-19	1	1			1	1
Depression	1	1	1	1		
Dizziness	4	4	4	4		
Drug ineffective	1	1			1	1
Dry mouth		1				1
Ear pruritus	1	1	1	1		
Fatigue	2	3	2	3		
Feeling hot	1	2	1	1		1
Haemorrhage	1	1			1	1
Headache	6	6	6	6		
Heart rate increased	1	2	1	2		
Herpes virus infection	1	1	1	1		
Hyperaesthesia	1	2	1	2		
Hyperhidrosis	1	1	1	1		
Hypersensitivity		1		1		
Hypoaesthesia	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Lacrimation increased	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Malaise	4	4	4	4		
Micturition urgency		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mobility decreased	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	2	2	2	2		
Oropharyngeal pain	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	5	5	5	5		
Pallor	1	1	1	1		
Paraesthesia	1	2	1	1		1
Peripheral swelling	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	6	6	6	6		
Skin lesion		1		1		
Somnolence	1	1	1	1		
Thirst		1				1
Tremor		1				1
Urticaria		1		1		
Vaccination site coldness	1	1	1	1		
Vaccination site erythema	3	3	3	3		
Vaccination site movement impairment	1	1	1	1		
Vaccination site nodule	1	1	1	1		
Vaccination site pain	4	4	4	4		
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		
Vomiting	3	3	3	3		
	85	101	82	92	3	9

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Arthralgia	1	1			1	1
Asthenia	2	2	2	2		
Body temperature increased	1	1	1	1		
Chest discomfort	1	1	1	1		
Chills	3	3	2	2	1	1
Cold sweat	1	1	1	1		
Drug ineffective	1	1			1	1
Dysgeusia	1	1	1	1		
Dyspnoea	1	1			1	1
Fatigue	2	2	2	2		
Gait disturbance	1	1	1	1		
Headache	4	4	3	3	1	1
Laryngeal oedema	1	1			1	1
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Malaise	3	3	2	2	1	1
Myalgia	2	2	1	1	1	1
Nausea	2	2	2	2		
No adverse event	1	1	1	1		
Oedema peripheral	1	1			1	1
Pruritus	1	1	1	1		
Pyrexia	3	3	2	2	1	1
Rash	1	1	1	1		
Rash maculo-papular	1	1			1	1
Rash pruritic	1	1	1	1		
Rash vesicular	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Sensation of foreign body	1	1			1	1
Swelling face	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site nodule	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	1	1	1	1		
	46	46	32	32	14	14

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site erythema	1	1	1	1
Vaccination site mass	1	1	1	1
	2	2	2	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure increased	1	1	1	1		
Burning sensation	2	2	2	2		
Chest pain	1	1	1	1		
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Eczema	1	1	1	1		
Erythema	1	1	1	1		
Feeling abnormal	2	2	2	2		
Feeling hot	1	1	1	1		
Gait disturbance	1	1	1	1		
Headache	5	5	5	5		
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Muscle fatigue	1	1	1	1		
Myalgia	2	2	2	2		
Nasopharyngitis	1	1	1	1		
Nausea	1	1	1	1		
Off label use	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	4	4	4	4		
Pain of skin	1	1	1	1		
Presyncope	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	1	1	1	1		
Swelling face	1	1	1	1		
Tinnitus	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site pain	4	4	4	4		

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
46	46	2	2

Vaccination site pruritus

1

1

Vaccination site swelling

1

1

48

48

46

46

2

2

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Country Where Event Occurred

**ICELAND**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	1	1	1	1
Bone pain	1	1	1	1
Chills	1	1	1	1
Discomfort	1	1	1	1
Dizziness	1	1	1	1
Dry mouth	1	1	1	1
Dry throat	1	1	1	1
Fatigue	1	1	1	1
Feeling cold	1	1	1	1
Headache	1	1	1	1
Hypoaesthesia	3	3	3	3
Nasopharyngitis	1	1	1	1
Oropharyngeal pain	2	2	2	2
Pruritus	1	1	1	1
Pyrexia	3	3	3	3
Sensory loss	1	1	1	1
Thirst	1	1	1	1
Vaccination site pain	1	1	1	1
	23	23	23	23

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Blood pressure increased	1	1	1	1		
Bone pain	1	1	1	1		
Bradycardia	1	1			1	1
Chest discomfort	1	1	1	1		
Chills	1	1	1	1		
Cold sweat	1	1	1	1		
Dizziness	2	2	2	2		
Erythema	1	1	1	1		
Fatigue	4	4	4	4		
Feeling cold	1	1	1	1		
Headache	8	8	8	8		
Head discomfort	1	1	1	1		
Hot flush	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Limb discomfort	1	1	1	1		
Malaise	4	4	4	4		
Migraine	1	1	1	1		
Myalgia	1	1	1	1		
Nausea	4	4	4	4		
Ocular discomfort	1	1	1	1		
Pain	1	1	1	1		
Pallor	1	1	1	1		
Pharyngeal swelling	1	1	1	1		
Pyrexia	3	3	3	3		
Swelling	1	1	1	1		
Tachycardia	1	1	1	1		
Tremor	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	52	52	51	51	1	1

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain	1	1	1	1
Cough	1	1	1	1
Fatigue	1	1	1	1
Headache	2	2	2	2
Heart rate increased	1	1	1	1
Myalgia	1	1	1	1
Nasopharyngitis	1	1	1	1
Pyrexia	2	2	2	2
Vaccination site pain	2	2	2	2
	13	13	13	13

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Cough	1	1	1	1		
Death	1	1			1	1
Dyspnoea	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	1	1	1	1		
Pyrexia	1	1	1	1		
	7	7	6	6	1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm	1	1			1	1
Asthenia	1	1	1	1		
Cardiac failure	2	2			2	2
Cough	1	1			1	1
Death	1	1			1	1
Disease progression	1	1			1	1
Dizziness	1	1	1	1		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Malaise	3	3	1	1	2	2
Myocardial infarction	1	1			1	1
Nasopharyngitis	2	2	2	2		
Pneumonia	2	2			2	2
Pyrexia	5	5	3	3	2	2
Respiration abnormal	1	1			1	1
Rhinorrhoea	2	2	2	2		
Sepsis	1	1			1	1
Sudden death	1	1			1	1
Vaccination site erythema	2	2	2	2		
Vaccination site inflammation	1	1	1	1		
	31	31	15	15	16	16

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear pain	1	1	1	1
Headache	1	1	1	1
Myalgia	1	1	1	1
Oropharyngeal pain	1	1	1	1
Pyrexia	1	1	1	1
	5	5	5	5

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Country Where Event Occurred

**INDIA**

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Suspected counterfeit product		1		1
		1		1

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Country Where Event Occurred

**IRELAND**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blindness	1	1	1	1
Cold sweat	1	1	1	1
Deafness	1	1	1	1
Dizziness	1	1	1	1
Dyspnoea	1	1	1	1
Heart rate increased	1	1	1	1
Syncope	1	1	1	1
	7	7	7	7

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	1	1	1	1
Fatigue	1	1	1	1
Headache	1	1	1	1
Lymphadenopathy	1	1	1	1
Pyrexia	1	1	1	1
	5	5	5	5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Injected limb mobility decreased	1	1			1	1
Pain	1	1			1	1
Periarthritis	1	1			1	1
Syncope	1	1			1	1
	6	6	2	2	4	4

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sudden death	1	1	1	1
	1	1	1	1

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death	1	1	1	1
	1	1	1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
IVth nerve paralysis	1	1			1	1
No adverse event	1	1	1	1		
Visual impairment	1	1			1	1
	3	3	1	1	2	2

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Country Where Event Occurred

**ISRAEL**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	1	3	1	3
	1	3	1	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Asthenia	2	2	2	2		
Cerebrovascular accident	1	1			1	1
Dizziness	1	1	1	1		
Erythema	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	1	1	1	1		
Gingival pain	1	1	1	1		
Headache	3	3	3	3		
Heart rate increased	1	1	1	1		
Hypoaesthesia	2	3	2	3		
Infection	1	1	1	1		
Lung disorder	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Muscle contractions involuntary	1	1	1	1		
Neuritis	1	1	1	1		
Off label use	1	1	1	1		
Oropharyngeal pain	2	2	2	2		
Overdose		1		1		
Pain	2	2	2	2		
Pain in extremity	3	3	3	3		
Pain in jaw	1	1	1	1		
Palpitations	1	1	1	1		
Paraesthesia	1	1	1	1		
Peripheral swelling	1	1	1	1		
Product preparation error		1		1		
Product use issue	1	1	1	1		
Pyrexia	5	5	5	5		
Skin disorder		1		1		
Systemic inflammatory response syndrome	1	1			1	1
Tenderness		1		1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	1	1	1		
Toothache	1	1	1	1		
Vaccination site bruising	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site pain	4	5	4	5		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	1	1	1		
	52	58	49	55	3	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain		1				1		
Ageusia	1	1			1	1		
Allergy to vaccine	1	1					1	1
Anaesthesia oral		1				1		
Anaphylactic reaction	1	1					1	1
Arthralgia	4	4			4	4		
Asthenia	8	9			8	9		
Atrial f brillation		1						1
Back pain	2	2			2	2		
Blood chloride increased	1	1					1	1
Blood glucose increased	1	1					1	1
Blood pressure increased	2	2					2	2
Blood pressure systolic increased	1	1			1	1		
Cardiac arrest	1	1					1	1
Chills	5	5			4	4	1	1
Choking	2	2					2	2
Cough	2	2			2	2		
COVID-19			1	1				
Decreased appetite	2	2			1	1	1	1
Diarrhoea	2	2			1	1	1	1
Disease recurrence	1	2			1	1		1
Dizziness	9	11			7	9	2	2
Drug ineffective			1	1				
Dysgeusia	2	3			2	3		
Dyspepsia	1	1			1	1		
Dysphagia	4	4			3	3	1	1
Dyspnoea	3	4			1	2	2	2
Ear pain	1	1			1	1		
Eosinophilic oesophagitis	1	1			1	1		
Erythema		1				1		
Exposure during pregnancy		1				1		
Exposure to SARS-CoV-2			1	1				

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial paralysis	2	2
Fatigue	7	8
Feeling abnormal	2	2
Feeling hot		1
Feeling of body temperature change		1
Food craving	1	1
Glomerular filtration rate decreased	1	1
Hangover	1	1
Headache	12	13
Heart rate increased	4	4
Hepatitis	1	1
Herpes zoster	1	1
Hot flush	1	1
Hyperhidrosis	1	1
Hypersensitivity	1	1
Hypertension		1
Hypoaesthesia	5	6
Hypoaesthesia oral	4	4
Impaired quality of life	1	1
Inappropriate schedule of product administration	1	1
Inflammatory marker increased		1
Influenza like illness	2	2
Insomnia	1	1
International normalised ratio increased	1	1
Joint swelling	1	1
Leukocytosis	1	1
Limb discomfort	1	1
Lymphadenopathy	2	2
Lymphopenia	1	1
Malaise	4	4
Mean cell haemoglobin decreased	1	1
Migraine	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		6	7	1	1
		2	2		
			1		
			1		
		1	1		
				1	1
		1	1		
		10	11	2	2
		4	4		
				1	1
		1	1		
		1	1		
		1	1		
				1	1
			1		
		5	6		
		3	3	1	1
		1	1		
		1	1		
					1
		2	2		
		1	1		
				1	1
		1	1		
				1	1
		2	2		
				1	1
		2	2	2	2
				1	1
		1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Miliaria	1	1
Multiple sclerosis	1	1
Multiple sclerosis relapse	1	1
Myalgia	6	6
Nausea	5	6
Neuralgia	1	1
Neutrophil count increased	1	1
Odynophagia	2	2
Off label use		1
Oropharyngeal pain	3	3
Otitis media	1	1
Oxygen saturation decreased	1	1
Pain	1	1
Pain in extremity	5	5
Palpitations	3	3
Paraesthesia	7	7
Paraesthesia oral	3	3
Parosmia	1	1
Pelvic pain	1	1
Pericarditis		1
Pharyngeal swelling	1	1
Pleuritic pain		1
Poor quality product administered	1	1
Presyncope	1	1
Product use issue		1
Pruritus	2	2
Pyrexia	4	4
Rash	3	3
Rash pruritic	1	1
Sinus tachycardia	1	1
Sleep disorder due to general medical condition, insomnia type		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
				1	1
		6	6		
		5	6		
		1	1		
				1	1
		2	2		
			1		
		3	3		
		1	1		
				1	1
		1	1		
		5	5		
		3	3		
		6	6	1	1
		2	2	1	1
		1	1		
		1	1		
					1
		1	1		
					1
		1	1		
		1	1		
			1		
		1	1	1	1
		3	3	1	1
		1	1	2	2
		1	1		
		1	1		
			1		

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Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Sneezing	1	1
Swollen tongue	2	2
Syncope	1	1
Tachycardia	1	1
Taste disorder	1	1
Throat tightness	1	1
Tongue discomfort	1	1
Urticaria	2	2
Vaccination site erythema	1	1
Vaccination site pain	11	14
Vision blurred	1	1
Vomiting	1	2
Weight decreased	2	2
Wrong technique in product usage process	1	1
Yawning	1	1
	206	234

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	2
				1	1
				1	1
		1	1		
				1	1
		1	1		
		1	1	1	1
		1	1		
		11	14		
		1	1		
		1	2		
		1	1	1	1
		1	1		
		1	1		
		3	3		
		157	180	49	54

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2	1	1	1	1
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Anger	1	1	1	1		
Angina pectoris	1	1			1	1
Anosmia	1	1	1	1		
Aphonia	1	1			1	1
Arrhythmia	2	2			2	2
Arthralgia	1	2	1	2		
Asthenia	8	9	8	9		
Atrial fibrillation	1	1			1	1
Back pain	3	3	3	3		
Blood chloride increased	1	1	1	1		
Blood glucose increased	2	2	1	1	1	1
Blood pressure increased	2	2	1	1	1	1
Bone pain		1		1		
Cardiac arrest	3	3			3	3
Cerebellar haemorrhage	1	1			1	1
Cerebral ischaemia	1	1			1	1
Chest discomfort		1		1		
Chest pain	1	1	1	1		
Chills	3	3	3	3		
Cough	1	1	1	1		
C-reactive protein increased	1	1	1	1		
Death		1				1
Diarrhoea	1	1	1	1		
Dizziness	2	2	2	2		
Drug ineffective	1	2			1	2
Dysgeusia	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Erythema	3	3	3	3		
Facial asymmetry	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial paralysis	3	3
Fatigue	1	2
Feeling abnormal	1	1
Feeling cold	1	1
Feeling hot	2	2
Formication	2	2
Headache	5	6
Hyperhidrosis	1	1
Hypersensitivity		1
Hypertension	1	1
Hypoaesthesia	4	4
Hypoaesthesia oral		1
Inappropriate schedule of product administration	1	1
Influenza		1
Influenza like illness	2	2
Lip pruritus		1
Lip swelling	2	2
Lymphocyte count increased	1	1
Malaise	7	7
Mean cell haemoglobin concentration decreased	1	1
Mean cell haemoglobin decreased	2	2
Mean cell volume decreased	1	1
Mean platelet volume increased	1	1
Muscle twitching	1	1
Muscular weakness	1	1
Myalgia	2	3
Nasopharyngitis	1	1
Nausea	3	3
Neck pain	2	2
Oropharyngeal discomfort		1
Oropharyngeal pain	1	1
Pain	4	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
		3	3
1	2		
1	1		
2	2		
2	2		
5	6		
1	1		
	1		
		1	1
4	4		
	1		
1	1		
	1		
2	2		
	1		
1	1	1	1
1	1		
6	6	1	1
1	1		
2	2		
1	1		
1	1		
1	1		
2	3		
1	1		
3	3		
2	2		
	1		
1	1		
4	4		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	7	7	7	7		
Palpitations	2	2	2	2		
Paraesthesia	6	7	6	7		
Paraesthesia oral	2	3	2	3		
Peripheral swelling	1	1			1	1
Pharyngeal paraesthesia		1		1		
Pharyngeal swelling		1		1		
Poor quality product administered		2		2		
Product deposit		1		1		
Product packaging quantity issue		1		1		
Pulse abnormal	1	1			1	1
Pyrexia	2	3	2	3		
Rash	1	2	1	2		
Rash macular	1	1	1	1		
Red blood cell count increased	1	1	1	1		
Respiratory arrest	1	1			1	1
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive	1	2			1	2
Sensory disturbance	1	1	1	1		
Sensory loss		1		1		
Skin burning sensation	1	1	1	1		
Swelling face	1	1	1	1		
Swollen tongue	1	1			1	1
Tachycardia	3	3	3	3		
Therapeutic response unexpected	1	1	1	1		
Thrombosis	1	1			1	1
Tremor	1	1	1	1		
Urticaria	1	2		1	1	1
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	11	12	11	12		
Wheezing	1	1			1	1
	155	183	124	149	31	34

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Arthralgia	3	3	2	2	1	1
Asthenia	7	9	7	9		
Asthma	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure decreased	1	1	1	1		
Blood pressure increased	3	4	2	3	1	1
Cardiac arrest		1				1
Cardiac disorder	1	1			1	1
Cardiac failure		1				1
Cerebrovascular accident	1	1			1	1
Chest pain	1	1			1	1
Chills	5	5	5	5		
Cold sweat	1	1	1	1		
Cough	1	1	1	1		
COVID-19	3	3			3	3
Death	2	2			2	2
Decreased appetite	2	2	2	2		
Depression	1	1	1	1		
Diarrhoea	2	2	2	2		
Dizziness	4	6	3	5	1	1
Drug ineffective	3	3			3	3
Dysgeusia	2	2	2	2		
Dyspepsia	3	3	3	3		
Dyspnoea	4	5	2	3	2	2
Dyspnoea exertional	1	1	1	1		
Dysstasia	1	1			1	1
Ear discomfort	1	1	1	1		
Ear pain	1	1	1	1		
Erythema	2	2	2	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye haemorrhage	1	1
Eye pain	1	1
Facial paralysis	2	3
Fall	1	1
Fatigue	2	3
Feeling abnormal	3	4
Feeling cold	1	2
Feeling hot	1	2
Gait disturbance	2	2
Haemolytic anaemia	1	1
Headache	5	5
Heart rate increased		1
Hip fracture	1	1
Hyperhidrosis	1	1
Hypertension	2	2
Hypoaesthesia	3	3
Hypoaesthesia teeth	1	1
Hypotension	1	1
Hypoventilation	1	1
Illness	1	1
Influenza	1	1
Insomnia		1
Jaundice	1	1
Loss of consciousness	1	2
Lymphocytosis	1	1
Malaise		1
Movement disorder	1	1
Multiple sclerosis relapse	1	1
Myalgia	3	4
Myocardial infarction	1	1
Nausea	4	5
Overdose	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		2	3
		1	1
2	3		
1	1	2	3
1	2		
1	2		
		2	2
		1	1
5	5		
	1		
		1	1
1	1		
		2	2
3	3		
1	1		
1	1		
		1	1
1	1		
1	1		
1	1		
		1	2
1	1		
	1		
		1	1
		1	1
2	3	1	1
		1	1
3	4	1	1
1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	1	1	1	1		
Pain in extremity	4	5	4	5		
Pain in jaw	1	1	1	1		
Palpitations	2	2	2	2		
Pancreatitis	1	1			1	1
Paraesthesia	1	2	1	2		
Paraesthesia oral	1	1	1	1		
Pelvic fracture	1	1			1	1
Product preparation error	1	1	1	1		
Pyrexia	4	4	4	4		
Rash	2	2	2	2		
Respiratory rate increased	1	1			1	1
Rhinorrhoea	1	1	1	1		
Rib fracture	1	1			1	1
Skin burning sensation	1	1	1	1		
Speech disorder	1	1	1	1		
Syncope	2	2			2	2
Thrombosis	2	2			2	2
Tremor	2	3	2	3		
Underdose	1	1	1	1		
Urticaria	2	2	1	1	1	1
Vomiting	3	3	3	3		
	143	165	96	113	47	52

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac arrest	1	1			1	1
Cardiac disorder	1	1			1	1
Circulatory collapse	1	1			1	1
Contusion	1	1			1	1
Crying	1	1	1	1		
Death	1	2			1	2
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspepsia	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Eye irritation	2	2	1	1	1	1
Fall	1	1			1	1
Feeling cold		1		1		
Headache	1	1	1	1		
Hypertension	1	1	1	1		
Lacrimation increased	2	2	1	1	1	1
Malaise	1	1	1	1		
Movement disorder	1	1	1	1		
Myalgia	1	1	1	1		
Pain	1	1	1	1		
Personality change	1	1	1	1		
Pleural effusion	1	1			1	1
Respiratory distress	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
Sepsis	1	1			1	1
Suffocation feeling	1	1	1	1		
Syncope		1				1
Vomiting	1	1	1	1		
	29	32	15	16	14	16

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Abdominal pain		1		1			
Acute myocardial infarction	1	1			1		1
Adverse event	1	1	1	1			
Adverse reaction	1	1	1	1			
Alopecia	1	1	1	1			
Anosmia		1		1			
Arthralgia	2	2	1	1	1		1
Arthropathy	1	1	1	1			
Asthenia	25	27	25	27			
Back pain	1	1	1	1			
Balance disorder		1		1			
Blood pressure increased	1	1			1		1
Chills	11	12	11	12			
Condition aggravated	1	1	1	1			
Confusional state	1	1	1	1			
Coronavirus infection	1	2	1	1			1
Coronavirus test positive	1	1			1		1
Cough	2	2	2	2			
COVID-19	3	3	1	1	2		2
Death	1	1			1		1
Depressed level of consciousness	1	1			1		1
Depressed mood	1	1	1	1			
Diarrhoea	2	2	2	2			
Dizziness	5	7	5	7			
Drug ineffective	9	10	2	2	7		8
Dry mouth	1	1	1	1			
Dyschromatopsia	1	1			1		1
Dysgeusia	2	2	2	2			
Dysphagia	1	1	1	1			
Dyspnoea	2	2	1	1	1		1
Ear pain	1	1	1	1			
Exposure via breast milk	1	1	1	1			

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye infection		1
Eye pain	1	1
Facial paralysis	2	2
Fall	1	1
Fatigue	11	15
Feeling abnormal	2	3
Feeling cold	3	3
Gastroenteritis viral	1	1
Headache	17	17
Head discomfort	2	2
Head injury	1	1
Heart rate increased	1	1
Hypersensitivity	1	2
Hypoaesthesia	5	7
Hypoaesthesia oral	2	3
Inappropriate schedule of product administration	3	3
Incomplete course of vaccination	1	1
Incorrect route of product administration	1	1
Influenza like illness	4	4
Initial insomnia		1
Limb discomfort	1	1
Lip pruritus	1	1
Liquid product physical issue		14
Lymphadenopathy	1	2
Malaise	4	5
Mobility decreased		1
Multiple sclerosis relapse	1	1
Muscle contractions involuntary	1	1
Myalgia	15	15
Myocardial infarction	1	1
Nasopharyngitis	1	1
Nausea	8	9

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		1	1
		2	2
1	1		
11	15		
2	3		
3	3		
1	1		
16	16	1	1
2	2		
		1	1
1	1		
		1	2
5	7		
2	3		
3	3		
1	1		
1	1		
4	4		
	1		
1	1		
1	1		
	14		
1	2		
3	4	1	1
			1
		1	1
1	1		
14	14	1	1
		1	1
1	1		
8	9		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neck pain		1
Neuralgic amyotrophy	2	2
Oral herpes	3	3
Oropharyngeal pain	2	2
Overdose	1	2
Pain	4	4
Pain in extremity	9	11
Pain in jaw	1	1
Paraesthesia	1	3
Paraesthesia oral	3	4
Paralysis		1
Paraplegia	1	1
Pericarditis	1	1
Poor quality product administered	1	26
Poor quality sleep		1
Product complaint		1
Product packaging quantity issue	1	11
Product preparation error	1	2
Product preparation issue	1	1
Pruritus	1	1
Pyrexia	22	23
Rash	2	3
Rhinalgia		1
Rhinorrhoea	1	1
SARS-CoV-2 ant body test negative	1	1
SARS-CoV-2 test positive	3	3
Seizure	1	1
Sneezing	1	1
Somnolence	1	1
Stress	1	1
Sudden cardiac death	1	1
Suspected COVID-19	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
2	2		
2	2	1	1
1	2		
4	4		
9	11		
1	1		
1	3		
3	4		
			1
		1	1
		1	1
1	26		
	1		
	1		
1	11		
1	2		
1	1		
1	1		
20	21	2	2
2	2		1
	1		
1	1		
		3	3
		1	1
1	1		
1	1		
1	1		
		1	1
		1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Swollen tongue		1					1
Syncope	4	4			4		4
Therapeutic response unexpected	1	1	1	1			
Underdose	1	2	1	2			
Vaccination site erythema	2	3	2	3			
Vaccination site hypersensitivity		1		1			
Vaccination site movement impairment		1		1			
Vaccination site pain	17	27	17	27			
Vaccination site swelling	5	7	5	7			
Vision blurred	2	2	2	2			
Vomiting	4	4	4	4			
Wrong technique in product usage process	2	2	2	2			
	281	386	239	337	42		49

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Country Where Event Occurred

**ITALY**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	1	1	1	1
Product administered to patient of inappropriate age	1	1	1	1
	2	2	2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anal incontinence	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Arthralgia	6	6	6	6		
Asthenia	11	11	10	10	1	1
Back pain	1	1	1	1		
Bronchospasm	1	1			1	1
Chills	5	5	5	5		
Confusional state	1	1			1	1
Depressed level of consciousness	1	1			1	1
Diarrhoea	6	6	6	6		
Dizziness	3	3	3	3		
Dry mouth	1	1	1	1		
Dysgeusia	3	3	3	3		
Dyspepsia	1	1	1	1		
Dysphagia	1	1	1	1		
Dyspnoea	1	1	1	1		
Erythema	2	2	1	1	1	1
Fatigue	2	2	2	2		
Feeling hot	1	1	1	1		
Feeling of body temperature change	1	1	1	1		
Flushing	1	1	1	1		
Gastritis	1	1	1	1		
Headache	22	22	22	22		
Hot flush	2	2	2	2		
Hyperhidrosis	3	3	2	2	1	1
Hypoaesthesia	2	2	2	2		
Hypoaesthesia oral	1	1	1	1		
Hypotension	4	4	3	3	1	1
Influenza like illness	1	1	1	1		
Laryngeal oedema	1	1			1	1
Laryngeal pain	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Limb discomfort	2	2
Lip oedema	1	1
Lip swelling	1	1
Loss of consciousness	1	1
Lymphadenopathy	1	1
Lymph node pain	1	1
Malaise	4	4
Mechanical urticaria	1	1
Musculoskeletal pain	1	1
Myalgia	4	4
Nausea	9	9
Obstructive airways disorder	1	1
Overdose	1	1
Pain in extremity	5	5
Pallor	1	1
Paraesthesia	2	2
Paraesthesia oral	1	1
Pharyngeal erythema	1	1
Presyncope	2	2
Pruritus	2	2
Pyrexia	16	16
Rash	4	4
Rhinorrhoea	1	1
Sensation of foreign body	1	1
Sinus tachycardia	1	1
Somnolence	2	2
Swelling	1	1
Swelling face	1	1
Tachycardia	7	7
Tachycardia paroxysmal	1	1
Throat tightness	1	1
Tonic clonic movements	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
		1	1
1	1		
		1	1
1	1		
1	1		
4	4		
1	1		
1	1		
4	4		
9	9		
		1	1
1	1		
5	5		
1	1		
2	2		
1	1		
1	1		
2	2		
2	2		
15	15	1	1
4	4		
1	1		
1	1		
1	1		
2	2		
1	1		
1	1		
7	7		
		1	1
1	1		
		1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	1	1	1		
Underdose	1	1	1	1		
Urticaria	2	2	2	2		
Vaccination site discomfort	2	2	2	2		
Vaccination site erythema	2	2	2	2		
Vaccination site induration	1	1	1	1		
Vaccination site joint warmth	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	16	16	16	16		
Vaccination site paraesthesia	3	3	3	3		
Vaccination site swelling	2	2	2	2		
Vertigo	3	3	3	3		
Vision blurred	2	2	2	2		
Vomiting	1	1	1	1		
	207	207	192	192	15	15

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	4	5	4	5		
Abdominal pain upper	5	5	5	5		
Ageusia	1	1	1	1		
Agitation	3	3	3	3		
Allodynia	1	1	1	1		
Anaesthesia	1	1			1	1
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	3	3			3	3
Angioedema	2	2			2	2
Anosmia	1	1	1	1		
Arthralgia	17	17	17	17		
Asphyxia	1	1			1	1
Asthenia	15	15	14	14	1	1
Aura	1	1	1	1		
Axillary pain	3	3	2	2	1	1
Back pain	2	2	1	1	1	1
Balance disorder	1	1	1	1		
Band sensation	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure diastolic increased	1	1	1	1		
Blood pressure increased	5	5	3	3	2	2
Body temperature decreased	2	2	2	2		
Body temperature increased		1		1		
Bone pain	2	2	2	2		
Bradycardia	1	1			1	1
Chest discomfort	3	3	2	2	1	1
Chest pain	1	1	1	1		
Chills	16	17	16	17		
Confusional state	2	2	2	2		
Constipation	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cough	6	6
COVID-19	2	2
Cranial nerve disorder	1	1
Decreased appetite	1	1
Dermatitis	1	1
Diarrhoea	12	12
Discomfort	1	1
Dizziness	5	5
Drug ineffective	2	2
Dry mouth	6	6
Dry throat	1	1
Dysaesthesia	1	1
Dysgeusia	9	9
Dysphagia	7	7
Dysphonia	1	1
Dyspnoea	9	9
Erythema	14	14
Extremity contracture	1	1
Eye irritation	1	1
Eyelid oedema	1	1
Eye pain	2	2
Eye pruritus	1	1
Face oedema	1	1
Facial spasm	1	1
Fatigue	11	11
Feeling cold	4	4
Feeling hot	8	8
Flushing	5	5
Haematoma	1	1
Headache	53	53
Hot flush	5	5
Hyperhidrosis	5	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	5	1	1
		2	2
		1	1
1	1		
		1	1
12	12		
1	1		
5	5		
		2	2
4	4	2	2
1	1		
1	1		
7	7	2	2
4	4	3	3
1	1		
6	6	3	3
12	12	2	2
1	1		
1	1		
		1	1
2	2		
1	1		
		1	1
		1	1
11	11		
3	3	1	1
6	6	2	2
5	5		
1	1		
52	52	1	1
5	5		
5	5		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypersensitivity	1	1
Hypertension	5	5
Hypertensive crisis	3	3
Hypoaesthesia	6	6
Hypoaesthesia oral	4	4
Hypotension	3	3
Incorrect dose administered	2	2
Incorrect route of product administration	1	1
Influenza like illness	1	2
Injection site pain	2	2
Insomnia	2	2
Intranasal hypoaesthesia	1	1
Joint range of motion decreased	1	1
Lacrimation increased	2	2
Laryngeal oedema	3	3
Laryngospasm	1	1
Limb discomfort	2	2
Lip oedema	5	5
Lip pruritus	1	1
Localised oedema	1	1
Lymphadenitis	2	2
Lymphadenopathy	13	13
Lymph node pain	2	2
Lymphoedema	1	1
Malaise	8	9
Migraine	4	4
Monoparesis	1	1
Mucosal dryness	1	1
Muscle contractions involuntary	1	1
Muscle rigidity	1	1
Muscular weakness	1	1
Musculoskeletal pain	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
2	2	3	3
		3	3
6	6		
4	4		
2	2	1	1
2	2		
1	1		
1	2		
1	1	1	1
2	2		
1	1		
1	1		
2	2		
		3	3
		1	1
2	2		
4	4	1	1
1	1		
1	1		
2	2		
13	13		
2	2		
1	1		
8	9		
4	4		
1	1		
1	1		
		1	1
		1	1
1	1		
3	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal stiffness	1	1
Myalgia	22	22
Nasal congestion	1	1
Nasopharyngitis	2	2
Nausea	17	17
Neck pain	2	2
Neuralgia	1	1
Neuritis	1	1
Night sweats	1	1
Nuchal rigidity	1	1
Ocular hyperaemia	1	1
Oral herpes	1	1
Oropharyngeal pain	2	2
Oropharyngeal swelling	1	1
Overdose	2	2
Pain	10	10
Pain in extremity	16	16
Palatal oedema	1	1
Palatal swelling	1	1
Pallor	1	1
Palpitations	2	2
Paraesthesia	14	14
Paraesthesia oral	13	13
Paresis	1	1
Paresis cranial nerve	1	1
Parosmia	1	1
Periorbital oedema	1	1
Peripheral coldness	2	2
Pharyngeal paraesthesia	1	1
Pharyngitis	1	1
Presyncope	4	4
Pruritus	15	15

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
21	21	1	1
1	1		
1	1	1	1
16	16	1	1
2	2		
1	1		
1	1		
1	1		
		1	1
1	1		
1	1		
2	2		
1	1		
2	2		
9	9	1	1
16	16		
		1	1
1	1		
1	1		
2	2		
11	11	3	3
10	10	3	3
1	1		
1	1		
1	1		
		1	1
2	2		
1	1		
1	1		
3	3	1	1
13	13	2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Pyrexia	45	45
Rash	12	12
Rash erythematous	1	1
Rash pruritic	1	1
Reduced facial expression	1	1
Renal pain	1	1
Respiratory distress	1	1
Retching	1	1
Rhinorrhoea	1	1
Skin reaction	1	1
Somnolence	9	9
Speech disorder	1	1
Spinal pain	4	4
Swelling	2	2
Swelling face	1	1
Swelling of eyelid	1	1
Swollen tongue	3	3
Tachycardia	11	11
Tachycardia paroxysmal	1	1
Tachypnoea	1	1
Throat irritation	3	3
Throat tightness	8	8
Tongue disorder	1	1
Tongue dry	3	3
Tongue oedema	2	2
Tonsillar erythema	1	1
Tonsillar hypertrophy	1	1
Tremor	5	5
Underdose	2	2
Urticaria	17	17
Vaccination site discomfort	1	1
Vaccination site erythema	5	6

Spontaneous			
Nonserious		Serious	
I	C	I	C
44	44	1	1
11	11	1	1
1	1		
1	1		
		1	1
1	1		
		1	1
1	1		
1	1		
1	1		
9	9		
1	1		
4	4		
2	2		
		1	1
1	1		
2	2	1	1
9	9	2	2
1	1		
1	1		
2	2	1	1
4	4	4	4
1	1		
1	1	2	2
1	1	1	1
1	1		
1	1		
4	4	1	1
2	2		
16	16	1	1
1	1		
4	5	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint swelling	1	1	1	1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site oedema	2	2	2	2		
Vaccination site pain	60	61	59	60	1	1
Vaccination site pruritus	3	3	3	3		
Vaccination site swelling	5	5	4	4	1	1
Vaccination site urticaria	5	5	4	4	1	1
Vaccination site warmth	3	4	2	3	1	1
Vasoconstriction	1	1	1	1		
Vasomotor rhinitis	1	1	1	1		
Vertigo	12	12	11	11	1	1
Vision blurred	1	1	1	1		
Visual impairment	1	1	1	1		
Vomiting	7	7	7	7		
Wrong technique in product usage process	1	1	1	1		
	758	766	660	668	98	98

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal pain	5	5			5	5		
Abdominal pain upper	3	3			3	3		
Acute coronary syndrome	1	1					1	1
Acute myocardial infarction	1	1					1	1
Administration site reaction	1	1					1	1
Allergy to vaccine	1	1					1	1
Anaesthesia	1	1			1	1		
Anaphylactic shock	2	2					2	2
Anxiety	2	2			2	2		
Arthralgia	15	16			13	14	2	2
Asthenia	7	8			7	8		
Axillary pain	2	2			2	2		
Back pain	1	1			1	1		
Balance disorder	1	1			1	1		
Blood pressure increased	1	1			1	1		
Body temperature increased	2	2			1	1	1	1
Bone pain	1	1			1	1		
Breast discomfort	1	1					1	1
Breast pain	1	1					1	1
Breast swelling	1	1					1	1
Burning sensation	1	1			1	1		
Chest discomfort	1	1			1	1		
Chills	16	16	1	1	14	14	2	2
Confusional state	2	2			2	2		
Corneal bleeding	1	1					1	1
Cough	1	1			1	1		
Crying	1	1			1	1		
Death	1	1					1	1
Decreased appetite	1	1			1	1		
Depressed level of consciousness	2	2			1	1	1	1
Diarrhoea	5	5			5	5		
Disorientation	1	1			1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dizziness	10	10
Dry mouth	3	3
Dysaesthesia	1	1
Dysgeusia	2	2
Dysphagia	1	1
Dyspnoea	2	2
Ear pain	1	1
Ear pruritus	1	1
Erythema	9	9
Eye irritation	1	1
Eye pruritus	1	1
Face oedema	1	1
Facial pain	1	1
Facial paralysis	1	1
Fatigue	10	10
Feeling abnormal	2	2
Feeling cold	1	1
Feeling hot	6	6
Flushing	1	1
Gastrointestinal disorder	1	1
Gingival swelling	1	1
Headache	34	35
Head discomfort	1	1
Heart rate decreased	1	1
Hot flush	1	1
Hyperaesthesia	1	1
Hyperhidrosis	3	3
Hyperpyrexia	2	2
Hypersensitivity	1	1
Hypertension	2	2
Hypertensive crisis	3	3
Hyperthermia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	10		
		3	3		
		1	1		
		2	2		
		1	1		
1	1			2	2
		1	1		
		1	1		
		7	7	2	2
		1	1		
		1	1		
		1	1		
		1	1		
				1	1
1	1	9	9	1	1
		2	2		
1	1	1	1		
		6	6		
		1	1		
		1	1		
		1	1		
1	1	32	33	2	2
		1	1		
		1	1		
		1	1		
		3	3		
				2	2
		1	1		
		1	1	1	1
				3	3
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoaesthesia oral	2	2
Hypoglycaemia	1	1
Hypotension	3	3
Incorrect route of product administration	1	1
Inflammation	1	1
Influenza like illness	1	2
Injection site pain	3	3
Insomnia	1	1
Intranasal paraesthesia	1	1
Irritability	1	1
Laryngeal oedema	3	3
Limb discomfort	1	1
Lip pruritus	1	1
Lip swelling	1	1
Localised oedema	1	1
Lymphadenopathy	10	10
Lymphangitis	1	1
Lymph node pain	2	2
Malaise	6	6
Mastitis	1	1
Migraine	2	2
Muscle spasms	1	1
Musculoskeletal pain	2	2
Myalgia	14	14
Nasal congestion	1	1
Nausea	19	19
Neck pain	1	1
Neuralgia	1	1
Oedema mouth	1	1
Oedema peripheral	1	1
Off label use	2	2
Oral discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
		1	1		
		2	2	1	1
		1	1		
				1	1
		1	2		
		3	3		
		1	1		
		1	1		
		1	1		
		1	1		
				3	3
		1	1		
		1	1		
		1	1		
		7	7	3	3
				1	1
		2	2		
		4	4	2	2
				1	1
		2	2		
		1	1		
		2	2		
		13	13	1	1
		1	1		
		18	18	1	1
		1	1		
		1	1		
				1	1
		1	1		
		2	2		
		1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral dysaesthesia	1	1
Oral herpes	1	1
Oropharyngeal pain	2	2
Overdose	1	1
Pain	3	3
Pain in extremity	8	8
Palpitations	1	1
Paraesthesia	11	11
Paraesthesia oral	6	6
Periorbital swelling	1	1
Peripheral coldness	1	1
Peripheral swelling	1	1
Pharyngeal paraesthesia	1	1
Pharyngeal swelling	1	1
Photophobia	1	1
Polyuria	1	1
Presyncope	3	3
Product use issue	1	1
Pruritus	10	10
Pyrexia	30	30
Rash	6	6
Rash erythematous	2	2
Rhinorrhoea	2	2
Sciatica	1	1
Sinus tachycardia	1	1
Sneezing	1	1
Somnolence	3	3
Stupor	2	2
Swelling	1	1
Syncope	1	1
Tachycardia	7	7
Tenderness	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		2	2		
		1	1		
		2	2	1	1
		6	6	2	2
		1	1		
		10	10	1	1
		5	5	1	1
		1	1		
		1	1		
		1	1		
		1	1		
		1	1	1	1
		1	1		
		1	1		
		3	3		
		1	1		
		9	9	1	1
1	1	28	28	2	2
		6	6		
		2	2		
		2	2		
		1	1		
				1	1
		1	1		
		3	3		
		2	2		
				1	1
				1	1
		5	5	2	2
		1	1		

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\* I=Interval, C=Cumulative  
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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Throat irritation	1	1
Throat tightness	3	3
Tongue discomfort	1	1
Tongue oedema	1	1
Tongue pruritus	1	1
Tremor	2	2
Underdose	2	2
Urticaria	8	8
Vaccination site discolouration	1	1
Vaccination site erythema	4	4
Vaccination site hypoaesthesia	1	1
Vaccination site lymphadenopathy	1	1
Vaccination site movement impairment	1	1
Vaccination site oedema	2	2
Vaccination site pain	56	56
Vaccination site paraesthesia	1	1
Vaccination site pruritus	1	1
Vaccination site rash	1	1
Vaccination site swelling	3	3
Vaccination site warmth	1	1
Vertigo	5	5
Vision blurred	2	2
Vomiting	2	2
	492	496

Non Interventional Study		Spontaneous					
Serious		Nonserious		Serious			
I	C	I	C	I	C		
		1	1				
		3	3				
		1	1				
				1	1		
		1	1				
		2	2				
		2	2				
		7	7	1	1		
		1	1				
		4	4				
		1	1				
				1	1		
		1	1				
		2	2				
		55	55	1	1		
		1	1				
				1	1		
		1	1				
		3	3				
		1	1				
		5	5				
		2	2				
		1	1	1	1		
		6	6	425	429	67	67

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	3	3	3	3		
Blood pressure increased	1	1	1	1		
Bone pain	1	1	1	1		
Confusional state	1	1	1	1		
Cough	2	2	2	2		
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Dry mouth	1	1	1	1		
Dysphonia	1	1	1	1		
Dyspnoea	1	1	1	1		
Erythema	2	2	2	2		
Flatulence	1	1	1	1		
Flushing	1	1	1	1		
Gastrointestinal sounds abnormal	1	1	1	1		
Headache	3	3	3	3		
Herpes zoster	1	1	1	1		
Hypotension	1	1	1	1		
Inspiratory capacity abnormal	1	1	1	1		
Laryngeal oedema	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Migraine	1	1	1	1		
Myalgia	3	3	3	3		
Nausea	3	3	3	3		
Neck pain	1	1	1	1		
Oedema mouth	1	1	1	1		
Oxygen saturation decreased	1	1	1	1		
Pain in extremity	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Parotid gland enlargement	1	1	1	1		
Periorbital swelling	1	1	1	1		
Peripheral coldness	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngitis	1	1	1	1		
Pyrexia	5	5	5	5		
SARS-CoV-2 test positive	1	1			1	1
Tachycardia	1	1			1	1
Torticollis	1	1	1	1		
Tremor	2	2	2	2		
Vaccination site pain	13	13	13	13		
Vertigo	1	1	1	1		
Vomiting	1	1	1	1		
	68	68	64	64	4	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	1			1	1
Acute myocardial infarction	1	1			1	1
Acute respiratory failure	1	1			1	1
Allergic respiratory symptom	1	1			1	1
Anaphylactic reaction	1	1			1	1
Arteriosclerosis	1	1			1	1
Asthenia	1	1			1	1
Atrioventricular block complete	1	1			1	1
Bradycardia	1	1			1	1
Cardiac failure	1	1			1	1
Cerebellar haemorrhage	1	1			1	1
Cerebrovascular accident	1	1			1	1
Circulatory collapse	1	1			1	1
Coma scale abnormal	1	1			1	1
Condition aggravated	1	1			1	1
Death	2	2			2	2
Deep vein thrombosis	1	1			1	1
Dehydration	1	1			1	1
Dermatitis allergic	1	1			1	1
Dermatitis exfoliative generalised	1	1			1	1
Dysphagia	1	1			1	1
Dyspnoea	4	4			4	4
Dysuria	1	1			1	1
Fall	1	1			1	1
General physical health deterioration	1	1			1	1
Hemiparesis	1	1			1	1
Myocardial ischaemia	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pulmonary embolism	1	1			1	1
Pyrexia	1	1			1	1
Q fever	1	1			1	1
Rash	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Renal failure	1	1			1	1
Respiratory arrest	1	1			1	1
Restlessness	1	1			1	1
Sudden death	1	1			1	1
Systolic hypertension	1	1			1	1
Urticaria	1	1			1	1
Vomiting	1	1			1	1
Weight decreased	1	1			1	1
	44	44	1	1	43	43

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
		3	3
		2	2
2	2		
3	3		
1	1		
		1	1
1	1		
	1		
1	1		
		3	3
		1	1
1	1		
2	2		
8	8	8	8
2	2		
1	1		
4	4		
1	1		
1	1		
1	1		
7	7		
1	1	1	1
1	1		
1	1	1	1
1	1		
1	1		
1	1		
1	1		
1	1		
1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Influenza like illness	2	2
Insomnia	1	1
Laryngeal oedema	1	1
Limb discomfort	1	1
Lip oedema	2	2
Lymphadenopathy	7	7
Malaise	2	2
Migraine	1	1
Musculoskeletal pain	3	3
Myalgia	3	3
Nausea	2	2
Off label use	1	1
Pain	1	1
Pain in extremity	4	4
Pallor	1	1
Paraesthesia	2	2
Peripheral coldness	1	1
Pityriasis rosea	1	1
Poor quality product administered	1	1
Product administered at inappropriate site	1	1
Product administration error	1	1
Product label confusion		1
Product preparation issue	1	1
Product use issue	1	1
Pyrexia	9	9
Rash	2	2
SARS-CoV-2 ant body test positive	2	2
SARS-CoV-2 test positive	5	5
Skin reaction	1	1
Somnolence	1	1
Swelling face	1	1
Syncope	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
1	1		
		1	1
1	1		
2	2		
7	7		
2	2		
1	1		
3	3		
3	3		
2	2		
1	1		
1	1		
4	4		
1	1		
2	2		
1	1		
1	1		
1	1		
1	1		
1	1		
1	1		
1	1		
9	9		
2	2		
2	2		
		5	5
1	1		
1	1		
1	1		
		1	1

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 \* AE=Adverse Event  
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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	1	1	1		
Underdose	2	2	2	2		
Urticaria	5	5	5	5		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	2	2	2	2		
Vaccination site pain	17	17	17	17		
Vaccination site paraesthesia	1	1	1	1		
Vaccination site swelling	2	2	2	2		
Vaccination site urticaria	1	1	1	1		
Vertigo	2	2	1	1	1	1
Wrong technique in product usage process	1	1	1	1		
	154	156	125	127	29	29

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Country Where Event Occurred

**KUWAIT**

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Lymphadenopathy	1	1	1	1
Myalgia	1	1	1	1
Neck pain	1	1	1	1
Pyrexia	1	1	1	1
Swelling	1	1	1	1
Tenderness	1	1	1	1
Vaccination site pain	1	1	1	1
Vaccination site swelling	1	1	1	1
	9	9	9	9

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Country Where Event Occurred

**LATVIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	3	3	2	2	1	1
Asthenia	2	2	2	2		
Asthma	1	1	1	1		
Body temperature increased	1	1	1	1		
Burning sensation	1	1			1	1
Chest pain	1	1	1	1		
Cough	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Dyspnoea	1	1	1	1		
Erythema	1	1			1	1
Fatigue	2	2	2	2		
Headache	2	2	1	1	1	1
Myalgia	1	1	1	1		
Neuralgia	1	1			1	1
Pain in extremity	1	1			1	1
Paraesthesia	1	1			1	1
Pruritus	1	1			1	1
Pyrexia	1	1	1	1		
Throat irritation	1	1	1	1		
Vaccination site pain	3	3	3	3		
	28	28	18	18	10	10

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1			1	1
Arthralgia	2	2	2	2		
Asthenia	2	2	1	1	1	1
Blood pressure increased	1	1			1	1
Body temperature increased	3	3	2	2	1	1
Chills	1	1	1	1		
Cold sweat	1	1			1	1
Diarrhoea	1	1	1	1		
Dry mouth	1	1			1	1
Dysgeusia	1	1			1	1
Feeling hot	1	1	1	1		
Headache	1	1	1	1		
Lymph node pain	1	1			1	1
Musculoskeletal discomfort	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	1	1	1	1		
Palatal swelling	1	1	1	1		
Peripheral coldness	2	2	1	1	1	1
Pyrexia	1	1	1	1		
Syncope	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	3	3	3	3		
Vaccination site pruritus	2	2	2	2		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		
	35	35	24	24	11	11

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1	1	1		
Body temperature increased	2	2	2	2		
COVID-19	3	3			3	3
Drug ineffective	3	3			3	3
Fatigue	1	1	1	1		
Illness	1	1	1	1		
Lymphadenitis	1	1	1	1		
Malaise	1	1	1	1		
Night sweats	1	1	1	1		
	14	14	8	8	6	6

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure decreased	1	1	1	1
Dizziness	1	1	1	1
Headache	1	1	1	1
Myalgia	1	1	1	1
Pain in extremity	1	1	1	1
	5	5	5	5

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Drug ineffective	1	1			1	1
Eye pain	1	1	1	1		
Headache	1	1			1	1
Pain in extremity	1	1	1	1		
Pyrexia	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
	6	6	2	2	4	4

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Country Where Event Occurred

**LITHUANIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Myalgia	1	1	1	1
Pain in extremity	1	1	1	1
Peripheral swelling	1	1	1	1
Pyrexia	1	1	1	1
Tachycardia	1	1	1	1
	6	6	6	6

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	2	2	2	2
Back pain	1	1	1	1
Chills	1	1	1	1
Dizziness	1	1	1	1
Headache	3	3	3	3
Myalgia	3	3	3	3
Overdose	1	1	1	1
Pain in extremity	1	1	1	1
Pyrexia	4	4	4	4
Sensitive skin	1	1	1	1
Tremor	1	1	1	1
Vaccination complication	1	1	1	1
Vaccination site pain	1	1	1	1
	21	21	21	21

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
Neck pain	1	1	1	1
Vaccination site erythema	1	1	1	1
Vaccination site pain	1	1	1	1
	4	4	4	4

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
Dizziness	1	1	1	1
Headache	1	1	1	1
Myalgia	1	1	1	1
Pyrexia	1	1	1	1
Underdose	1	1	1	1
	6	6	6	6

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Country Where Event Occurred

**LUXEMBOURG**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Herpes zoster	1	1	1	1
Oral herpes	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**MALTA**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea		1		1		
Dizziness		1		1		
Dyspnoea	1	1			1	1
Erythema		1		1		
Facial paralysis	1	1	1	1		
Fatigue	1	2	1	2		
Hot flush		1		1		
Hypersensitivity		1				1
Hypertension		1				1
Hypoaesthesia	1	1	1	1		
Lethargy	1	2	1	2		
Malaise	1	1	1	1		
Myalgia	2	2	2	2		
Nausea		1		1		
Pain	1	1	1	1		
Palpitations		1		1		
Paraesthesia	1	2	1	2		
Rash erythematous		1		1		
Rash pruritic	1	1			1	1
Somnolence	1	1	1	1		
Tachycardia		1				1
Vaccination site pain	1	1	1	1		
Vaccination site urticaria		1		1		
Vomiting		1		1		
Wheezing	1	1			1	1
	14	29	11	23	3	6

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.



Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea	1	1	1	1
	1	1	1	1

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**MEXICO**

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\* AE=Adverse Event  
\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain	2	2	2	2
Arthralgia	9	9	9	9
Asthenia	6	6	6	6
Body temperature increased	2	2	2	2
Chills	3	3	3	3
Cough	2	2	2	2
Decreased appetite	1	1	1	1
Diarrhoea	1	1	1	1
Discomfort	1	1	1	1
Dizziness	4	4	4	4
Dysgeusia	1	1	1	1
Dyspnoea	1	1	1	1
Ear pain	1	1	1	1
Erythema	1	1	1	1
Fatigue	1	1	1	1
Headache	13	14	13	14
Inflammation	1	1	1	1
Local reaction	1	1	1	1
Lymphadenopathy	2	2	2	2
Mobility decreased	1	1	1	1
Myalgia	10	10	10	10
Nausea	2	2	2	2
Oedema	3	3	3	3
Pain	3	3	3	3
Pain in extremity		1		1
Paraesthesia	2	2	2	2
Pyrexia	9	9	9	9
Rash	1	1	1	1
Sensory loss	1	1	1	1
Swelling	1	1	1	1
Tachycardia	2	2	2	2
Vaccination site erythema	1	1	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site induration	2	2	2	2
Vaccination site nodule	2	2	2	2
Vaccination site pain	10	10	10	10
Vomiting	1	1	1	1
	104	106	104	106

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Abdominal pain upper	2	2	2	2		
Ageusia	1	1	1	1		
Akathisia	1	1	1	1		
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Angioedema	1	2			1	2
Anosmia	1	1	1	1		
Arthralgia	25	25	24	24	1	1
Asthenia	17	17	15	15	2	2
Asthma	1	1	1	1		
Axonal neuropathy	1	1			1	1
Back pain	1	1	1	1		
Blood pressure increased	1	1			1	1
Body temperature increased	2	2	2	2		
Burning sensation	2	2			2	2
Chest discomfort	1	1	1	1		
Chest pain	1	1	1	1		
Chills	11	11	11	11		
Cough	7	7	7	7		
COVID-19	1	1			1	1
COVID-19 pneumonia	2	2			2	2
Cyanosis		1		1		
Decreased appetite	1	1	1	1		
Demyelination	2	2			2	2
Diarrhoea	4	4	4	4		
Discomfort	6	6	6	6		
Dizziness	12	12	12	12		
Drug ineffective	4	4			4	4
Dyspnoea	5	6	2	3	3	3
Encephalitis post immunisation		1				1
Epigastric discomfort	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema	1	1
Eye inflammation	1	1
Eye pain	1	1
Eye swelling	1	2
Face oedema	1	1
Fatigue	4	4
Feeling cold	1	1
Feeling hot	2	2
Gastrointestinal motility disorder	1	1
Headache	37	37
Hyperhidrosis	1	1
Hypersensitivity	2	3
Hypertension	2	2
Hypertensive crisis	1	1
Hypoaesthesia	1	1
Inflammation	1	1
Lip oedema	1	1
Local reaction	1	1
Loss of consciousness		1
Loss of personal independence in daily activities	1	1
Lymphadenopathy	1	1
Mechanical urticaria	1	1
Mobility decreased	2	2
Mononeuropathy	1	1
Muscle contractions involuntary	1	1
Muscle contracture	1	1
Muscle spasms	1	2
Muscle spasticity	1	1
Muscular weakness	1	1
Myalgia	22	22
Myelitis transverse		1
Nasal congestion		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
1	1		
	1	1	1
1	1		
4	4		
1	1		
2	2		
1	1		
34	34	3	3
1	1		
2	3		
1	1	1	1
		1	1
		1	1
1	1		
1	1		
			1
		1	1
1	1		
1	1		
1	1		1
		1	1
1	1		
21	21	1	1
			1
	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nausea	14	14
Neck pain	1	1
Nerve degeneration	1	1
Neuritis	2	2
Nodule	1	1
Oedema	3	3
Oropharyngeal pain	2	2
Pain	10	10
Pain in extremity	2	2
Palpitations	1	1
Paraesthesia	3	4
Paraesthesia oral	2	2
Paralysis		1
Pelvic pain	1	1
Peripheral motor neuropathy	1	1
Peroneal nerve injury	1	1
Pruritus	4	5
Pyrexia	17	17
Radiculopathy	2	2
Rash	10	11
Rash maculo-papular	1	1
Respiratory distress		1
Rhinorrhoea	6	6
Sacroiliitis	1	1
SARS-CoV-2 test positive	1	1
Sciatica	1	1
Sciatic nerve neuropathy	1	1
Seizure	3	4
Sensory loss	1	1
Slow response to stimuli	1	1
Sneezing		1
Somnolence	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
12	12	2	2
1	1		
		1	1
		2	2
1	1		
3	3		
2	2		
9	9	1	1
2	2		
1	1		
1	1	2	3
1	1	1	1
			1
1	1		
		1	1
		1	1
3	4	1	1
17	17		
		2	2
8	8	2	3
1	1		
			1
6	6		
		1	1
		1	1
		1	1
		3	4
		1	1
1	1		
	1		
1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Syncope	2	2			2	2
Tachycardia	8	8	8	8		
Throat irritation	1	2	1	2		
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site inflammation	1	1	1	1		
Vaccination site nodule	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	26	26	25	25	1	1
Vaccination site reaction	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vertigo	1	1	1	1		
Vomiting	2	2	2	2		
	352	371	292	300	60	71

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	2	2		
Chills	1	1	1	1		
Dizziness	2	2	1	1	1	1
Dysgeusia	1	1	1	1		
Headache	3	3	3	3		
Hot flush	1	1	1	1		
Hypertensive crisis	1	1			1	1
Masticatory pain	1	1	1	1		
Myalgia	1	1	1	1		
Oedema	1	1	1	1		
Pain	1	1	1	1		
Paraesthesia	1	1	1	1		
Parotid gland enlargement	1	1	1	1		
Parotitis	1	1	1	1		
Pyrexia	2	2	2	2		
Tachycardia	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	3	3	3	3		
	25	25	22	22	3	3

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3		
		1	1
		1	1
		5	5
		1	1
		1	1
		7	7
1	1		
		1	1
	1		
		1	1
1	1		
2	2		
1	1		
	1		
1	1	1	1
1	1		
2	2		
1	1		
1	1	1	1
2	2		
3	3	3	3
2	2		
3	3	1	1
2	2		
1	1	1	1
2	2	2	2
1	1	1	1
1	2		
1	1		
		1	1

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
23	26	29	29

52

55

23

26

29

29

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Country Where Event Occurred

**NETHERLANDS**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergy to vaccine	1	1	1	1
Chest discomfort	1	1	1	1
Chills	1	1	1	1
Dizziness	1	1	1	1
Head discomfort	1	1	1	1
Hyperventilation	1	1	1	1
Palpitations	1	1	1	1
Rash	1	1	1	1
Urticaria	1	1	1	1
	9	9	9	9

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Angioedema	1	1			1	1
Axillary pain	1	1	1	1		
Cough	1	1	1	1		
Erythema	1	1	1	1		
Headache	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Sneezing	1	1	1	1		
Tongue oedema	1	1			1	1
Urticaria	1	1	1	1		
	15	15	12	12	3	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Anxiety	1	1			1	1
Chills	1	1	1	1		
Diarrhoea	1	1	1	1		
Dizziness	1	1	1	1		
Dysphagia	1	1			1	1
Erythema	1	1			1	1
Headache	2	2	2	2		
Influenza like illness	1	1	1	1		
Malaise	1	1			1	1
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Paraesthesia	1	1			1	1
Peripheral coldness	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Pruritus	1	1			1	1
Rash maculo-papular	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vomiting	1	1	1	1		
	20	20	12	12	8	8

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error	1	1	1	1
Exposure via breast milk	1	1	1	1
Headache	1	1	1	1
Product label confusion	1	1	1	1
Product preparation error	1	1	1	1
	5	5	5	5

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Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Chest discomfort	1	1	1	1
Chills	1	1	1	1
Disorientation	1	1	1	1
Dizziness	1	1	1	1
Fatigue	1	1	1	1
Headache	1	1	1	1
Pain in extremity	1	1	1	1
Poor quality sleep	1	1	1	1
	9	9	9	9

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Country Where Event Occurred

**NORWAY**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dizziness	1	1	1	1
Headache	1	1	1	1
Nausea	1	1	1	1
Pyrexia	1	1	1	1
	4	4	4	4

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blepharospasm	1	1	1	1		
Burning sensation	1	1			1	1
Chest discomfort	1	1			1	1
Chills	1	1	1	1		
Cold sweat	1	1			1	1
Dizziness	1	1			1	1
Dyspnoea	1	1			1	1
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Hypersensitivity	1	1			1	1
Pain in extremity	1	1	1	1		
Pyrexia	1	1	1	1		
	12	12	6	6	6	6

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Fatigue	1	1	1	1
Injection site muscle weakness	1	1	1	1
Vaccination site pain	1	1	1	1
	4	4	4	4

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure decreased	2	2			2	2
Body temperature increased	1	1	1	1		
Cardiovascular disorder	1	1			1	1
Cough	1	1			1	1
Diarrhoea	1	1			1	1
Disease recurrence	1	1			1	1
Dyspnoea	1	1			1	1
Fatigue	1	1	1	1		
Feeling hot	1	1	1	1		
Flushing	1	1	1	1		
General physical health deterioration	2	2			2	2
Heart rate irregular	1	1	1	1		
Malaise	2	2	1	1	1	1
Malignant hypertension	1	1			1	1
Nausea	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pneumonia	1	1			1	1
Pyrexia	1	1			1	1
Rales	1	1			1	1
Respiratory rate increased	1	1			1	1
Retching	1	1	1	1		
Somnolence	1	1			1	1
Vaccination site pain	1	1			1	1
	26	26	7	7	19	19

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	1			1	1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Anxiety	1	1	1	1		
Apathy	1	1			1	1
Blood pressure diastolic decreased	1	1	1	1		
Body temperature decreased	1	1	1	1		
Cardiac failure	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	2	2			2	2
Cold sweat	2	2			2	2
Concomitant disease aggravated	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	3	3			3	3
Coordination abnormal	1	1			1	1
Death	8	8			8	8
Decreased appetite	2	2			2	2
Delirium	1	1			1	1
Depressed level of consciousness	2	2			2	2
Diarrhoea	1	1			1	1
Dysphagia	1	1			1	1
Dyspnoea	2	2			2	2
Fatigue	3	3			3	3
Feeling hot	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
General physical health deterioration	6	6			6	6
Hallucination	1	1			1	1
Heart rate increased	2	2			2	2
Hyperventilation	1	1	1	1		
Hypophagia	1	1			1	1
Hypotension	2	2			2	2
Infection	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	1	1			1	1
Intracardiac thrombus	1	1			1	1
Local reaction	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	1	1			1	1
Nausea	1	1			1	1
Oxygen saturation decreased	2	2			2	2
Pallor	2	2			2	2
Pneumonia	2	2			2	2
Pupil fixed	2	2			2	2
Pyrexia	3	3			3	3
Respiratory arrest	1	1			1	1
Respiratory rate increased	2	2			2	2
Restlessness	1	1	1	1		
Somnolence	1	1			1	1
Sudden death	3	3			3	3
Syncope	2	2			2	2
Tremor	1	1			1	1
Urinary tract infection	1	1	1	1		
Vaccination site erythema	1	1			1	1
Vaccination site pain	1	1	1	1		
Vaccination site swelling	2	2	1	1	1	1
Vomiting	5	5	1	1	4	4
	93	93	9	9	84	84

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect dose administered	1	1	1	1
Poor quality product administered	6	6	6	6
Product administered at inappropriate site	1	1	1	1
Product preparation error	2	2	2	2
Product temperature excursion issue	6	6	6	6
Wrong technique in product usage process	1	1	1	1
	17	17	17	17

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Country Where Event Occurred

**OMAN**

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Fatigue		1		1
Gastritis		1		1
Headache		1		1
Pain		1		1
Pyrexia		1		1
		6		6

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Country Where Event Occurred

**POLAND**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety	1	1	1	1
Diarrhoea	1	1	1	1
Exposure via breast milk	2	2	2	2
Pyrexia	1	1	1	1
	5	5	5	5

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 \* AE=Adverse Event  
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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1			1	1
Ageusia	1	1	1	1		
Arthralgia	2	2	1	1	1	1
Asthenia	1	1	1	1		
Chills	1	1	1	1		
Dysgeusia	1	1	1	1		
Epistaxis	1	1	1	1		
Fatigue	1	1	1	1		
Headache	2	2	2	2		
Myalgia	2	2	1	1	1	1
Nausea	1	1	1	1		
Neck pain	2	2	1	1	1	1
Pain in extremity	3	3	2	2	1	1
Pancreatitis	1	1			1	1
Pyrexia	3	3	2	2	1	1
Spinal pain	1	1			1	1
Taste disorder	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site pain	5	5	4	4	1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
	34	34	25	25	9	9

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Arrhythmia	1	1			1	1
Arthralgia	5	6	5	6		
Arthritis		1		1		
Asthenia	6	7	6	7		
Asymptomatic COVID-19	1	1			1	1
Blood pressure increased	1	1	1	1		
Chest discomfort	1	1	1	1		
Chills	5	5	4	4	1	1
Cough	2	2	2	2		
COVID-19	1	1			1	1
Disease recurrence	1	1			1	1
Drug ineffective	3	3			3	3
Dyspnoea	1	1	1	1		
Dysstasia	1	1	1	1		
Ear pain	1	1	1	1		
Feeling abnormal	1	1	1	1		
Haematoma	1	1	1	1		
Headache	6	7	6	7		
Heart rate increased	1	1	1	1		
Hypersensitivity	2	2	2	2		
Inappropriate schedule of product administration	1	1	1	1		
Influenza like illness	1	1	1	1		
Initial insomnia	1	1	1	1		
Insomnia	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Lymphadenopathy	3	3	3	3		
Maternal exposure during pregnancy	1	1	1	1		
Myalgia	5	5	5	5		
Nausea	3	3	3	3		
Oropharyngeal pain	2	2	2	2		
Pain	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Painful respiration	1	1	1	1		
Pain in extremity	3	4	3	4		
Paraparesis	1	1			1	1
Peripheral swelling	1	1	1	1		
Presyncope	1	1	1	1		
Pulpitis dental		1		1		
Pyrexia	7	8	6	7	1	1
Rash macular	1	1	1	1		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Taste disorder	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Throat irritation	1	1	1	1		
Toothache		1		1		
Tremor	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site extravasation	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	12	13	12	13		
Vaccination site pruritus	2	2	2	2		
Vaccination site reaction	2	2	2	2		
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		
Visual field defect	1	1	1	1		
Vomiting	1	1	1	1		
	109	118	98	107	11	11

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	4	4	4	4		
Blood pressure increased	1	1			1	1
Body temperature increased	2	2	2	2		
Bone pain	1	1	1	1		
Chest discomfort	1	1	1	1		
Conjunctival hyperaemia	1	1	1	1		
Cough	1	1	1	1		
COVID-19	3	3			3	3
Decreased activity	1	1	1	1		
Dizziness	2	2	2	2		
Drug ineffective	3	3			3	3
Dry mouth	1	1	1	1		
Dysuria	1	1	1	1		
Fatigue	1	1	1	1		
Feeling abnormal	1	1	1	1		
Feeling hot	1	1	1	1		
Gait disturbance	1	1	1	1		
Headache	4	4	4	4		
Heart rate increased	1	1			1	1
Herpes virus infection	1	1	1	1		
Hot flush	1	1	1	1		
Influenza like illness	1	1	1	1		
Malaise	1	1	1	1		
Migraine	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	1	1	1	1		
Neck pain	1	1	1	1		
Oropharyngeal pain	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	2	2	2	2		
Pallor	1	1	1	1		
Paraesthesia	1	1	1	1		
Paresis	1	1	1	1		
Pneumonia	1	1			1	1
Pyrexia	3	3	3	3		
Spinal pain	1	1	1	1		
Swelling	1	1	1	1		
Tremor	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vision blurred	1	1	1	1		
	62	62	53	53	9	9

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erythema	1	1	1	1
Helplessness	1	1	1	1
Hyperaesthesia	1	1	1	1
Pain	1	1	1	1
Pain in extremity	1	1	1	1
Pyrexia	1	1	1	1
Swelling	1	1	1	1
	7	7	7	7

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Ageusia	1	1	1	1		
Anosmia	3	3	3	3		
Arthralgia	11	11	11	11		
Asthenia	15	15	14	14	1	1
Axillary pain	3	3	3	3		
Back pain	2	2	2	2		
Blood pressure decreased	1	1	1	1		
Blood urine present	1	1	1	1		
Bone pain	2	2	2	2		
Breast pain	1	1	1	1		
Burning sensation	1	1	1	1		
Chills	8	8	8	8		
Circumstance or information capable of leading to medication error	1	1	1	1		
COVID-19	7	7			7	7
Crying	1	1	1	1		
Cystitis	1	1	1	1		
Decreased appetite	2	2	2	2		
Diarrhoea	4	4	4	4		
Dizziness	3	3	3	3		
Drug ineffective	7	7			7	7
Dysgeusia	1	1	1	1		
Dyspnoea	1	1	1	1		
Epistaxis	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Exposure via breast milk	5	5	5	5		
Eye pain	1	1	1	1		
Fatigue	4	4	4	4		
Feeling abnormal	2	2	2	2		
Feeling cold	2	2	1	1	1	1
Headache	13	13	12	12	1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes virus infection	2	2
Herpes zoster	1	1
Hot flush	2	2
Hyperaesthesia teeth	1	1
Hyperhidrosis	1	1
Hypoaesthesia	3	3
Hypoaesthesia oral	2	2
Incorrect dose administered	1	1
Incorrect route of product administration	2	2
Inflammation	2	2
Influenza like illness	2	2
Insomnia	1	1
Iritis	1	1
Lymphadenopathy	3	3
Lymph node pain	1	1
Malaise	7	7
Myalgia	11	11
Nausea	5	5
Needle issue	1	1
Oedema	1	1
Off label use	8	8
Oxygen saturation decreased	1	1
Pain	1	1
Pain in extremity	8	8
Pain of skin	1	1
Pallor	1	1
Paralysis	1	1
Paresis	1	1
Poor quality sleep	1	1
Product label confusion	2	2
Product use issue	8	8
Pruritus	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
1	1		
1	1	1	1
1	1		
1	1		
2	2	1	1
1	1	1	1
1	1		
2	2		
2	2		
2	2		
1	1		
1	1		
3	3		
1	1		
7	7		
11	11		
5	5		
1	1		
1	1		
7	7	1	1
		1	1
1	1		
8	8		
1	1		
		1	1
		1	1
		1	1
1	1		
2	2		
7	7	1	1
1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	18	18	17	17	1	1
Rash	2	2	2	2		
Retching	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Sinusitis	1	1	1	1		
Somnolence	3	3	3	3		
Suppressed lactation	2	2	1	1	1	1
Swelling	1	1	1	1		
Tachycardia	2	2			2	2
Tonsillar hypertrophy	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site infection	1	1	1	1		
Vaccination site macule	1	1	1	1		
Vaccination site movement impairment	2	2	2	2		
Vaccination site pain	18	18	18	18		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	4	4	4	4		
Vaccination site scab	1	1	1	1		
Vaccination site swelling	2	2	2	2		
Vaccination site vesicles	1	1	1	1		
Vaccination site warmth	1	1	1	1		
Vomiting	3	3	3	3		
	260	260	230	230	30	30

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Country Where Event Occurred

**PORTUGAL**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Eructation	1	1	1	1
Exposure via breast milk	1	2	1	2
	2	3	2	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature increased	1	1	1	1		
Chills	1	1			1	1
COVID-19	1	1			1	1
Decreased appetite	1	1	1	1		
Dermatitis allergic	1	1			1	1
Drug ineffective	2	2			2	2
Erythema	1	1			1	1
Face oedema	1	1			1	1
Fatigue	1	1			1	1
Headache	1	1			1	1
Myalgia	1	1	1	1		
Nausea	2	2	1	1	1	1
Overdose	2	2	2	2		
Presyncope	1	1	1	1		
Rash	1	1	1	1		
Rash pruritic	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Somnolence	1	1	1	1		
Tremor	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	5	5	3	3	2	2
Vaccination site swelling	1	1	1	1		
	31	31	17	17	14	14

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	1	1			1	1
Allergy to vaccine	2	2			2	2
Anaphylactic reaction	1	1			1	1
Arthritis reactive	1	1			1	1
Blood pressure increased	1	1			1	1
Chest pain	2	2			2	2
Chills	3	3	2	2	1	1
Cough	2	2			2	2
COVID-19	4	4			4	4
Diarrhoea	1	1	1	1		
Drug ineffective	4	4			4	4
Dry eye	1	1	1	1		
Dysphagia	1	1			1	1
Eructation	1	1	1	1		
Erythema	3	3	1	1	2	2
Exophthalmos	1	1	1	1		
Eyelid oedema	1	1			1	1
Eye movement disorder	1	1			1	1
Eye pain	1	1	1	1		
Eye paraesthesia	1	1			1	1
Facial paralysis	1	1	1	1		
Fatigue	3	3	3	3		
Feeling abnormal	1	1	1	1		
Feeling hot	1	1			1	1
Flushing	2	2			2	2
Functional gastrointestinal disorder	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Headache	8	9	5	6	3	3
Hypersensitivity	1	1			1	1
Hypoaesthesia oral	2	2			2	2
Hypothyroidism	1	1			1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect route of product administration	2	2
Intercostal neuralgia	1	1
Lip oedema	1	1
Lip pruritus	1	1
Lymphadenopathy	4	4
Malaise	2	2
Migraine	2	2
Myalgia	11	11
Nausea	3	3
Nystagmus	1	1
Ocular discomfort	1	1
Odynophagia	2	3
Off label use	1	1
Oropharyngeal oedema	1	1
Oropharyngeal pain	1	1
Overdose	2	2
Pain	1	1
Pain in extremity	1	1
Pain in jaw	1	1
Pallor	2	2
Paraesthesia	3	3
Paraesthesia oral	2	2
Pharyngeal paraesthesia	1	1
Presyncope	2	2
Productive cough	1	1
Product use issue	1	1
Pruritus	3	3
Pyrexia	5	5
Rash	3	3
Rash maculo-papular	1	1
Rhinorrhoea	1	1
Scar	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
1	1		
		1	1
		1	1
2	2	2	2
1	1	1	1
		2	2
6	6	5	5
1	1	2	2
		1	1
1	1		
		1	1
		2	2
1	1		
		1	1
		1	1
2	2		
1	1		
		1	1
		1	1
2	2		
1	1		
		2	2
		1	1
1	1	1	1
		1	1
1	1		
2	2	1	1
3	3	2	2
1	1	2	2
		1	1
1	1		
2	2	1	1
3	3	2	2
1	1		
		1	1
1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory loss	1	1			1	1
Somnolence	3	3	1	1	2	2
Stomatitis	1	1	1	1		
Tachycardia	3	3	1	1	2	2
Tachypnoea	1	1			1	1
Taste disorder	1	1	1	1		
Tenosynovitis	1	1	1	1		
Throat irritation	2	2	2	2		
Throat tightness	1	1			1	1
Thyroid function test abnormal	1	1	1	1		
Tongue eruption	1	1			1	1
Tongue oedema	2	2			2	2
Tongue pruritus	1	1			1	1
Urticaria	1	1			1	1
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	14	14	10	10	4	4
Vertigo positional	1	1			1	1
Vomiting	1	1			1	1
Weight decreased	1	1	1	1		
	161	163	71	73	90	90

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Balance disorder		1				1
Chest discomfort	1	1			1	1
Chills	1	1			1	1
Circumoral oedema	1	1			1	1
COVID-19	1	1			1	1
Dizziness		1				1
Drug ineffective	1	1			1	1
Dysgeusia	1	1			1	1
Erythema		1				1
Eye irritation	1	1	1	1		
Fatigue	2	2	1	1	1	1
Headache	2	2	2	2		
Hypersensitivity		1				1
Hypoaesthesia oral	2	2			2	2
Laryngeal oedema	2	2			2	2
Lip oedema	2	2			2	2
Lymphadenopathy	1	1			1	1
Malaise		1				1
Muscular weakness	1	1			1	1
Myalgia	2	2	1	1	1	1
Nasal obstruction	1	1			1	1
Nausea	1	2			1	2
Oropharyngeal discomfort	1	1			1	1
Palmar-plantar erythrodysesthesia syndrome	1	1			1	1
Palpitations	1	1	1	1		
Paraesthesia	1	1			1	1
Peripheral coldness	1	1			1	1
Pharyngeal hypoaesthesia	1	1			1	1
Pruritus	2	3			2	3

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	2	2			2	2
Rash	1	2			1	2
Rhinorrhoea	1	1			1	1
Sinus tachycardia		1				1
Tongue dry	1	1			1	1
Vaccination site pain	1	1	1	1		
Vaccination site pruritus		1				1
	40	50	10	10	30	40

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardio-respiratory arrest	1	1	1	1
	1	1	1	1

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death	2	2	2	2
	2	2	2	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Amnesia	1	1	1	1		
Asthenia	1	1	1	1		
Chest pain	1	1	1	1		
Chills	1	1	1	1		
COVID-19	9	9			9	9
Decreased appetite	1	1	1	1		
Diarrhoea	1	1	1	1		
Dizziness	2	2	2	2		
Drug ineffective	11	11			11	11
Dysarthria	1	1	1	1		
Dysgeusia	1	1	1	1		
Embolism	1	1			1	1
Erythema	3	3	2	2	1	1
Exposure via breast milk	2	2	2	2		
Face oedema	3	3	1	1	2	2
Fatigue	1	1	1	1		
Headache	8	8	7	7	1	1
Hyperglycaemia	1	1			1	1
Hyperhidrosis	1	1			1	1
Hypersensitivity	5	5	4	4	1	1
Hypoaesthesia	2	2	2	2		
Hypoaesthesia oral	2	2	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1		
Laryngeal oedema	2	2			2	2
Lip oedema	1	1			1	1
Localised oedema	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	4	4	4	4		
Maternal exposure during pregnancy	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Migraine	2	2
Myalgia	6	6
Nausea	5	5
Odynophagia	1	1
Off label use	2	2
Oral disorder	1	1
Oropharyngeal oedema	1	1
Pain in extremity	1	1
Pallor	1	1
Paraesthesia	2	2
Paraesthesia oral	2	2
Presyncope	1	1
Productive cough	1	1
Product use issue	1	1
Pruritus	1	1
Pyrexia	5	5
Rash	6	6
Rash maculo-papular	1	1
Rash pruritic	1	1
Respiratory tract congestion	1	1
Rhinorrhoea	1	1
SARS-CoV-2 test positive	3	3
Somnolence	2	2
Stomatitis	1	1
Tachycardia	2	2
Taste disorder	1	1
Throat irritation	1	1
Tongue disorder	1	1
Tongue oedema	1	1
Tremor	1	1
Upper-airway cough syndrome	1	1
Urticaria	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	1
6	6		
5	5		
		1	1
2	2		
		1	1
1	1		
1	1		
1	1	1	1
1	1	1	1
1	1		
		1	1
1	1		
		1	1
5	5		
5	5	1	1
1	1		
1	1		
		1	1
		1	1
		3	3
1	1	1	1
1	1		
2	2		
1	1		
1	1		
		1	1
1	1		
		1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria cholinergic	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	18	18	17	17	1	1
Vaccination site swelling	1	1	1	1		
Vomiting	2	2	1	1	1	1
	156	156	104	104	52	52

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Country Where Event Occurred

**PUERTO RICO**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Axillary pain	1	1	1	1
Bone disorder	1	1	1	1
Bone pain	1	1	1	1
Chills	1	1	1	1
Fatigue	1	2	1	2
Headache	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1
Inflammation		1		1
Nodule		1		1
Off label use	1	1	1	1
Pain in extremity		1		1
Palpitations		1		1
Vaccination site erythema	1	1	1	1
Vaccination site inflammation	1	1	1	1
Vaccination site pain	1	2	1	2
Vaccination site swelling	1	1	1	1
	12	18	12	18

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia		1		1		
Asthenia		1		1		
Burning sensation	1	1	1	1		
Chills	2	2	2	2		
Decreased appetite		1		1		
Diarrhoea	1	1	1	1		
Dyskinesia	1	1			1	1
Dysphonia		1		1		
Erythema	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	3	3	3	3		
Gait disturbance		1		1		
Gingival bleeding	1	1	1	1		
Haematoma	1	1	1	1		
Headache	2	6	2	6		
Heart rate decreased	1	1			1	1
Hypertension		1		1		
Hypoaesthesia		2		2		
Limb discomfort		1		1		
Lymphadenopathy	1	1	1	1		
Malaise		1		1		
Migraine	1	1			1	1
Movement disorder	1	1	1	1		
Musculoskeletal stiffness		1		1		
Myalgia	1	1	1	1		
Nausea		2		2		
Neck pain	1	1	1	1		
Neuralgia		1		1		
Night sweats	1	1			1	1
Pain		2		2		
Pain in extremity	2	2	2	2		
Paraesthesia		1		1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	1	1	1	1		
Pyrexia	3	5	3	5		
Sinus arrhythmia	1	1			1	1
Speech disorder		1		1		
Swelling face		1		1		
Tachycardia		1		1		
Taste disorder		1		1		
Vaccination site discomfort		1		1		
Vaccination site induration		1		1		
Vaccination site pain		2		2		
Vaccination site swelling		1		1		
	28	60	22	54	6	6

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain		1		1
Arthralgia		1		1
Depression	1	1	1	1
Diarrhoea		1		1
Head discomfort	1	1	1	1
Hypoaesthesia		1		1
Joint range of motion decreased		1		1
Muscle spasms	1	1	1	1
Nausea		1		1
Pain in extremity		1		1
Paraesthesia	1	1	1	1
Respiratory rate decreased	1	1	1	1
	5	12	5	12

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort	1	1	1	1
Arthralgia	1	1	1	1
Burning sensation	1	1	1	1
Headache	2	2	2	2
Hypoaesthesia	1	1	1	1
Rash	1	1	1	1
	7	7	7	7

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Fatigue	1	1	1	1
Maternal exposure during pregnancy	1	1	1	1
Pain	1	1	1	1
Pain in extremity		1		1
Pyrexia	2	2	2	2
	6	7	6	7

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Country Where Event Occurred

**QATAR**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness		1				1
Erythema		1				1
Myalgia		1		1		
Nausea		1				1
		4		1		3

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Overdose	1	1	1	1
Product preparation error	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**ROMANIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angina pectoris	1	1			1	1
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Breast pain	1	1	1	1		
Chills	3	3	3	3		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue	3	3	3	3		
Headache	2	2	2	2		
Lymphadenopathy	1	1	1	1		
Migraine	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	3	3	3	3		
Off label use	1	1	1	1		
Pain in extremity	2	2	2	2		
Panic attack		1		1		
Product use issue	1	1	1	1		
Pyrexia	3	3	3	3		
Rash	1	1	1	1		
Scar pain	1	1	1	1		
Suppressed lactation	1	1	1	1		
Vaccination site pain	8	8	8	8		
Vaccination site swelling	1	1	1	1		
	40	41	37	38	3	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	1	1	1	1		
Anxiety	2	2	1	1	1	1
Arthralgia	7	7	5	5	2	2
Asthenia	4	4	3	3	1	1
Axillary pain	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure increased		1		1		
Chest discomfort	1	1	1	1		
Chest pain	1	1			1	1
Chills	9	10	8	9	1	1
Cough	1	1			1	1
COVID-19	1	1			1	1
Decreased appetite	1	1	1	1		
Drug administered in wrong device	1	1	1	1		
Drug ineffective	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia	1	1	1	1		
Ear pain	1	1	1	1		
Facial pain	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	8	8	7	7	1	1
General physical health deterioration		1		1		
Headache	14	15	12	13	2	2
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1	1	1		
Hypertension	4	4			4	4
Hypertensive crisis	1	1			1	1
Hyperthermia	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Injected limb mobility decreased	1	1	1	1		
Lip oedema	1	1	1	1		
Lymphadenopathy	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Malaise	3	3
Maternal exposure during pregnancy	1	1
Migraine	1	1
Muscle contractions involuntary	1	1
Myalgia	14	15
Nausea	6	6
Nystagmus	1	1
Pain	3	3
Pain in extremity	3	4
Palpitations	2	2
Paraesthesia	4	4
Paraesthesia ear	1	1
Peripheral coldness	1	1
Presyncope	2	2
Pruritus	2	2
Pyrexia	9	9
Rash	3	3
Rash erythematous	2	2
Somnolence	1	1
Spinal pain	1	1
Tachycardia	2	2
Vaccination site erythema	2	2
Vaccination site induration	2	2
Vaccination site movement impairment	1	1
Vaccination site pain	13	14
Vaccination site pruritus	1	1
Vaccination site reaction	1	1
Ventricular extrasystoles	1	1
Vertigo	1	1
Vestibular disorder	1	1
Vomiting	3	3
Wrong technique in product usage process	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3		
1	1		
		1	1
1	1		
12	13	2	2
5	5	1	1
1	1		
3	3		
3	4		
		2	2
3	3	1	1
1	1		
1	1		
2	2		
2	2		
9	9		
3	3		
		2	2
1	1		
1	1		
		2	2
2	2		
2	2		
1	1		
13	14		
1	1		
1	1		
1	1		
1	1		
2	2	1	1
2	2		

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Age Range

31 - 50 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
131	138	31	31

162

169

131

138

31

31

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Anaphylactoid reaction	1	1			1	1
Anxiety	1	1			1	1
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Balance disorder	1	1			1	1
Chills	2	2	1	1	1	1
Dry mouth	1	1			1	1
Dysgeusia	1	1			1	1
Dyspnoea	1	1			1	1
Erythema	2	2	1	1	1	1
Facial paralysis	1	1			1	1
Fatigue	2	2	1	1	1	1
Feeling cold	1	1			1	1
Feeling hot	1	1			1	1
Headache	2	2	1	1	1	1
Hypersensitivity	1	1	1	1		
Hypertension	1	1			1	1
Hypoaesthesia	1	1			1	1
Hypocalcaemia	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Insomnia	1	1	1	1		
Joint ankylosis	1	1			1	1
Laryngeal oedema	1	1			1	1
Lip oedema	1	1			1	1
Lymphadenopathy	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	1	1			1	1
Pain in extremity	1	1			1	1
Pruritus	1	1			1	1
Pyrexia	2	2	2	2		
Rash	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Seizure	1	1			1	1
Somnolence	1	1	1	1		
Tachycardia	1	1			1	1
Thirst	1	1			1	1
Tongue oedema	1	1			1	1
Tremor	1	1			1	1
Urticaria	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vertigo	1	1			1	1
Wrong technique in product usage process	1	1	1	1		
	49	49	20	20	29	29

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	1	1	1	1
Anaphylactic shock	1	1			1	1
Angle closure glaucoma	1	1			1	1
Anosmia	2	2	1	1	1	1
Anxiety	3	3	3	3		
Arthralgia	5	5	5	5		
Asthenia	4	4	4	4		
Back pain	1	1	1	1		
Blood pressure abnormal	1	1	1	1		
Body temperature abnormal	1	1	1	1		
Body temperature increased	1	1	1	1		
Chest discomfort	1	1	1	1		
Chills	6	6	6	6		
Circumstance or information capable of leading to medication error	3	3	3	3		
Cough	2	2	1	1	1	1
COVID-19	9	9			9	9
Crying	1	1	1	1		
Diarrhoea	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	7	7	7	7		
Drug ineffective	17	17			17	17
Dyspnoea	1	1			1	1
Emotional distress	1	1	1	1		
Epiglottic oedema	1	1			1	1
Erythema	7	8	7	8		
Erythema nodosum	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Eyelid oedema	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	5	5	5	5		
Fear	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling abnormal	1	1
Feeling cold	1	1
Feeling hot	1	1
Flushing	1	1
Headache	13	13
Heart rate increased	1	1
Horner's syndrome	1	1
Hyperhidrosis	3	3
Incorrect route of product administration	1	1
Inflammation	1	1
Injected limb mobility decreased	2	2
Intercepted medication error	1	1
Limb injury	1	1
Lip oedema	1	1
Lip swelling	1	1
Lymphadenopathy	6	6
Malaise	2	2
Medication error	3	3
Muscle swelling	1	1
Muscular weakness	2	2
Myalgia	7	7
Nasal discomfort	1	1
Nasal oedema	1	1
Nausea	3	3
Odynophagia	1	1
Oedema	1	1
Oedema peripheral	1	1
Off label use	2	2
Oropharyngeal discomfort	1	1
Pain	4	4
Pain in extremity	15	20
Panic attack	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
1	1		
1	1		
13	13		
1	1		
		1	1
2	2	1	1
1	1		
1	1		
2	2		
1	1		
		1	1
1	1		
		1	1
6	6		
2	2		
3	3		
1	1		
2	2		
7	7		
1	1		
		1	1
3	3		
1	1		
1	1		
		1	1
2	2		
		1	1
4	4		
15	20		
1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Paraesthesia	4	4
Paraesthesia oral	1	1
Presyncope	1	1
Product preparation error	7	11
Product preparation issue	5	6
Product quality issue		1
Product use issue	1	1
Pruritus	2	2
Pyrexia	18	18
Rash	2	2
Rash pruritic	1	1
SARS-CoV-2 test negative	1	1
SARS-CoV-2 test positive	7	7
Skin discolouration	1	1
Somnolence	2	2
Suspected COVID-19	1	1
Syncope	1	1
Systolic hypertension	1	1
Tachycardia	2	2
Transaminases increased	1	1
Tremor	1	1
Underdose	1	1
Urticaria	1	2
Urticaria papular	1	1
Vaccination site discomfort	3	3
Vaccination site erythema	13	13
Vaccination site inflammation	1	1
Vaccination site lymphadenopathy	2	2
Vaccination site movement impairment	2	2
Vaccination site nodule	1	1
Vaccination site pain	26	27
Vaccination site warmth	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	4		
1	1		
1	1		
7	11		
5	6		
	1		
1	1		
2	2		
18	18		
2	2		
1	1		
1	1		
		7	7
1	1		
2	2		
		1	1
		1	1
		1	1
2	2		
1	1		
1	1		
1	1		
1	2		
1	1		
3	3		
13	13		
1	1		
2	2		
2	2		
1	1		
26	27		
1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	1	1	1	1		
Wrong technique in product usage process	9	10	9	10		
	294	309	243	258	51	51

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Country Where Event Occurred

**SAUDI ARABIA**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Arthralgia	1	1	1	1		
Chills	1	1	1	1		
Dizziness	1	1	1	1		
Fatigue	2	2	2	2		
Headache	1	1	1	1		
Hyperhidrosis	2	2	2	2		
Hypotension	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Mouth ulceration	1	1	1	1		
Myalgia	2	2	2	2		
Pain of skin	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pollakiuria	1	1	1	1		
Pyrexia	2	2	2	2		
Syncope	1	1			1	1
Vaccination site pain	1	1	1	1		
Vaginal infection	1	1	1	1		
	23	23	21	21	2	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Headache	1	1	1	1
Herpes zoster	1	1	1	1
Nasopharyngitis	1	1	1	1
Pain	1	1	1	1
Rhinorrhoea	1	1	1	1
Vaccination site pain	1	1	1	1
	7	7	7	7

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Movement disorder	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
	2	2	2	2

Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Pain in extremity	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**SERBIA**

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anaphylactoid reaction	1	1			1	1
Anosmia	1	1	1	1		
Arthralgia	2	2	2	2		
Asphyxia	1	1			1	1
Asthenia	3	3	3	3		
Axillary pain	1	1	1	1		
Body temperature increased	3	3	2	2	1	1
Bone pain	1	1	1	1		
Chills	1	1	1	1		
Confusional state	1	1	1	1		
Cough	1	1			1	1
Erythema	1	1	1	1		
Fatigue	3	3	3	3		
Headache	1	1	1	1		
Hyperhidrosis	2	2	2	2		
Hypertension	1	1			1	1
Inflammatory marker increased	1	1	1	1		
Influenza like illness	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Malaise	2	2	2	2		
Muscular weakness	2	2	2	2		
Myalgia	4	4	4	4		
Nausea	3	3	3	3		
Pain in extremity	1	1	1	1		
Peripheral swelling	1	1			1	1
Pyrexia	9	9	9	9		
Rash	1	1	1	1		
Skin reaction	1	1			1	1
Tachycardia	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site oedema	1	1	1	1		
Vaccination site pain	5	5	5	5		
Vomiting	1	1	1	1		
	62	62	54	54	8	8

Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	1	1			1	1
Bone pain	1	1	1	1		
Chest discomfort	1	1	1	1		
Chills	2	2	1	1	1	1
Dizziness	1	1	1	1		
Dry mouth	1	1	1	1		
Erythema	1	1	1	1		
Fatigue	1	1	1	1		
Headache	2	2	2	2		
Hypertension	1	1	1	1		
Lymphadenopathy	1	1			1	1
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Pain in jaw	1	1	1	1		
Palpitations	1	1	1	1		
Phlebitis	1	1			1	1
Pyrexia	3	3	2	2	1	1
Vaccination site pain	1	1	1	1		
	22	22	17	17	5	5

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Fall	1	1	1	1		
Fear of death	1	1	1	1		
Huntington's disease	1	1			1	1
Pyrexia	1	1	1	1		
	5	5	4	4	1	1

Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	1	1	1		
Vaccination site haematoma	1	1			1	1
	2	2	1	1	1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Blood pressure increased	1	1	1	1		
Chest pain	1	1	1	1		
Diarrhoea	1	1	1	1		
Erythema	1	1	1	1		
Headache	1	1	1	1		
Hypersensitivity	2	2	1	1	1	1
Intraocular pressure increased	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	1	1	1	1		
Monocyte count increased	1	1	1	1		
Nausea	2	2	2	2		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	2	2	2	2		
Paraesthesia	1	1	1	1		
Pyrexia	4	4	4	4		
Rash	1	1			1	1
Rash macular	1	1			1	1
Sleep disorder	1	1	1	1		
Swelling of eyelid	1	1	1	1		
Tinnitus	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site pain	5	5	5	5		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		
	36	36	31	31	5	5

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Country Where Event Occurred

**SINGAPORE**

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	5	5			5	5
Chills	1	1	1	1		
Eye swelling	1	1	1	1		
Pyrexia	1	1	1	1		
Urticaria	1	1	1	1		
	9	9	4	4	5	5

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Country Where Event Occurred

**SLOVAKIA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Body temperature	1	1			1	1
Body temperature increased	1	1	1	1		
Chills	2	2	1	1	1	1
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Erythema	1	1			1	1
Headache	2	2	1	1	1	1
Hyperhidrosis	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Paraesthesia	1	1			1	1
Pruritus	1	1			1	1
Rhinitis	1	1	1	1		
Throat tightness	1	1	1	1		
Vaccination site pain	3	3	2	2	1	1
Vaccination site swelling	1	1			1	1
	21	21	11	11	10	10

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Burning sensation	1	1	1	1		
Chills	2	2	2	2		
COVID-19	1	1			1	1
Diplopia	1	1	1	1		
Dizziness	1	1	1	1		
Drug ineffective	2	2			2	2
Dyspnoea	1	1	1	1		
Headache	1	1	1	1		
Hypertension	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Pain in extremity	1	1	1	1		
Palpitations	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Tachycardia	1	1	1	1		
Throat irritation	1	1	1	1		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site pain	2	2	2	2		
	22	22	18	18	4	4

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1	1	1		
Chills	1	1	1	1		
Hypertension	1	1	1	1		
Pyrexia	1	1	1	1		
Syncope	1	1			1	1
	5	5	4	4	1	1

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Drug ineffective	1	1	1	1
SARS-CoV-2 test positive	1	1	1	1
	2	2	2	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Chills	2	2	2	2		
Cough	2	2	2	2		
COVID-19	1	1			1	1
Drug ineffective	2	2			2	2
Fatigue	1	1	1	1		
Headache	2	2	2	2		
Maternal exposure during pregnancy	1	1	1	1		
Myalgia	1	1	1	1		
Pain in extremity	3	3	3	3		
Pyrexia	3	3	3	3		
Rash	1	1	1	1		
Rash pruritic	1	1	1	1		
SARS-CoV-2 ant body test positive	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
Vaccination site pain	1	1	1	1		
Vaccination site urticaria	1	1	1	1		
Vomiting	1	1	1	1		
	26	26	21	21	5	5

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Country Where Event Occurred

**SLOVENIA**

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site pain	1	1	1	1		
Sudden death	1	1			1	1
	2	2	1	1	1	1

Age Range

**Greater than or equal to 80 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Asthenia	2	2	2	2		
Disease recurrence	1	1			1	1
Fatigue	1	1	1	1		
Hypertension	1	1			1	1
Nausea	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vertigo	1	1			1	1
Vomiting	1	1			1	1
White blood cell count increased	1	1	1	1		
	12	12	6	6	6	6

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Wrong technique in product usage process	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**SPAIN**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposure via breast milk	1	1	1	1
	1	1	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anaphylactic shock	2	2			2	2
Anxiety	1	1	1	1		
Asthenia	1	1	1	1		
Chills	1	1	1	1		
Circumoral swelling	1	1	1	1		
Diarrhoea	1	1	1	1		
Dizziness	1	1	1	1		
Dry throat	1	1	1	1		
Erythema	2	2	2	2		
Fatigue	1	1	1	1		
Headache	2	2	2	2		
Laryngeal oedema	1	1			1	1
Lip pruritus	1	1	1	1		
Malaise	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	3	3	3	3		
Pain in extremity	2	2	2	2		
Palatal oedema	1	1			1	1
Palpitations	1	1	1	1		
Pruritus	2	2	1	1	1	1
Pyrexia	6	6	6	6		
Rash	1	1	1	1		
Temperature regulation disorder	1	1	1	1		
Throat irritation	1	1	1	1		
Urticaria	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	4	4	4	4		
Vomiting	1	1	1	1		
	45	45	39	39	6	6

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	1	1	1	1
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction		1				1
Aphthous ulcer	1	1	1	1		
Arthralgia	2	2	2	2		
Asthenia	1	1	1	1		
Body temperature increased	1	1	1	1		
Chest pain	1	1	1	1		
Chills	4	4	4	4		
Cough	2	2	2	2		
COVID-19	1	1			1	1
Death	1	1			1	1
Depressed mood	1	1	1	1		
Diarrhoea	3	3	2	2	1	1
Discomfort	2	2	2	2		
Dizziness	8	8	8	8		
Drug ineffective	1	1			1	1
Dry mouth	1	1	1	1		
Dysgeusia	1	1			1	1
Dyspnoea	1	1			1	1
Erythema	1	1	1	1		
Face oedema	1	1			1	1
Facial paralysis	1	1			1	1
Fatigue	2	2	1	1	1	1
Feeling cold	1	1			1	1
Feeling drunk	1	1	1	1		
Flatulence	1	1			1	1
Formication	2	2	2	2		
Glossitis	1	1			1	1
Headache	19	19	15	15	4	4
Hyperglycaemia	1	1	1	1		
Hyperhidrosis	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #	Spontaneous			
	Spontaneous AE	Spontaneous AE	Nonserious		Serious	
			I	C	I	C
Immunisation reaction	1	1	1	1		
Insulin resistance	1	1	1	1		
Joint contracture	1	1	1	1		
Lip oedema	1	1	1	1		
Malaise	6	6	5	5	1	1
Migraine	2	2	1	1	1	1
Mobility decreased	1	1			1	1
Movement disorder	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	2	1	1	1	1
Myalgia	5	5	5	5		
Nasal congestion	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	6	6	4	4	2	2
Neck pain	1	1			1	1
Nervousness	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	1	1			1	1
Paraesthesia	5	5	5	5		
Pelvic pain	1	1	1	1		
Periorbital oedema	1	1	1	1		
Peripheral swelling	1	1			1	1
Pruritus	2	2	2	2		
Pyrexia	9	9	9	9		
Rash	2	2	2	2		
Rash pruritic	1	1			1	1
Rhinitis	1	1	1	1		
Rhinorrhoea	2	2	2	2		
Sensory loss	1	1	1	1		
Somnolence	2	2	2	2		
Stomatitis	2	2	1	1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Temperature regulation disorder	1	1	1	1		
Throat irritation	1	1	1	1		
Tongue oedema	1	1	1	1		
Tongue pruritus	1	1			1	1
Tongue ulceration	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	7	7	6	6	1	1
Vaginal haemorrhage	1	1	1	1		
Vomiting	3	3	2	2	1	1
	153	154	122	122	31	32

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Arthralgia	3	3	2	2	1	1
Burning sensation mucosal	1	1	1	1		
Chills	3	3	3	3		
Diarrhoea	2	2	2	2		
Dizziness	1	1			1	1
Dysgeusia	1	1	1	1		
Dysphagia	1	1			1	1
Dyspnoea	1	1			1	1
Eye pruritus	1	1	1	1		
Fatigue	1	1	1	1		
Headache	5	5	5	5		
Hypotension	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Joint range of motion decreased	1	1			1	1
Laryngeal oedema	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	3	3	3	3		
Myalgia	5	5	5	5		
Nausea	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	3	3	2	2	1	1
Palpitations	1	1	1	1		
Pyrexia	10	10	10	10		
Rash	2	2	2	2		
Tachycardia	1	1	1	1		
Tension headache	1	1	1	1		
Tongue discomfort	1	1	1	1		
Vaccination complication	1	1	1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation	1	1			1	1
Vaccination site pain	4	4	4	4		
Vaccination site swelling	2	2	2	2		
Vomiting	2	2	2	2		
Wrong technique in product usage process	1	1	1	1		
	70	70	59	59	11	11

Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Diarrhoea	2	3	2	3		
Dyspnoea	1	1			1	1
Headache	1	1	1	1		
Hypersensitivity	1	1			1	1
Multiple organ dysfunction syndrome	1	1			1	1
Petechiae	1	1	1	1		
Pyrexia	3	3	3	3		
Respiratory distress	1	1			1	1
Sudden death	1	1			1	1
Vaccination site inflammation	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vomiting		1		1		
	16	18	10	12	6	6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	2	2			2	2
Angular cheilitis	1	1	1	1		
Arthralgia	1	1	1	1		
Aspiration	1	1			1	1
Asthenia	1	1	1	1		
Balance disorder	1	1	1	1		
Cardio-respiratory distress	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Depressed mood	1	1	1	1		
Diarrhoea	5	5	5	5		
Drug interaction	1	1	1	1		
Dysarthria	1	1	1	1		
Dyspnoea	3	3			3	3
Euphoric mood	1	1	1	1		
Fatigue	1	1	1	1		
Haematoma muscle	1	1			1	1
Headache	2	2	1	1	1	1
Hypotension	3	3	1	1	2	2
Hypoxia	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Intestinal ischaemia	1	1			1	1
Malaise	3	3	1	1	2	2
Muscle contractions involuntary	1	1	1	1		
Myalgia	1	1	1	1		
Overdose	1	1	1	1		
Palpitations	1	1			1	1
Peripheral ischaemia	1	1			1	1
Pneumonia	1	1			1	1
Presyncope	1	1			1	1
Psychomotor hyperactivity	1	1	1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	16	16	13	13	3	3
Rash	1	1	1	1		
Rectal haemorrhage	1	1			1	1
Respiratory failure	1	1			1	1
Sepsis	1	1			1	1
Somnolence	1	1	1	1		
Sudden death	2	2			2	2
Troponin T increased	1	1			1	1
Vaccination complication	1	1			1	1
Vaccination site inflammation	5	5	5	5		
Vaccination site joint erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vaccination site warmth	1	1	1	1		
Vomiting	2	2	2	2		
	80	80	49	49	31	31

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure increased	1	1			1	1
Bruxism	1	1	1	1		
Chest pain	1	1			1	1
Confusional state	1	1			1	1
COVID-19	5	5			5	5
Diarrhoea	2	2	2	2		
Discomfort	1	1	1	1		
Dizziness	1	1			1	1
Drug ineffective	6	6			6	6
Dry mouth	1	1			1	1
Dysgeusia	1	1	1	1		
Dyspnoea	1	1			1	1
Exposure during pregnancy	1	1	1	1		
Fatigue	2	2	1	1	1	1
Feeling abnormal	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	4	4	4	4		
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Influenza like illness	1	1	1	1		
Jaw disorder	1	1	1	1		
Loss of consciousness	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	2	2	2	2		
Muscle contracture	1	1	1	1		
Muscle tightness	1	1	1	1		
Myalgia	1	1	1	1		
Myoclonus	1	1			1	1
Nasal congestion	1	1	1	1		
Nausea	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	2	2	2	2		
Oral discomfort	1	1	1	1		
Pain in extremity	1	1	1	1		
Palpitations	1	1			1	1
Paraesthesia	2	2	2	2		
Paraesthesia oral	1	1	1	1		
Peripheral swelling	1	1	1	1		
Product use issue	2	2	2	2		
Pruritus	2	2	1	1	1	1
Pyrexia	1	1	1	1		
Rash	1	1	1	1		
Respiratory arrest	1	1			1	1
SARS-CoV-2 test positive	2	2	1	1	1	1
Skin lesion	1	1	1	1		
Somnolence	1	1	1	1		
Speech disorder	1	1			1	1
Stomatitis	1	1	1	1		
Tachycardia	1	1			1	1
Tension headache	1	1	1	1		
Throat irritation	1	1	1	1		
Tongue eruption	1	1	1	1		
Tongue pruritus	1	1	1	1		
Underdose	1	1	1	1		
Urinary tract infection	1	1	1	1		
Vaccination site pain	7	7	7	7		
	83	83	57	57	26	26

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Country Where Event Occurred

**SWEDEN**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Chills	1	1	1	1
Cough	1	1	1	1
Epistaxis	1	1	1	1
Fatigue	2	2	2	2
Headache	3	3	3	3
Insomnia	1	1	1	1
Myalgia	1	1	1	1
Nausea	1	1	1	1
Pain	1	1	1	1
Pain in extremity	1	1	1	1
Palpitations	1	1	1	1
Rhinorrhoea	1	1	1	1
Vaccination site erythema	1	1	1	1
Vaccination site swelling	1	1	1	1
Vaccination site warmth	1	1	1	1
	19	19	19	19

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Arthralgia	1	1	1	1		
Axillary pain	1	1	1	1		
Chills	5	5	5	5		
C-reactive protein increased	1	1			1	1
Diarrhoea	1	1	1	1		
Dizziness	1	1			1	1
Fatigue	5	5	3	3	2	2
Feeling abnormal	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	8	8	7	7	1	1
Injected limb mobility decreased	1	1	1	1		
Malaise	1	1	1	1		
Memory impairment	1	1			1	1
Migraine	2	2	2	2		
Myalgia	4	4	3	3	1	1
Nausea	3	3	3	3		
Neck pain	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Oropharyngeal spasm	1	1			1	1
Pain	2	2	1	1	1	1
Pain in extremity	4	4	4	4		
Palpitations	1	1	1	1		
Paraesthesia	2	2	1	1	1	1
Paraesthesia oral	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pharyngeal swelling	1	1	1	1		
Poor quality product administered	2	2	2	2		
Post viral fatigue syndrome	1	1	1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product colour issue	2	2	2	2		
Productive cough	1	1			1	1
Pyrexia	7	7	5	5	2	2
Sensation of foreign body	1	1			1	1
Throat tightness	1	1			1	1
Upper respiratory tract congestion	1	1	1	1		
Vaccination site pain	3	3	3	3		
Vertigo positional	1	1	1	1		
	76	76	60	60	16	16

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Cardiac arrest	1	1			1	1
Chills	3	3	2	2	1	1
Diarrhoea	2	2	2	2		
Dizziness	1	1	1	1		
Erysipelas	1	1			1	1
Facial paresis	1	1			1	1
Fatigue	1	1	1	1		
Feeling abnormal	1	1	1	1		
Formication	1	1	1	1		
General physical health deterioration	1	1			1	1
Hallucination, visual	1	1			1	1
Headache	3	3	3	3		
Heart rate increased	1	1			1	1
Joint range of motion decreased	1	1	1	1		
Lip swelling	1	1			1	1
Muscular weakness	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	3	3	2	2	1	1
Oral pruritus	1	1			1	1
Oropharyngeal pain	1	1			1	1
Pain in extremity	1	1	1	1		
Palpitations	1	1	1	1		
Pneumonia	1	1			1	1
Pyrexia	3	3	2	2	1	1
Respiratory distress	1	1			1	1
Sleep talking	1	1			1	1
Swelling face	1	1	1	1		
Tachycardia	1	1			1	1
Throat irritation	1	1			1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tongue pruritus	1	1			1	1
Upper respiratory tract infection	1	1			1	1
Vaccination site erythema	2	2	1	1	1	1
Vaccination site pain	3	3	2	2	1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	3	3	2	2	1	1
Vaccination site warmth	2	2	1	1	1	1
Vomiting	1	1	1	1		
	56	56	33	33	23	23

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1	1	1		
Acute kidney injury	1	1			1	1
Anaphylactic shock	1	1			1	1
Arthralgia	1	1			1	1
Blood pressure abnormal	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Death	1	1			1	1
Dehydration	1	1			1	1
Dermatitis	1	1	1	1		
Dyspnoea	3	3			3	3
Fatigue	1	1	1	1		
Fibromyalgia	1	1			1	1
General physical health deterioration	1	1			1	1
Hypertension	1	1			1	1
Hypoaesthesia	1	1			1	1
Infection	2	2			2	2
Insomnia	1	1	1	1		
Myalgia	1	1			1	1
Nausea	1	1	1	1		
Pharyngitis	1	1	1	1		
Pulmonary oedema	1	1			1	1
Pulse abnormal	1	1			1	1
Pyrexia	3	3	2	2	1	1
Respiratory rate increased	1	1			1	1
Skin ulcer	1	1			1	1
Sudden death	1	1			1	1
Underdose	1	1	1	1		
Vomiting	1	1	1	1		
	33	33	10	10	23	23

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1			1	1
Blood pressure decreased	1	1	1	1		
Blood pressure diastolic decreased	1	1	1	1		
Cardiac arrest	2	3			2	3
Cardiac disorder	1	1			1	1
Cardiac failure	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chronic obstructive pulmonary disease	2	2			2	2
Circulatory collapse	1	1			1	1
Confusional state	1	1			1	1
Cough	2	2			2	2
COVID-19	1	1			1	1
Crepitations	1	1	1	1		
Death	9	9			9	9
Depressed level of consciousness	1	1			1	1
Diarrhoea	3	3	1	1	2	2
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	4	4			4	4
Dysstasia	1	1	1	1		
Erythema	1	1	1	1		
Escherichia sepsis	1	1			1	1
Fatigue	2	2	1	1	1	1
General physical health deterioration	3	3	1	1	2	2
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypotension	2	2			2	2
Infection	1	1			1	1
Ischaemic stroke	2	2			2	2
Loss of consciousness	1	1			1	1
Lymphadenopathy	1	1			1	1
Myocardial infarction	1	1			1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	2	2	2	2		
Pneumonia bacterial	1	1			1	1
Productive cough	1	1			1	1
Pruritus	1	1			1	1
Pulmonary oedema	1	1			1	1
Pyrexia	2	2			2	2
Respiratory distress	1	1			1	1
Sepsis	1	1			1	1
Sudden death	2	2			2	2
Swelling	1	1	1	1		
Swelling face	1	1	1	1		
Systemic inflammatory response syndrome	1	1			1	1
Tachypnoea	1	1	1	1		
Urinary tract infection	1	1			1	1
Urosepsis	2	2			2	2
Urticaria	1	1	1	1		
Vaccination site pain	1	1	1	1		
Wheezing	1	1	1	1		
	75	76	19	19	56	57

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error	29	29	29	29
Myalgia	2	2	2	2
Pain in extremity	5	5	5	5
Paraesthesia	1	1	1	1
Poor quality product administered	33	33	33	33
Product administered at inappropriate site	1	1	1	1
Product colour issue	34	34	34	34
Pyrexia	2	2	2	2
Underdose	1	1	1	1
Vaccination site hypoaesthesia	1	1	1	1
	109	109	109	109

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Country Where Event Occurred

**SWITZERLAND**

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenia	1	1	1	1
Fatigue	1	1	1	1
Feeling cold	1	1	1	1
Myalgia	1	1	1	1
Pyrexia	1	1	1	1
Skin lesion	1	1	1	1
Vaccination site pain	1	1	1	1
	7	7	7	7

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death	2	2			2	2
Dizziness	1	1	1	1		
Dysgeusia	1	1	1	1		
Nausea	1	1	1	1		
Vaccination site pain	1	1	1	1		
	6	6	4	4	2	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Anal haemorrhage	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Back pain	1	1	1	1		
Blood pressure decreased	2	2	1	1	1	1
Coma	1	1			1	1
C-reactive protein increased	1	1			1	1
Death	1	1			1	1
Gastric disorder	1	1	1	1		
General physical health deterioration	2	2			2	2
Heart rate decreased	1	1			1	1
Heart rate increased	1	1	1	1		
Malaise	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pneumonia	1	1			1	1
Respiratory failure	1	1			1	1
Restlessness	1	1	1	1		
Somnolence	1	1			1	1
Tachypnoea	1	1			1	1
Urethral pain	1	1	1	1		
Vaccination site pain	1	1	1	1		
	24	24	11	11	13	13

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Fatigue	1	1	1	1
Pain in extremity	1	1	1	1
	3	3	3	3

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Country Where Event Occurred

**UNITED ARAB EMIRATES**

Age Range

**31 - 50 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Chest pain	1	1	1	1
Depressed level of consciousness	1	1	1	1
Depressed mood	1	1	1	1
Dizziness	1	1	1	1
Headache	1	1	1	1
Hypertension	1	1	1	1
Nausea	1	1	1	1
	7	7	7	7

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
Fatigue	1	1	1	1
Pyrexia	1	1	1	1
	3	3	3	3

Age Range

**65 - 79 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pyrexia	1	1	1	1
Vaccination site pain	2	2	2	2
	3	3	3	3

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Erectile dysfunction	1	1			1	1
Facial paralysis	1	1			1	1
Headache	1	1	1	1		
Hypertension	1	1	1	1		
Hypoacusis	1	1			1	1
Hypoaesthesia	1	1			1	1
Off label use		1		1		
Product use issue		1		1		
	9	11	3	5	6	6

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Country Where Event Occurred

**UNITED KINGDOM**

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	2	1	2		
African trypanosomiasis	1	1			1	1
Angioedema	1	1			1	1
Arthralgia	6	6			6	6
Back pain	1	1			1	1
Balance disorder		1		1		
Blood pressure increased	1	1			1	1
Blood urine present	1	1	1	1		
Body temperature increased	3	3	1	1	2	2
Chills	4	5	1	2	3	3
Cough	2	2	1	1	1	1
Decreased appetite	2	2	1	1	1	1
Disease recurrence	1	1			1	1
Dizziness	1	1	1	1		
Dizziness exertional	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	1	1			1	1
Erythema	1	1			1	1
Exertional headache	1	1	1	1		
Exposure via breast milk	2	2	2	2		
Fatigue	10	11	3	4	7	7
Feeling abnormal	2	2	2	2		
Feeling of body temperature change		1		1		
Fibromyalgia	1	1			1	1
Flushing		1				1
Gait disturbance		1		1		
Headache	5	6	1	2	4	4
Hyperchlorhydria	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Illness	1	1			1	1
Infantile vomiting	1	1	1	1		
Lethargy	1	1	1	1		

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Loss of consciousness	1	1
Lymphadenopathy	1	1
Malaise	3	4
Mobility decreased		1
Muscle spasms	1	1
Musculoskeletal stiffness	1	1
Myalgia	2	3
Nausea	5	5
Neck pain	1	1
Off label use	10	10
Oropharyngeal pain	1	1
Pain	3	4
Pain in extremity	3	3
Product administered to patient of inappropriate age	7	9
Product use issue	3	3
Pruritus	2	3
Pyrexia	9	10
Q fever	1	1
Rash	1	1
Rash papular	1	1
Rash pruritic	2	2
Renal failure	1	1
Respiratory rate decreased	1	1
Sleep disorder	2	2
Spinal pain	1	1
Suspected COVID-19	1	1
Syncope	3	3
Urticaria	1	1
Vaccination site joint movement impairment	1	1
Vaccination site pain	4	4
Vomiting	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
2	3	1	1
	1		
		1	1
		1	1
	1	2	2
4	4	1	1
		1	1
10	10		
		1	1
1	2	2	2
1	1	2	2
6	8	1	1
3	3		
1	1	1	2
3	4	6	6
		1	1
		1	1
		1	1
		2	2
		1	1
		1	1
1	1	1	1
1	1		
		1	1
		3	3
		1	1
		1	1
3	3	1	1
		1	1

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Age Range

Less than or equal to 17 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	129	145	57	71	72	74

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2			2	2
Abdominal distension	1	2	1	2		
Abdominal pain	6	7		1	6	6
Abdominal pain upper	12	17	4	8	8	9
Abdominal tenderness	1	1			1	1
Abnormal dreams	3	4	2	3	1	1
Abortion spontaneous	1	1			1	1
Adverse drug reaction	1	1			1	1
Ageusia	6	6	2	2	4	4
Agitation	1	1			1	1
Alanine aminotransferase increased	1	1			1	1
Allergy to vaccine		1				1
Allodynia	1	1			1	1
Anaphylactic reaction	10	11			10	11
Anaphylactoid reaction		1				1
Angioedema	2	2			2	2
Anosmia	3	3	2	2	1	1
Anticholinergic syndrome	1	1			1	1
Anxiety	4	5	3	4	1	1
Aphasia	1	1			1	1
Arthralgia	79	88	21	27	58	61
Arthritis	1	1			1	1
Aspartate aminotransferase increased	1	1			1	1
Asthenia	19	20	10	10	9	10
Asthma	3	4			3	4
Aura	1	2	1	2		
Axillary mass	1	2		1	1	1
Axillary pain	10	15	3	7	7	8
Back pain	19	22	4	7	15	15
Balance disorder		1				1
Blepharospasm	1	1			1	1
Blood glucose increased	1	1			1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood ketone body present	1	1
Blood pressure decreased		2
Blood pressure orthostatic decreased		1
Blood test abnormal	1	1
Body temperature abnormal		1
Body temperature increased	4	5
Bone pain	8	8
Bradycardia	2	2
Burning sensation	3	4
Cardiac arrest	1	1
Cardiac disorder	1	1
Cellulitis	2	2
Chest discomfort	14	15
Chest pain	15	18
Chills	141	154
Cluster headache	1	1
Cold sweat	8	10
Condition aggravated	2	2
Confusional state	2	3
Conjunctival haemorrhage	1	1
Constipation	1	1
Contusion	3	4
Cortisol decreased	1	1
Cough	22	24
COVID-19	8	8
Crying	1	1
Cyanosis	1	1
Deafness	1	1
Decreased appetite	11	13
Dehydration	5	5
Delirium	1	1
Delusion	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		1
		1	1
	1		
1	2	3	3
4	4	4	4
		2	2
1	2	2	2
		1	1
		1	1
		2	2
3	4	11	11
2	4	13	14
51	61	90	93
		1	1
4	5	4	5
1	1	1	1
		2	3
		1	1
1	2	2	2
		1	1
5	7	17	17
		8	8
1	1		
		1	1
		1	1
4	5	7	8
1	1	4	4
		1	1
		1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dermatitis	2	2
Dermatitis allergic	2	3
Diabetes mellitus inadequate control		1
Diabetic complication	1	1
Diabetic ketoacidosis	1	1
Diarrhoea	19	22
Diplopia	1	1
Discoloured vomit	1	1
Discomfort	6	6
Disease recurrence	4	4
Disorientation	2	2
Disturbance in attention		1
Dizziness	71	86
Dizziness postural	5	7
Drug ineffective	21	22
Dry eye	1	1
Dry mouth	2	3
Dry throat	1	1
Dysgeusia	2	4
Dyskinesia	1	1
Dysphagia	2	2
Dysphonia	1	2
Dyspnoea	34	35
Dyspnoea exertional	1	2
Dysstasia	1	1
Dystonia	1	1
Ear pain	5	6
Ear pruritus	1	1
Eczema	2	2
Epistaxis	1	1
Eructation	1	1
Erythema	17	23

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	1
		2	3
			1
		1	1
		1	1
6	9	13	13
1	1		
1	1		
3	3	3	3
1	1	3	3
		2	2
	1		
33	41	38	45
1	1	4	6
		21	22
		1	1
1	2	1	1
		1	1
	1	2	3
1	1		
1	1	1	1
		1	2
5	5	29	30
	1	1	1
		1	1
		1	1
1	1	4	5
		1	1
1	1	1	1
		1	1
		1	1
8	13	9	10

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Expired product administered	1	1
Exposure during pregnancy	1	1
Exposure to SARS-CoV-2	1	1
Eye disorder	1	1
Eye irritation	3	3
Eye pain	16	16
Eye pruritus	2	2
Eye swelling	1	1
Facial pain	3	3
Facial paralysis	2	2
Facial paresis	1	1
Fall	1	1
Fatigue	182	215
Feeling abnormal	7	7
Feeling cold	14	15
Feeling drunk	1	2
Feeling hot	16	20
Feeling of body temperature change	5	6
Flank pain	1	1
Fluid intake reduced	1	1
Flushing	3	5
Folliculitis		1
Formication	1	1
Frequent bowel movements	1	2
Frustration tolerance decreased	1	1
Gait disturbance	1	1
Gait inability	2	2
Gastroenteritis viral	1	1
Gastroesophageal reflux disease	1	1
Generalised tonic-clonic seizure		1
Groin pain	1	1
Haematemesis	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
		1	1
		1	1
1	1	2	2
5	5	11	11
1	1	1	1
		1	1
		3	3
		2	2
		1	1
1	1		
69	91	113	124
2	2	5	5
8	9	6	6
		1	2
10	12	6	8
2	3	3	3
		1	1
		1	1
	1	3	4
	1		
		1	1
		1	2
1	1		
1	1		
1	1	1	1
1	1		
		1	1
			1
1	1		
		2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haematochezia	1	1
Haemorrhage subcutaneous	1	1
Hallucination	5	5
Hallucination, olfactory		1
Hallucination, tactile	1	1
Headache	262	309
Head discomfort	2	2
Head injury	2	2
Heart rate abnormal	1	1
Heart rate increased	8	9
Heat stroke	1	1
Hot flush	7	11
Hunger	1	1
Hyperaesthesia	3	3
Hyperglycaemia	1	1
Hyperhidrosis	26	27
Hyperpyrexia	1	1
Hypersensitivity	8	10
Hypersomnia	1	1
Hypertension	3	5
Hypoacusis		1
Hypoaesthesia	16	20
Hypoaesthesia oral	3	4
Hypoglycaemia	1	3
Hypokinesia	1	1
Hypopnoea	1	1
Hyporeflexia	1	1
Hypotension	2	3
Hypothermia	1	1
Idiopathic intracranial hypertension	1	1
Illness	9	11
Incorrect route of product administration	6	7

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		5	5
			1
		1	1
100	131	162	178
		2	2
1	1	1	1
		1	1
2	3	6	6
1	1		
5	7	2	4
1	1		
1	1	2	2
		1	1
9	10	17	17
		1	1
3	3	5	7
		1	1
2	3	1	2
			1
2	5	14	15
2	2	1	2
	1	1	2
		1	1
		1	1
1	1	1	2
		1	1
		1	1
3	4	6	7
6	7		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Infection	1	1
Inflammation	1	1
Influenza	9	10
Influenza like illness	24	27
Injection site pain	1	1
Insomnia	21	21
Irritability	1	1
Irritable bowel syndrome	2	2
Joint range of motion decreased	2	2
Joint stiffness	2	2
Joint swelling	1	1
Lacrimation increased	3	3
Lacunar infarction	1	1
Lethargy	27	32
Limb discomfort	18	24
Lip swelling	3	5
Local reaction	1	1
Loss of consciousness	6	7
Loss of personal independence in daily activities	1	1
Lower respiratory tract infection	1	1
Lymphadenitis	1	1
Lymphadenopathy	50	62
Lymph node pain	11	14
Lymphoedema	1	1
Malaise	54	61
Menopausal symptoms	1	1
Mental fatigue	1	1
Middle insomnia	3	3
Migraine	34	36
Migraine with aura	3	3
Mobility decreased	2	2
Monoplegia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
4	5	5	5
12	15	12	12
1	1		
9	9	12	12
1	1		
		2	2
		2	2
1	1	1	1
		1	1
2	2	1	1
		1	1
8	10	19	22
9	12	9	12
1	2	2	3
		1	1
		6	7
		1	1
		1	1
1	1		
21	29	29	33
7	10	4	4
		1	1
24	29	30	32
1	1		
		1	1
3	3		
8	8	26	28
2	2	1	1
1	1	1	1
		1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mood altered	2	2
Mouth ulceration	2	3
Movement disorder	2	2
Muscle fatigue	3	5
Muscle rigidity	1	1
Muscle spasms	4	6
Muscle swelling	1	1
Muscular weakness	8	11
Musculoskeletal chest pain	2	2
Musculoskeletal discomfort	2	2
Musculoskeletal pain	1	1
Musculoskeletal stiffness	9	13
Myalgia	162	185
Mydriasis	1	1
Nasal congestion	2	3
Nasopharyngitis	8	13
Nausea	155	186
Neck mass	1	1
Neck pain	13	17
Neurogenic shock	2	2
Nightmare	1	3
Night sweats	12	13
Nodule		1
Odynophagia		1
Off label use	5	7
Oral herpes	1	1
Oropharyngeal blistering	1	1
Oropharyngeal discomfort	3	3
Oropharyngeal pain	22	29
Pain	91	101
Painful respiration	2	2
Pain in extremity	88	100

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	1
	1	2	2
		2	2
	2	3	3
		1	1
2	3	2	3
		1	1
1	4	7	7
1	1	1	1
1	1	1	1
		1	1
4	4	5	9
43	63	119	122
		1	1
2	3		
5	9	3	4
50	69	105	117
		1	1
1	3	12	14
		2	2
	2	1	1
8	9	4	4
	1		
			1
5	7		
1	1		
		1	1
1	1	2	2
9	15	13	14
39	45	52	56
		2	2
37	43	51	57

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pain of skin	4	4
Pallor	6	8
Palpitations	11	13
Panic attack	1	1
Papule	2	2
Paraesthesia	18	21
Paraesthesia oral	5	8
Paranasal sinus inflammation	1	1
Parosmia	2	2
Pericarditis	1	1
Peripheral coldness	2	3
Peripheral swelling	19	20
Petechiae	1	2
Pharyngeal inflammation	1	1
Pharyngeal oedema	1	1
Pharyngeal swelling	2	2
Pharyngitis streptococcal	1	1
Phonophobia	1	1
Photophobia	4	6
Photosensitivity reaction		1
Pleurisy	1	1
Pleuritic pain	1	1
Pollakiuria	1	1
Poor quality sleep	1	1
Presyncope	8	10
Productive cough	2	2
Product use issue	4	6
Pruritus	22	27
Pupillary reflex impaired	1	1
Pupils unequal	2	2
Purpura	2	2
Pyrexia	224	252

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	3	3
4	5	2	3
3	5	8	8
		1	1
		2	2
6	9	12	12
1	1	4	7
		1	1
1	1	1	1
		1	1
2	2		1
5	6	14	14
	1	1	1
		1	1
		2	2
		1	1
1	1		
1	1	3	5
			1
		1	1
		1	1
		1	1
5	6	3	4
1	1	1	1
4	6		
9	14	13	13
		1	1
		2	2
1	1	1	1
51	69	173	183

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash	23	30
Rash erythematous	11	13
Rash macular	5	6
Rash papular	2	3
Rash pruritic	5	7
Renal pain	1	1
Restless legs syndrome	2	2
Restlessness	2	3
Rhabdomyolysis	2	2
Rhinitis	1	2
Rhinorrhoea	6	6
Salivary hypersecretion	1	1
Scrotal pain	1	1
Seasonal allergy	1	1
Seizure	3	3
Sensation of foreign body	1	1
Sensitive skin	2	2
Sensory disturbance	1	1
Serositis	1	1
Sinus bradycardia		1
Sinus congestion	1	1
Sinus headache	3	3
Sinus pain	2	3
Sinus tachycardia		1
Skin burning sensation	3	3
Skin discolouration	3	3
Skin exfoliation	1	1
Skin swelling	1	2
Skin tightness	1	1
Skin warm	3	3
Sleep disorder	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
6	10	17	20
4	6	7	7
3	4	2	2
	1	2	2
1	3	4	4
1	1		
1	1	1	1
2	3		
		2	2
1	2		
4	4	2	2
1	1		
1	1		
1	1		
		3	3
		1	1
		2	2
		1	1
		1	1
			1
1	1		
		3	3
		2	3
	1		
		3	3
		3	3
		1	1
1	2		
		1	1
1	1	2	2
1	1	2	2

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorder due to a general medical condition	2	2	1	1	1	1
Sneezing	3	3	2	2	1	1
Somnolence	10	12	4	5	6	7
Stress	1	1	1	1		
Suspected COVID-19	14	15			14	15
Sweating fever	5	6			5	6
Swelling	8	9	5	6	3	3
Swelling face	3	3			3	3
Swelling of eyelid	3	3			3	3
Swollen tongue	2	3	1	1	1	2
Symptom recurrence	1	1	1	1		
Syncope	17	20			17	20
Synovial cyst	1	1	1	1		
Tachycardia	13	17	4	6	9	11
Tachypnoea	1	1	1	1		
Taste disorder	1	1			1	1
Temporomand bular joint syndrome	1	1	1	1		
Tenderness	3	3			3	3
Tension headache	6	6	2	2	4	4
Thirst	2	3	1	2	1	1
Throat irritation	2	3			2	3
Throat tightness	4	6			4	6
Thunderclap headache	1	1			1	1
Tinnitus	3	5	1	2	2	3
Tonsillar hypertrophy	1	2			1	2
Tonsillitis	1	2			1	2
Toothache	1	1			1	1
Transient ischaemic attack	1	1			1	1
Tremor	17	21	6	7	11	14
Unresponsive to stimuli	2	2			2	2
Upper-airway cough syndrome	1	1	1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary retention	1	1
Urinary tract infection	1	1
Urine output decreased	1	1
Urticaria	12	21
Vaccination complication	1	1
Vaccination site bruising	2	2
Vaccination site discolouration	1	2
Vaccination site discomfort	4	5
Vaccination site erythema	16	26
Vaccination site hypoaesthesia	2	3
Vaccination site induration		2
Vaccination site infection		1
Vaccination site inflammation	4	7
Vaccination site joint movement impairment	1	2
Vaccination site joint pain	3	3
Vaccination site mass	3	5
Vaccination site movement impairment	3	4
Vaccination site oedema		1
Vaccination site pain	105	135
Vaccination site paraesthesia	1	3
Vaccination site pruritus	8	11
Vaccination site rash	5	7
Vaccination site reaction	2	2
Vaccination site swelling	19	23
Vaccination site urticaria	2	2
Vaccination site warmth	9	17
Vaginal haemorrhage	1	1
Vasodilatation	1	1
Ventricular fibrillation	1	1
Vertigo	10	11
Viral labyrinthitis	1	1
Viral pharyngitis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	1
3	11	9	10
1	1		
2	2		
1	2		
2	3	2	2
7	16	9	10
1	2	1	1
	2		
	1		
2	4	2	3
		1	2
1	1	2	2
	2	3	3
		3	4
	1		
44	68	61	67
	1	1	2
3	5	5	6
1	3	4	4
		2	2
7	11	12	12
1	1	1	1
3	11	6	6
		1	1
		1	1
		1	1
2	2	8	9
1	1		
		1	1

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Age Range

18 - 30 years

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3	6	6
1	1	2	2
10	15	26	30
		2	2
1	1	1	3
2	2		
1027	1394	2035	2230

Vision blurred  
Visual impairment  
Vomiting  
Vomiting projectile  
Wheezing

9  
3  
36  
2  
2  
2

9  
3  
45  
2  
4  
2

3,062

3,624

1027

1394

2035

2230

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal discomfort	7	9
Abdominal distension	2	2
Abdominal pain	21	25
Abdominal pain lower	2	2
Abdominal pain upper	21	24
Abdominal tenderness	1	1
Abnormal dreams	3	4
Abnormal sensation in eye	1	1
Abortion spontaneous	1	1
Aerophagia	1	1
Ageusia	8	11
Agitation	1	1
Alcohol interaction		1
Allergic cough	1	1
Allergy to vaccine	5	7
Alopecia	1	1
Anal haemorrhage		1
Anaphylactic reaction	35	37
Anaphylactoid reaction	1	2
Angina pectoris	1	1
Angioedema	6	7
Anosmia	5	6
Antibody test positive	1	1
Anxiety	12	17
Apathy	1	1
Aphasia	1	1
Aphonia	1	2
Aphthous ulcer	2	2
Appendicitis	1	1
Arrhythmia	2	2
Arrhythmia supraventricular	1	1
Arthralgia	202	228

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	5	4	4
		2	2		
		9	13	12	12
		1	1	1	1
		9	11	12	13
				1	1
		2	3	1	1
		1	1		
				1	1
				1	1
		2	5	6	6
				1	1
					1
			2	5	5
		1	1		
					1
				35	37
				1	2
				1	1
				6	7
		1	2	4	4
		1	1		
		3	5	9	12
				1	1
				1	1
				1	2
				2	2
				1	1
				2	2
				1	1
				1	1
		1	1	133	142

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthritis	2	2
Arthritis reactive		1
Asthenia	42	47
Asthenopia	2	3
Asthma	8	10
Asthma prophylaxis	1	1
Asymptomatic COVID-19	1	1
Atrial f brillation	1	1
Aura	3	3
Axillary mass	4	5
Axillary pain	33	41
Back pain	40	44
Balance disorder	4	4
Blepharitis	1	1
Blepharospasm	1	1
Blister	4	4
Blood glucose decreased	1	1
Blood glucose increased	1	1
Blood lactic acid increased	1	1
Blood potassium abnormal	1	1
Blood pressure decreased	1	1
Blood pressure increased	17	25
Blood test abnormal		1
Blood urine present	1	1
Body temperature	2	2
Body temperature abnormal	5	5
Body temperature decreased	2	2
Body temperature fluctuation		1
Body temperature increased	18	20
Bone pain	5	7
Bone swelling	1	2
Bradycardia	4	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
					1
		18	22	24	25
		1	2	1	1
		3	4	5	6
				1	1
				1	1
		1	1	2	2
		3	4	1	1
		11	18	22	23
		19	22	21	22
		1	1	3	3
		1	1		
				1	1
		2	2	2	2
				1	1
				1	1
				1	1
		1	1		
		11	15	6	10
					1
		1	1		
				2	2
				5	5
		1	1	1	1
			1		
		4	5	14	15
		4	6	1	1
			1	1	1
				4	5

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Bradyphrenia	1	1
Breast abscess	1	1
Breast mass	1	1
Breast pain	10	11
Breast swelling	2	2
Bronchospasm	3	3
Burning sensation	12	13
Cardiac arrest		1
Catarrh		1
Cellulitis	6	8
Chest discomfort	42	52
Chest pain	34	36
Chillblains	1	1
Chills	278	302
Cholecystitis infective	1	1
Circulatory collapse	1	2
Clumsiness	1	1
Cluster headache	5	5
Cognitive disorder	1	1
Cold sweat	19	27
Coma scale abnormal		1
Condition aggravated	7	8
Confusional state	12	13
Conjunctivitis	3	3
Constipation	2	2
Contraindicated product administered	1	1
Contusion	8	8
Coordination abnormal	1	1
Costochondritis	2	2
Costovertebral angle tenderness	1	1
Cough	44	50
COVID-19	20	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	1
		4	5	6	6
		2	2		
				3	3
		1	1	11	12
					1
			1		
				6	8
		11	16	31	36
		12	13	22	23
				1	1
1	1	89	106	189	196
				1	1
				1	2
				1	1
		1	1	4	4
				1	1
		8	10	11	17
					1
		1	2	6	6
		2	3	10	10
		1	1	2	2
		1	1	1	1
				1	1
		2	2	6	6
		1	1		
				2	2
		1	1		
		12	14	32	36
				20	22

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Crying	1	1
Deafness	1	1
Death	2	2
Decreased appetite	33	38
Deep vein thrombosis	1	1
Defaecation urgency	1	1
Dehydration	5	6
Delirium	6	6
Depersonalisation/derealisation disorder	2	2
Depressed level of consciousness	1	1
Depressed mood	2	2
Depression		1
Dermatitis	1	1
Dermatitis allergic	2	5
Diabetic ketoacidosis	1	1
Diarrhoea	77	93
Diarrhoea haemorrhagic		1
Diplopia	3	4
Discomfort	6	6
Disease recurrence	1	1
Disorganised speech	1	1
Disorientation	5	7
Dissociation	1	2
Disturbance in attention	9	10
Dizziness	168	205
Dizziness postural	11	12
Drug hypersensitivity	1	1
Drug ineffective	57	62
Dry eye	1	1
Dry mouth	11	15
Dry skin	5	5
Dry throat	4	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				2	2
		8	10	25	28
				1	1
				1	1
		5	6		
				6	6
		1	1	1	1
				1	1
				2	2
					1
		1	1		
			2	2	3
				1	1
		27	38	50	55
					1
		1	2	2	2
		3	3	3	3
				1	1
		1	1		
			2	5	5
		1	2		
		4	4	5	6
1	1	69	96	99	109
		1	2	10	10
				1	1
				57	62
				1	1
		1	4	10	11
		5	5		
		1	3	3	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysarthria	1	1
Dysgeusia	29	41
Dyskinesia	1	1
Dysmenorrhoea	1	2
Dyspepsia	6	6
Dysphagia	8	8
Dysphonia	3	5
Dyspnoea	67	80
Dyspnoea exertional	4	4
Dysstasia	1	1
Dysuria	1	1
Ear congestion	1	1
Ear discomfort	5	5
Ear disorder	1	1
Ear infection	2	2
Ear pain	18	20
Ear pruritus	1	1
Ear swelling		1
Eczema	1	1
Enuresis	1	1
Epilepsy	2	2
Epistaxis	6	8
Erectile dysfunction	1	1
Eructation	1	1
Erythema	44	52
Erythema multiforme	1	1
Exercise tolerance decreased	1	1
Exposure during pregnancy	1	1
Extrasystoles	3	3
Eye contusion	2	2
Eye disorder	2	2
Eye irritation	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		19	28	10	13
				1	1
			1	1	1
		3	3	3	3
		1	1	7	7
		1	1	2	4
		20	25	47	55
		2	2	2	2
		1	1		
		1	1		
		1	1		
		3	3	2	2
				1	1
		1	1	1	1
		10	11	8	9
		1	1		
					1
				1	1
				1	1
				2	2
		3	4	3	4
				1	1
				1	1
		21	26	23	26
				1	1
				1	1
		1	1		
		2	2	1	1
		1	1	1	1
		1	1	1	1
		1	1	2	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eyelid exfoliation	1	1
Eyelid function disorder	1	1
Eyelid pain	1	1
Eyelid rash	2	2
Eyelids pruritus	1	1
Eye movement disorder	2	2
Eye pain	22	24
Eye pruritus	9	9
Eye swelling	12	14
Face crushing	1	1
Facial neuralgia	1	1
Facial pain	5	5
Facial paralysis	14	15
Facial paresis	2	3
Facial spasm	2	2
Faeces discoloured	1	1
Faeces pale		1
Fall	1	1
Fatigue	396	454
Fear	1	1
Fear of injection	1	1
Feeding disorder	1	1
Feeling abnormal	35	40
Feeling cold	33	37
Feeling drunk	2	4
Feeling hot	45	61
Feeling jittery		2
Feeling of body temperature change	15	20
Fibromyalgia	1	1
Flank pain		1
Fluid retention		1
Flushing	22	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	1
				2	2
				1	1
				2	2
		7	9	15	15
		2	2	7	7
				12	14
				1	1
		1	1		
		2	2	3	3
				14	15
			1	2	2
		2	2		
		1	1		
			1		
		1	1		
3	3	143	180	253	274
		1	1		
		1	1		
		1	1		
		15	18	20	22
		14	17	19	20
		1	1	1	3
		20	31	25	30
			1		1
		8	12	7	8
				1	1
			1		
			1		
		8	14	14	15

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Foreign body sensation in eyes	1	1
Frequent bowel movements		2
Furuncle	1	1
Gait disturbance	8	10
Gait inability	2	2
Gastritis	1	1
Gastrointestinal pain	1	1
Gastrointestinal stoma complication	1	1
Gastroesophageal reflux disease	3	3
Generalised tonic-clonic seizure	1	1
Gingival bleeding	2	2
Gingival blister	1	1
Gingival pain	2	2
Gingivitis ulcerative	1	1
Glossitis	1	1
Glossodynia	3	4
Gout	1	1
Grip strength decreased	1	1
Groin pain	4	4
Haematemesis	1	1
Haematoma	1	1
Haematuria		1
Haemoglobin decreased	1	1
Haemoptysis		1
Haemorrhage urinary tract	1	1
Hallucination	5	5
Hallucination, visual	1	1
Hangover	1	1
Headache	576	659
Head discomfort	5	6
Head injury	4	4
Heart rate abnormal	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			2		
		1	1		
		2	3	6	7
		1	1	1	1
				1	1
				1	1
		1	1	2	2
				1	1
		1	1	1	1
		1	1		
		1	1	1	1
				1	1
		1	1		
		2	3	1	1
				1	1
		1	1		
		1	1	3	3
				1	1
			1		
				1	1
					1
				1	1
				5	5
				1	1
				1	1
		3	3	197	251
				379	408
				3	2
				2	2
				3	3
				1	1
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heart rate increased	27	30
Heart rate irregular	2	2
Heat oedema	1	1
Hemiparaesthesia	1	1
Hemiparesis	1	1
Hepatic pain	1	1
Herpes zoster	9	10
Hordeolum	1	1
Hot flush	21	26
Hyperacusis	1	1
Hyperaesthesia	3	3
Hyperglycaemia	3	5
Hyperhidrosis	42	48
Hypersensitivity	15	21
Hypersomnia	4	5
Hypertension	22	25
Hypoaesthesia	39	44
Hypoaesthesia eye	1	1
Hypoaesthesia oral	16	21
Hypoglycaemia	2	2
Hyposmia	3	3
Hypotension	13	15
Hypothermia	1	1
Illness	21	24
Immune thrombocytopenia	1	1
Impaired driving ability	2	2
Inappropriate schedule of product administration	1	1
Incision site pain		1
Incontinence	1	1
Incorrect dose administered	1	1
Incorrect route of product administration	2	9
Increased upper airway secretion	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	11	18	19
				2	2
		1	1		
				1	1
				1	1
		4	5	5	5
				1	1
		6	10	15	16
				1	1
		1	1	2	2
			1	3	4
		15	19	27	29
		1	3	14	18
		3	4	1	1
		7	9	15	16
		13	18	26	26
				1	1
		8	11	8	10
				2	2
		2	2	1	1
		5	7	8	8
				1	1
		8	8	13	16
				1	1
		1	1	1	1
		1	1		
					1
				1	1
		1	1		
		2	9		
				2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Increased viscosity of upper respiratory secretion	2	2
Indifference	1	1
Infection	1	1
Inflammation	7	7
Influenza	19	21
Influenza like illness	67	74
Initial insomnia	1	1
Injected limb mobility decreased	1	1
Injection related reaction	1	1
Injection site erythema	1	1
Injection site pain	1	1
Injection site pruritus	1	1
Injection site warmth	1	1
Insomnia	28	33
Intentional self-injury	1	1
Intranasal hypoaesthesia	1	1
Iridocyclitis	1	1
Irritability	2	2
Irritable bowel syndrome	2	2
Itching scar	1	1
Jaw clicking	1	1
Joint effusion	2	2
Joint range of motion decreased	5	6
Joint stiffness	3	5
Joint swelling	5	6
Joint warmth		1
Lacrimation increased	8	8
Lethargy	61	65
Limb discomfort	31	45
Limb immobilisation	1	1
Lip blister	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
				1	1
				1	1
		3	3	4	4
		8	10	11	11
		29	33	38	41
				1	1
				1	1
		1	1		
				1	1
		1	1		
		1	1		
		13	17	15	16
				1	1
				1	1
				1	1
				2	2
		1	1	1	1
				1	1
				2	2
		2	2	3	4
			1	3	4
			1	5	5
			1		
				8	8
		21	24	40	41
		11	21	20	24
		1	1		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip discolouration	1	1
Lip disorder		1
Lip dry	2	3
Lip oedema	1	1
Lip pain	3	3
Lip swelling	11	18
Livedo reticularis		1
Localised infection	1	1
Locked-in syndrome	1	1
Loss of consciousness	5	5
Loss of personal independence in daily activities	4	5
Lower respiratory tract infection	1	1
Lymphadenitis	2	2
Lymphadenopathy	139	160
Lymphatic disorder	1	1
Lymph node pain	28	34
Lymph node palpable	1	1
Lymphoedema	4	4
Maculopathy		1
Malaise	143	168
Malnutrition	1	1
Mass	1	1
Mastitis	2	2
Maternal exposure during pregnancy	1	2
Maternal exposure timing unspecified	1	1
Mechanical urticaria	1	1
Memory impairment	2	2
Menorrhagia	3	5
Menstruation irregular	1	2
Mental disorder		1
Mental fatigue	4	4
Metamorphopsia		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
		1	2	1	1
				1	1
		1	1	2	2
		1	5	10	13
			1		
				1	1
				1	1
				5	5
		1	1	3	4
				1	1
				2	2
		61	75	78	85
		1	1		
		16	19	12	15
		1	1		
				4	4
					1
		45	61	98	107
				1	1
				1	1
				2	2
		1	2		
		1	1		
		1	1	1	1
			2	3	3
			1	1	1
			1		
		2	2	2	2
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Metrorrhagia		1
Middle ear inflammation	1	1
Middle insomnia	1	1
Migraine	44	48
Migraine with aura	2	2
Miliaria	1	3
Mobility decreased	4	5
Mononeuropathy	1	1
Monoparesis	2	2
Monoplegia	2	2
Mood altered	1	1
Motion sickness	1	2
Mouth cyst	1	1
Mouth swelling	1	1
Mouth ulceration	7	10
Movement disorder	4	4
Multiple sclerosis	1	1
Multiple sclerosis relapse	2	2
Muscle contractions involuntary	1	1
Muscle fatigue	4	7
Muscle spasms	14	16
Muscle swelling	1	1
Muscle tightness	1	1
Muscle twitching	8	8
Muscular weakness	17	20
Musculoskeletal chest pain	3	3
Musculoskeletal discomfort	3	3
Musculoskeletal disorder	2	2
Musculoskeletal pain	4	4
Musculoskeletal stiffness	22	22
Myalgia	287	322
Myocarditis	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
				1	1
		14	17	30	31
				2	2
				1	3
		2	3	2	2
				1	1
		1	1	1	1
				2	2
		1	1		
		1	2		
		1	1		
		1	1		
		4	7	3	3
		1	1	3	3
				1	1
				2	2
		1	1		
		1	1	3	6
		3	4	11	12
		1	1		
		1	1		
		4	4	4	4
		7	10	10	10
				3	3
		3	3		
		1	1	1	1
		2	2	2	2
		9	9	13	13
2	2	97	117	190	205
				3	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myoclonus	1	1
Nail discolouration	1	1
Nasal congestion	5	6
Nasal discharge discolouration	1	1
Nasal discomfort	1	1
Nasal oedema	1	1
Nasopharyngitis	11	11
Nausea	274	324
Neck mass	1	1
Neck pain	48	58
Nephrotic syndrome	1	1
Nervousness	3	4
Neuralgia	4	4
Neurogenic shock	1	1
Neuropathy peripheral	2	2
Nightmare	3	3
Night sweats	17	17
Nipple pain	2	3
Nipple swelling	1	2
No adverse event	1	1
Obstructive airways disorder	1	1
Ocular discomfort	1	1
Ocular hyperaemia	4	5
Oedema mouth	1	1
Oedema peripheral	1	1
Oesophageal pain	1	1
Off label use	16	20
Optic neuritis	1	1
Oral discomfort	3	3
Oral herpes	2	2
Oral mucosa erosion		1
Oral mucosal blistering	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		2	3	3	3
		1	1		
		1	1		
		1	1		
		4	4	7	7
2	2	93	128	181	196
		1	1		
		17	25	31	33
				1	1
		1	1	2	3
				4	4
				1	1
				2	2
		1	1	2	2
		5	5	12	12
		1	2	1	1
		1	2		
		1	1		
				1	1
		1	1		
		1	1	3	4
		1	1		
				1	1
		1	1		
		15	19	1	1
				1	1
		1	1	2	2
		2	2		
			1		
		1	1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral pain	2	2
Oropharyngeal blistering	2	2
Oropharyngeal discomfort	2	2
Oropharyngeal pain	55	62
Oscillopsia	1	1
Overdose	1	3
Oxygen saturation decreased	3	5
Pain	158	179
Painful respiration	1	3
Pain in extremity	210	256
Pain in jaw	12	13
Pain of skin	5	6
Pallor	6	10
Palpitations	42	50
Panic attack	1	1
Papule		1
Paraesthesia	67	78
Paraesthesia oral	39	53
Paralysis	2	2
Parosmia	1	1
Partial seizures	1	1
Penile swelling	1	1
Periarthritis	1	1
Periorbital oedema	1	1
Periorbital swelling	2	2
Peripheral circulatory failure	1	2
Peripheral coldness	11	13
Peripheral sensory neuropathy	1	1
Peripheral swelling	44	47
Peroneal nerve palsy	1	1
Petechiae	2	2
Pharyngeal hypoaesthesia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
				2	2
				2	2
		25	32	30	30
		1	1		
		1	3		
				3	5
		60	74	98	105
		1	2		1
3	3	79	112	131	144
		4	5	8	8
		1	1	4	5
		3	4	3	6
		12	15	30	35
				1	1
			1		
		31	42	36	36
		14	23	25	30
				2	2
				1	1
				1	1
				1	1
		1	1		
				1	1
		1	1	1	1
				1	2
		3	4	8	9
				1	1
		12	14	32	33
				1	1
				2	2
				1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal inflammation	2	2
Pharyngeal oedema	2	2
Pharyngeal paraesthesia	3	3
Pharyngeal swelling	12	14
Pharyngeal ulceration	1	1
Pharyngitis	1	1
Photophobia	14	16
Piloerection	2	2
Pleurisy	1	1
Plicated tongue	1	1
Poisoning	1	1
Polymenorrhoea	2	2
Poor quality sleep	4	5
Post viral fatigue syndrome	2	2
Pre-existing condition improved		1
Presyncope	15	19
Primary cough headache	1	1
Procedural nausea	1	1
Productive cough		1
Product use issue	17	21
Pruritus	72	93
Pulmonary oedema	1	1
Pulmonary pain		1
Pustule	1	1
Pyelonephritis	1	1
Pyrexia	452	502
Radiculopathy	1	1
Rales	1	1
Rash	68	81
Rash erythematous	16	28
Rash macular	12	20
Rash maculo-papular		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				2	2
		1	1	2	2
		4	5	8	9
				1	1
				1	1
		4	5	10	11
		1	1	1	1
				1	1
				1	1
				1	1
		1	1	1	1
		1	2	3	3
				2	2
			1		
		9	11	6	8
				1	1
				1	1
					1
		16	20	1	1
		30	44	42	49
				1	1
					1
				1	1
				1	1
3	3	147	177	305	325
				1	1
				1	1
		29	37	39	44
		6	14	10	14
		7	13	5	7
					1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash morbilliform	1	1
Rash papular	2	4
Rash pruritic	20	23
Rash pustular	1	1
Rash vesicular	1	1
Raynaud's phenomenon	1	1
Reaction to preservatives	1	1
Rectal haemorrhage	1	1
Renal pain	6	6
Respiratory distress	1	1
Respiratory rate increased	2	3
Respiratory tract irritation	1	1
Restless legs syndrome	2	2
Restlessness	5	9
Retching	2	2
Retinal migraine	1	1
Rheumatoid arthritis	1	1
Rhinitis	2	2
Rhinorrhoea	13	14
Salivary gland pain	1	1
Salivary hypersecretion	1	2
SARS-CoV-2 ant body test negative	1	1
SARS-CoV-2 ant body test positive	1	1
SARS-CoV-2 test false positive	1	1
SARS-CoV-2 test positive	4	5
Sciatica	1	1
Secretion discharge	1	1
Sedation	1	1
Seizure	4	4
Sensation of foreign body	2	2
Sensitive skin	1	1
Sensory disturbance	4	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2	1	2
		6	6	14	17
				1	1
		1	1		
				1	1
				1	1
		4	4	2	2
				1	1
			1	2	2
		1	1		
				2	2
		2	4	3	5
				2	2
				1	1
				1	1
				2	2
		7	7	6	7
				1	1
			1	1	1
		1	1		
				4	5
				1	1
				1	1
		1	1		
				4	4
				2	2
		1	1		
		3	3	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensory loss	1	1
Sinonasal obstruction	1	1
Sinus congestion	2	2
Sinus headache	5	5
Sinusitis	1	1
Sinus pain	6	6
Sinus tachycardia	4	5
Skin abrasion	1	1
Skin burning sensation	9	9
Skin discolouration	1	1
Skin disorder	1	1
Skin exfoliation	1	1
Skin irritation	2	2
Skin laceration	1	1
Skin mass	1	1
Skin reaction		1
Skin sensitisation	2	2
Skin tightness	3	4
Skin warm	6	7
Sleep deficit	1	1
Sleep disorder	7	9
Sleep disorder due to a general medical condition	1	1
Sleep disorder due to general medical condition, insomnia type	2	2
Slow response to stimuli	1	1
Sneezing	6	6
Snoring	1	1
Somatic symptom disorder		1
Somnolence	20	23
Spinal disorder	1	1
Spinal pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		1	1	1	1
				5	5
		1	1		
		2	2	4	4
		1	1	3	4
				1	1
		3	3	6	6
		1	1		
		1	1		
				1	1
		2	2		
				1	1
		1	1		
			1		
				2	2
		2	2	1	2
		1	1	5	6
				1	1
		3	5	4	4
				1	1
		1	1	1	1
				1	1
		2	2	4	4
				1	1
					1
		10	12	10	11
		1	1		
				1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sputum purulent		1
Stiff leg syndrome	1	1
Stiff tongue	1	1
Sudden hearing loss	1	1
Superficial injury of eye	1	1
Superficial vein prominence	1	1
Supraventricular tachycardia	1	2
Suspected COVID-19	33	35
Sweating fever	2	2
Swelling	32	37
Swelling face	21	25
Swelling of eyelid		1
Swollen tongue	17	20
Syncope	31	37
Systemic inflammatory response syndrome	1	1
Systemic lupus erythematosus	1	1
Tachycardia	47	58
Tachypnoea	1	1
Taste disorder	5	6
Tearfulness	1	1
Temporomand bular joint syndrome	1	1
Tenderness	7	7
Tension headache	9	10
Therapeutic response unexpected	1	1
Thirst	7	7
Throat clearing	1	1
Throat irritation	4	8
Throat tightness	19	21
Thrombocytopenia	1	1
Thrombosis	1	1
Tinnitus	8	11
Tongue discomfort		2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
					1
				1	1
				1	1
				1	1
		1	1		
				1	2
				33	35
				2	2
		15	18	17	19
		2	3	19	22
					1
		3	4	14	16
				31	37
				1	1
				1	1
		11	17	36	41
				1	1
		4	5	1	1
				1	1
		1	1		
		4	4	3	3
		1	2	8	8
				1	1
		3	3	4	4
				1	1
		1	3	3	5
		3	4	16	17
				1	1
				1	1
		3	6	5	5
			2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue disorder	1	1
Tongue dry		1
Tongue eruption	1	1
Tongue erythema	1	1
Tongue movement disturbance	1	1
Tongue oedema	1	1
Tongue pruritus	1	1
Tongue ulceration	3	3
Tonsillar hypertrophy	1	1
Tonsillitis	2	2
Tonsillitis bacterial	1	1
Toothache	1	1
Torticollis	1	1
Tremor	36	39
Trigeminal neuralgia	1	1
Type IV hypersensitivity reaction	1	2
Urinary incontinence	1	1
Urinary tract infection	1	1
Urticaria	30	35
Vaccination complication	2	3
Vaccination site abscess	1	1
Vaccination site bruising	8	9
Vaccination site cellulitis	3	4
Vaccination site discolouration	2	2
Vaccination site discomfort	2	3
Vaccination site erythema	36	46
Vaccination site haemorrhage	1	1
Vaccination site hypoaesthesia	3	4
Vaccination site induration	5	5
Vaccination site inflammation	3	4
Vaccination site joint movement impairment	3	3
Vaccination site joint pain	2	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
			1		
				1	1
		1	1		
				1	1
		1	1		
				1	1
		1	1	2	2
				1	1
				2	2
				1	1
				1	1
		10	11	26	28
				1	1
				1	2
		1	1		
				1	1
		12	16	18	19
			1	2	2
				1	1
1	1	2	2	6	7
		1	1	2	3
				2	2
		1	2	1	1
		20	24	16	22
				1	1
			1	3	3
		3	3	2	2
		1	2	2	2
		2	2	1	1
		1	2	1	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site lymphadenopathy	2	2
Vaccination site macule	1	1
Vaccination site mass	9	11
Vaccination site movement impairment	6	7
Vaccination site pain	229	276
Vaccination site paraesthesia	2	2
Vaccination site pruritus	11	14
Vaccination site rash	9	13
Vaccination site reaction	7	9
Vaccination site swelling	49	62
Vaccination site urticaria		1
Vaccination site vesicles	2	2
Vaccination site warmth	25	29
Vaginal haemorrhage	3	3
Vein disorder	1	1
Vein rupture	1	1
Ventricular extrasystoles	3	3
Vertigo	11	13
Viral rash	2	2
Vision blurred	18	20
Visual field defect	2	2
Visual impairment	6	7
Vitreous floaters	1	1
Vocal cord disorder	1	1
Vomiting	76	88
Vomiting projectile	1	1
Vulvovaginal candidiasis	1	1
Wheezing	14	16
White blood cell count decreased	1	1
	6	8
	7,190	8,392

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		1	1		
		5	7	4	4
		2	3	4	4
2	2	104	136	125	140
		2	2		
		8	10	3	4
		4	7	5	6
		3	5	4	4
		24	31	25	31
			1		
				2	2
		12	14	13	15
				3	3
				1	1
				1	1
		1	1	2	2
		3	4	8	9
		1	1	1	1
		9	10	9	10
		1	1	1	1
		1	1	5	6
		1	1		
				1	1
1	1	24	35	52	53
				1	1
		1	1		
		4	5	10	11
				1	1
		6	8		
		23	23	2523	3285
				4667	5107

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal discomfort	3	4
Abdominal distension	2	2
Abdominal pain	13	15
Abdominal pain lower	1	1
Abdominal pain upper	11	14
Abdominal tenderness	1	2
Abnormal dreams	2	3
Abnormal sensation in eye	1	1
Ageusia	7	8
Agitation	2	2
Alanine aminotransferase increased	1	1
Allergic cough	1	1
Allergic oedema	1	1
Allergy to vaccine	2	5
Amblyopia	1	1
Anaphylactic reaction	10	11
Anaphylactic shock	1	2
Anaphylactoid reaction	1	2
Angioedema	3	4
Anosmia	5	5
Anxiety	6	10
Aphonia		1
Appetite disorder	1	1
Arrhythmia	1	1
Arrhythmia supraventricular	1	1
Arthralgia	127	147
Arthritis		1
Asthenia	23	25
Asthenopia	1	1
Asthma	2	2
Atrial fibrillation	3	3
Aura	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	2	2	2
				2	2
		6	7	7	8
		1	1		
		1	2	10	12
		1	2		
			1	2	2
				1	1
		2	2	5	6
		1	1	1	1
		1	1		
				1	1
				1	1
		1	4	1	1
		1	1		
				10	11
				1	2
				1	2
				3	4
		4	4	1	1
		2	6	4	4
					1
				1	1
				1	1
		1	1		
		37	49	90	98
			1		
		9	9	14	16
				1	1
		1	1	1	1
				3	3
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Auricular swelling	1	1
Axillary mass	2	2
Axillary pain	6	8
Back pain	24	26
Balance disorder	3	3
Bladder discomfort	1	1
Blister	4	4
Blood alkaline phosphatase increased	1	1
Blood glucose decreased	1	1
Blood glucose increased	1	1
Blood pH increased	1	1
Blood pressure decreased	2	2
Blood pressure increased	7	9
Blood pressure systolic decreased	1	1
Blood pressure systolic increased	1	2
Body temperature abnormal	6	6
Body temperature fluctuation	2	3
Body temperature increased	13	17
Bone pain	6	8
Breast discomfort	1	1
Breast pain	1	1
Breast swelling	1	1
Burning sensation	5	5
Cardiac arrest	2	2
Cardiac flutter	2	2
Cataplexy		1
Cellulitis	6	6
Cerebellar infarction		1
Cerebrovascular accident	1	1
Chapped lips	1	1
Cheilitis	1	1
Chest discomfort	12	14

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	2		
		4	4	2	4
		6	8	18	18
				3	3
		1	1		
		3	3	1	1
		1	1		
				1	1
				1	1
		1	1		
				2	2
		2	3	5	6
				1	1
			1	1	1
		1	1	5	5
			1	2	2
1	1	5	7	8	10
		1	2	5	6
		1	1		
				1	1
		1	1		
		2	2	3	3
				2	2
				2	2
					1
				6	6
					1
				1	1
		1	1		
				1	1
		5	6	7	8

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest pain	20	22
Chills	159	189
Chronic fatigue syndrome		1
Circulatory collapse	4	4
Clostridium difficile colitis	1	1
Cluster headache	1	1
Cold sweat	11	11
Condition aggravated	5	8
Confusional state	2	4
Conjunctival haemorrhage	1	1
Conjunctivitis	1	1
Coronary artery disease	1	1
Cough	28	32
COVID-19	12	13
COVID-19 pneumonia	1	1
Cyanosis	2	2
Death	3	3
Decreased appetite	17	20
Decreased interest	1	1
Dehydration	1	1
Depressed level of consciousness	1	1
Derealisation	1	1
Dermatitis allergic	3	5
Diabetic ketoacidosis		1
Diarrhoea	46	60
Diplopia	1	2
Discoloured vomit	1	1
Discomfort	2	3
Disease recurrence	3	3
Disorientation		2
Disturbance in attention	6	6
Dizziness	80	97

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	7	14	15
		47	69	112	120
			1		
				4	4
				1	1
				1	1
		3	3	8	8
		2	4	3	4
				2	4
				1	1
				1	1
				1	1
		7	10	21	22
				12	13
				1	1
				2	2
				3	3
		6	6	11	14
		1	1		
				1	1
				1	1
				1	1
		2	4	1	1
					1
		15	19	31	41
			1	1	1
		1	1		
		2	2		1
				3	3
			1		1
		1	1	5	5
		21	30	59	67

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dizziness postural	7	9
Drooling	1	1
Drug eruption	1	1
Drug hypersensitivity	1	1
Drug ineffective	27	29
Dry eye	1	2
Dry mouth	5	11
Dry throat	2	2
Dysarthria	2	2
Dysgeusia	9	16
Dyskinesia	1	1
Dyspepsia	2	2
Dysphagia	6	6
Dysphonia	5	5
Dyspnoea	20	25
Dyspnoea exertional	1	1
Dysstasia	3	3
Ear discomfort	1	1
Ear pain	4	5
Eczema	1	1
Emotional distress	1	1
Enlarged uvula	1	1
Enuresis	1	1
Eosinophilia	1	1
Epilepsy		1
Episcleritis	1	1
Epistaxis	1	2
Eructation	1	1
Erythema	17	21
Erythema multiforme	1	1
Exposure during pregnancy	1	1
Eye disorder	3	4

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	3	6	6
				1	1
				1	1
				1	1
				27	29
		1	2		
		2	5	3	6
				2	2
				2	2
		7	13	2	3
				1	1
		2	2		
		2	2	4	4
		1	1	4	4
		4	7	16	18
				1	1
		1	1	2	2
		1	1		
		1	1	3	4
				1	1
		1	1		
		1	1		
				1	1
					1
		1	1		
		1	2		
				1	1
		9	13	8	8
				1	1
		1	1		
		1	2	2	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye injury	1	1
Eye irritation	1	1
Eyelid ptosis		1
Eyelids pruritus	1	1
Eye movement disorder	1	1
Eye pain	6	9
Eye pruritus	4	5
Eye swelling	4	6
Facial discomfort		1
Facial pain	4	4
Facial paralysis	9	10
Facial paresis		1
Facial spasm		1
Fall	2	2
Fatigue	217	263
Feeding disorder	3	3
Feeling abnormal	23	28
Feeling cold	29	32
Feeling drunk	1	1
Feeling hot	16	27
Feeling of body temperature change	6	6
Fixed eruption	1	1
Flushing	6	12
Foreign body sensation in eyes	1	1
Gait disturbance	2	2
Gait inability	2	2
Gastric disorder	2	2
Gastritis		1
Gastrointestinal pain	2	2
Generalised tonic-clonic seizure	1	2
Genital herpes	1	1
Gingival bleeding	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
			1		
		1	1		
				1	1
		1	2	5	7
		1	1	3	4
		1	3	3	3
					1
		2	2	2	2
				9	10
			1		
			1		
		1	1	1	1
1	1	68	99	149	164
		2	2	1	1
		9	12	14	16
		11	12	18	20
				1	1
		6	15	10	12
		1	1	5	5
		1	1		
		3	8	3	4
				1	1
		1	1	1	1
				2	2
		1	1	1	1
			1		
		1	1	1	1
				1	2
				1	1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival pain	2	2
Glossodynia	2	3
Gout	1	1
Grip strength decreased	1	1
Groin pain	2	2
Haematoma	1	1
Hallucination	1	1
Hangover	4	4
Headache	331	388
Head discomfort	3	3
Head injury	1	1
Heart rate abnormal	1	1
Heart rate decreased	1	1
Heart rate increased	10	14
Heart rate irregular	1	1
Heat illness	1	1
Hepatitis	1	1
Herpes virus infection		1
Herpes zoster	6	7
Herpes zoster oticus	1	1
Herpes zoster reactivation	1	1
Hot flush	6	8
Hyperaesthesia	2	2
Hyperhidrosis	24	29
Hypersensitivity	9	14
Hypersomnia	2	3
Hypertension	11	15
Hypertensive crisis	1	1
Hypertonic bladder		1
Hypoacusis	1	1
Hypoaesthesia	11	18
Hypoaesthesia oral	9	11

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		1	1	1	2
				1	1
		1	1		
		2	2		
		1	1		
				1	1
		2	2	2	2
2	2	102	137	229	251
				3	3
				1	1
				1	1
		1	1		
		3	5	7	9
				1	1
				1	1
				1	1
					1
		1	2	5	5
				1	1
				1	1
		4	5	2	3
		2	2		
		6	10	18	19
		3	7	6	7
			1	2	2
		4	6	7	9
				1	1
			1		
		1	1		
		4	11	7	7
		4	6	5	5

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoglycaemia	1	1
Hypokinesia	1	1
Hyposmia	1	1
Hypotension	7	8
Hypothermia	1	1
Hypoxia	1	1
Illness	11	11
Immune-mediated adverse reaction		1
Inappropriate schedule of product administration	2	3
Incorrect route of product administration	3	4
Inflammation	2	2
Influenza	11	12
Influenza like illness	46	49
Initial insomnia	1	1
Injection site pain	2	2
Injury corneal	1	1
Insomnia	16	17
Intraocular pressure increased	1	1
Iridocyclitis	1	1
Irritability	1	1
Ischaemic stroke		1
Joint noise	1	1
Joint range of motion decreased	4	5
Joint stiffness	3	3
Joint swelling	4	6
Labyrinthitis	3	4
Lacrimation increased	1	1
Lethargy	29	36
Ligament sprain	1	1
Limb discomfort	10	13
Lip blister		1
Lip disorder		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
				1	1
		1	1	6	7
				1	1
				1	1
		2	2	9	9
			1		
		2	2		1
		3	4		
		2	2		
		3	4	8	8
		20	21	26	28
		1	1		
		1	1	1	1
				1	1
		7	7	9	10
				1	1
				1	1
					1
				1	1
		1	2	3	3
				3	3
		1	2	3	4
		1	1	2	3
		1	1		
		8	11	21	25
				1	1
		6	8	4	5
					1
			1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip pruritus	1	1
Lip swelling	7	11
Liver function test increased	1	1
Liver injury	1	1
Local reaction	3	4
Loss of consciousness	3	3
Lymphadenopathy	54	62
Lymph node pain	18	20
Malaise	97	118
Mass	1	1
Mastication disorder	1	1
Medication overuse headache	1	1
Menopausal symptoms	1	1
Mental impairment	2	2
Micturition disorder	1	1
Middle insomnia	2	2
Migraine	23	24
Migraine with aura		1
Mobility decreased	6	6
Motion sickness	1	1
Mouth swelling	3	3
Mouth ulceration	2	2
Movement disorder	1	1
Muscle contractions involuntary	1	1
Muscle fatigue	1	1
Muscle spasms	5	6
Muscle strain	1	1
Muscle swelling	1	1
Muscle tightness		1
Muscle twitching	1	2
Muscular weakness	10	11
Musculoskeletal discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	4	6	7
		1	1		
				1	1
		1	2	2	2
				3	3
		28	30	26	32
		6	6	12	14
		24	37	73	81
		1	1		
				1	1
				1	1
		1	1		
				2	2
				1	1
		1	1	1	1
		6	7	17	17
			1		
		3	3	3	3
		1	1		
				3	3
		1	1	1	1
		1	1		
				1	1
				1	1
					1
		1	2		
		2	3	8	8
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Musculoskeletal pain	4	4
Musculoskeletal stiffness	24	27
Myalgia	158	195
Myocardial infarction	1	1
Myocarditis	1	1
Myofascial pain syndrome		1
Nail discolouration	1	1
Nasal congestion	1	1
Nasal discomfort		1
Nasal obstruction	1	1
Nasal odour	1	1
Nasal pruritus	1	1
Nasopharyngitis	9	9
Nausea	164	202
Neck mass	1	1
Neck pain	23	28
Nervousness	1	2
Neuralgia	1	2
Nightmare	1	1
Night sweats	4	5
Occupational exposure to SARS-CoV-2	1	1
Ocular hyperaemia	3	3
Oedema	1	1
Oedema mouth	1	1
Off label use	4	7
Oral blood blister	1	1
Oral candidiasis	1	1
Oral discomfort		1
Oral herpes	1	3
Oral mucosal erythema	1	1
Oral pain	2	2
Oropharyngeal pain	22	28

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	3	3
		7	9	17	18
1	1	43	66	115	129
				1	1
			1		
				1	1
		1	1		
			1		
				1	1
		1	1		
		1	1		
		3	3	6	6
		47	74	117	128
				1	1
		11	15	12	13
				1	2
		1	1		1
		1	1		
		2	3	2	2
		1	1		
				3	3
		1	1		
				1	1
		4	7		
				1	1
		1	1		
					1
				1	3
				1	1
				2	2
		8	10	14	18

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orthostatic hypotension	1	1
Osteoarthritis	1	1
Oxygen saturation decreased	2	2
Pain	82	96
Pain in extremity	127	149
Pain in jaw	2	2
Pain of skin	1	1
Pallor	4	5
Palpitations	13	20
Panic disorder	1	1
Paraesthesia	26	35
Paraesthesia oral	24	32
Paralysis	1	1
Paranoia	1	1
Parosmia	1	1
Parotid gland enlargement	1	1
Parotitis	1	1
Periarthritis	1	1
Periorbital swelling		2
Peripheral coldness	3	5
Peripheral swelling	18	24
Pharyngeal disorder	1	1
Pharyngeal hypoaesthesia		1
Pharyngeal paraesthesia	1	2
Pharyngeal swelling	2	2
Pharyngitis streptococcal	1	1
Photophobia	1	3
Photopsia		1
Piloerection		1
Pleuritic pain	1	1
Pneumonia		1
Polymyalgia rheumatica	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
				2	2
		27	36	55	60
		51	67	76	82
		2	2		
				1	1
		1	2	3	3
		3	8	10	12
				1	1
		12	20	14	15
		11	18	13	14
				1	1
				1	1
		1	1		
		1	1		
		1	1		
				1	1
			2		
		1	2	2	3
		7	12	11	12
				1	1
			1		
				1	2
		1	1	1	1
				1	1
				1	3
			1		
					1
				1	1
					1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Poor quality sleep	2	2
Post lumbar puncture syndrome	1	1
Presyncope	7	8
Proctitis ulcerative	1	1
Product administered at inappropriate site	1	1
Productive cough	1	1
Product use issue	5	8
Pruritus	27	33
Pseudolymphoma	1	1
Psoriatic arthropathy	1	1
Pulmonary embolism	1	1
Pulmonary pain	1	1
Pyrexia	193	229
Rash	27	33
Rash erythematous	10	12
Rash macular	8	8
Rash maculo-papular	1	1
Rash papular	2	5
Rash pruritic	8	8
Rash vesicular	1	1
Rectal haemorrhage	1	1
Renal pain	1	1
Respiration abnormal		1
Respiratory disorder	3	4
Respiratory rate increased	3	3
Restlessness	2	4
Retching	3	4
Rheumatoid arthritis	1	1
Rhinitis	1	1
Rhinitis allergic	1	1
Rhinorrhoea	4	4
Sacroiliitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
				1	1
		3	3	4	5
				1	1
				1	1
		5	8		
		15	18	12	15
				1	1
				1	1
				1	1
		56	76	137	153
		11	16	16	17
		4	5	6	7
		5	5	3	3
		1	1		
		1	4	1	1
		3	3	5	5
				1	1
				1	1
				1	1
			1		
			1	3	3
				3	3
		2	2		2
			1	3	3
				1	1
		1	1		
				1	1
		3	3	1	1
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Salivary hypersecretion	2	4
SARS-CoV-2 test positive	2	2
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain		1
Scrotal swelling		1
Seizure	2	2
Sensitive skin	2	2
Sensory disturbance	2	4
Sepsis	1	1
Sinus headache		1
Sinus pain	2	2
Sinus tachycardia		1
Sjogren's syndrome		1
Skin burning sensation	2	2
Skin discolouration	1	1
Skin exfoliation	1	1
Skin induration	1	1
Skin lesion	2	2
Skin reaction	1	1
Skin swelling	1	1
Skin tightness	1	1
Skin warm	7	7
Sleep attacks	1	1
Sleep disorder	8	9
Sleep disorder due to a general medical condition	1	1
Sleep disorder due to general medical condition, insomnia type	1	1
Sneezing	6	7
Somnolence	16	18
Speech disorder	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	2	2
				2	2
					1
					1
					1
				2	2
				2	2
		2	3		1
				1	1
			1		
		1	1	1	1
			1		
					1
				2	2
				1	1
				1	1
		1	1		
		2	2		
				1	1
				1	1
				1	1
		3	3	4	4
				1	1
		6	7	2	2
				1	1
		1	1		
		6	7		
		5	6	11	12
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Spinal pain	1	1
Stoma site discharge		1
Stomatitis	1	1
Submaxillary gland enlargement	1	1
Supraventricular tachycardia	2	3
Suspected COVID-19	14	15
Sweating fever	1	1
Swelling	13	13
Swelling face	8	10
Swelling of eyelid	1	3
Swollen tongue	14	15
Syncope	15	17
Tachycardia	11	19
Tachypnoea	1	1
Taste disorder	5	5
Temperature regulation disorder	1	1
Tenderness	5	5
Tendon injury	1	1
Tension	1	1
Tension headache	4	4
Thinking abnormal	1	1
Thirst	4	4
Throat clearing	1	1
Throat irritation	3	3
Throat tightness	5	6
Tinnitus	5	7
Tongue discomfort	1	1
Tonsillar inflammation	1	1
Tonsillitis	1	1
Toothache	2	2
Toxic skin eruption	1	1
Tremor	19	22

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
		1	1		
		1	1		
		1	1	1	2
		1	1	13	14
				1	1
		4	4	9	9
		3	4	5	6
		1	3		
		3	4	11	11
				15	17
			7	11	12
				1	1
		3	3	2	2
				1	1
		5	5		
				1	1
				1	1
		1	1	3	3
				1	1
		2	2	2	2
				1	1
		1	1	2	2
		1	2	4	4
		4	4	1	3
				1	1
		1	1		
		1	1		
		1	1	1	1
				1	1
		4	5	15	17

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tri-iodothyronine decreased	1	1
Underdose	1	2
Unresponsive to stimuli	2	2
Upper respiratory tract congestion	1	1
Urinary incontinence	1	1
Urinary tract infection	2	2
Urticaria	6	7
Vaccination site bruising	3	3
Vaccination site cellulitis	2	2
Vaccination site discomfort	5	5
Vaccination site erythema	31	36
Vaccination site haematoma	1	1
Vaccination site hyperaesthesia	1	1
Vaccination site hypoaesthesia	1	1
Vaccination site induration	2	3
Vaccination site infection	1	1
Vaccination site inflammation	3	3
Vaccination site joint movement impairment	1	1
Vaccination site joint pain	1	1
Vaccination site mass	2	3
Vaccination site movement impairment	1	3
Vaccination site oedema	1	1
Vaccination site pain	117	144
Vaccination site paraesthesia	2	2
Vaccination site pruritus	12	12
Vaccination site rash	2	2
Vaccination site reaction	1	2
Vaccination site swelling	30	40
Vaccination site urticaria	1	1
Vaccination site warmth	16	20
Varicose vein	1	1
Vasculitic rash	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	2		
				2	2
				1	1
				1	1
				2	2
		3	4	3	3
		2	2	1	1
				2	2
		3	3	2	2
		20	24	11	12
				1	1
		1	1		
				1	1
		2	3		
				1	1
		2	2	1	1
				1	1
				1	1
				2	3
			1	1	2
				1	1
2	2	47	66	70	78
				2	2
		7	7	5	5
		1	1	1	1
			1	1	1
		16	23	14	17
				1	1
		10	13	6	7
		1	1		
				1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vasodilatation	1	1
Vena cava thrombosis	1	1
Ventricular f brillation	1	1
Vertigo	11	12
Vertigo positional	1	1
Vestibular migraine	1	1
Vestibular neuronitis	1	2
Viral rash	1	1
Viral upper respiratory tract infection	1	1
Vision blurred	8	9
Visual brightness	1	1
Visual impairment	1	1
Vitreous floaters		1
Vomiting	43	49
Vulvovaginal candidiasis	1	1
Vulvovaginal pruritus	1	1
Wheezing	4	6
	2	2
	3,722	4,486

Non Interventional Study		Spontaneous					
Serious		Nonserious		Serious			
I	C	I	C	I	C		
				1	1		
				1	1		
				1	1		
		1	2	10	10		
				1	1		
				1	1		
				1	2		
				1	1		
				1	1		
				8	9		
		1	1				
				1	1		
			1				
		15	18	28	31		
				1	1		
		1	1				
			2	4	4		
		2	2				
		7	7	1225	1702	2497	2784

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal distension	1	2			1	2
Abdominal pain	3	3			3	3
Abdominal pain upper	4	5			4	5
Accidental overdose	1	1	1	1		
Adverse drug reaction	1	1			1	1
Ageusia		1		1		
Agitation	1	1			1	1
Alanine aminotransferase increased	1	1			1	1
Allergy to vaccine	1	2		1	1	1
Anaphylactic reaction	1	1			1	1
Angina pectoris	1	1			1	1
Angioedema	1	1			1	1
Anosmia		1		1		
Anxiety	2	2			2	2
Aphasia	1	1			1	1
Arthralgia	14	15	2	2	12	13
Asthenia	7	7	2	2	5	5
Asthma	3	3			3	3
Atrial f brillation	1	1			1	1
Back pain	1	1			1	1
Balance disorder	1	1			1	1
Blood glucose increased	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Body temperature abnormal	1	1			1	1
Body temperature increased	3	3	2	2	1	1
Bradycardia	2	2			2	2
Bundle branch block right	1	1	1	1		
Cardiac arrest	4	4			4	4
Cardiac flutter	1	1			1	1
Cerebrovascular accident	2	2			2	2
Chest discomfort	2	2			2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest pain	3	3
Chills	20	22
Chromaturia	1	1
Circulatory collapse	2	2
Circumstance or information capable of leading to medication error		1
Communication disorder	1	1
Confusional state	1	1
Cough	7	9
COVID-19	6	6
Cyanosis	1	1
Death	8	8
Decreased appetite	5	5
Defaecation urgency	1	1
Delirium	2	2
Depressed mood		1
Depression	2	2
Diarrhoea	12	13
Discomfort	1	1
Disturbance in attention	1	1
Dizziness	17	20
Dizziness postural	2	2
Drug ineffective	10	10
Dry mouth	3	3
Dry skin	1	1
Dysgeusia	1	1
Dysmenorrhoea	1	1
Dyspnoea	8	9
Dyspnoea exertional		1
Eating disorder	1	1
Epilepsy	1	1
Epistaxis	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		3	3
2	4	18	18
		1	1
		2	2
	1		
		1	1
		1	1
4	6	3	3
		6	6
1	1		
		8	8
2	2	3	3
		1	1
		2	2
	1		
		2	2
3	3	9	10
1	1		
1	1		
4	7	13	13
1	1	1	1
		10	10
2	2	1	1
1	1		
		1	1
1	1		
1	2	7	7
	1		
		1	1
		1	1
		2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Erythema	4	6
Eye pain	1	1
Facial pain	1	1
Facial paralysis	1	1
Faeces discoloured	1	1
Fall	1	1
Fatigue	37	40
Feeling abnormal	2	2
Feeling cold	3	3
Feeling hot	3	5
Flank pain	1	1
Gait disturbance	2	2
Gamma-glutamyltransferase increased	1	1
Glossodynia	1	1
Headache	39	44
Heart rate increased	3	3
Hemiparesis	1	1
Herpes zoster		1
Hot flush	2	2
Hyperglycaemia	1	1
Hyperhidrosis	4	4
Hypersensitivity	1	1
Hypersomnia	1	1
Hypertension	2	2
Hypoaesthesia	3	3
Hypoaesthesia oral	1	1
Hyponatraemia	1	1
Hypotension	2	2
Hypothermia	1	1
Hypotonia	1	1
Illness	1	1
Immune system disorder	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3	3	3
1	1		
		1	1
		1	1
		1	1
7	9	30	31
		2	2
1	1	2	2
	2	3	3
1	1		
1	1	1	1
		1	1
1	1		
7	11	32	33
2	2	1	1
		1	1
	1		
		2	2
		1	1
		1	1
		1	1
		2	2
3	3		
1	1		
		1	1
		2	2
		1	1
		1	1
1	1		
		1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Inappropriate schedule of product administration	1	1
Incoherent	1	1
Incorrect route of product administration	2	2
Inflammation	1	1
Inflammatory marker increased	1	1
Influenza	1	1
Influenza like illness	11	11
Injection site pain	1	2
Jaundice	1	1
Joint stiffness	1	1
Joint swelling	2	2
Lacrimation increased	1	1
Lethargy	3	3
Limb discomfort	1	1
Lip swelling	1	2
Loss of consciousness	2	2
Loss of personal independence in daily activities	1	1
Lower respiratory tract infection	2	2
Lymphadenopathy	9	9
Lymph node pain	2	2
Malaise	14	15
Metamorphopsia	1	1
Migraine	2	2
Mobility decreased	3	3
Multiple sclerosis	1	1
Muscle rigidity	1	1
Muscle spasms	1	1
Muscle tone disorder	1	1
Muscular weakness	2	2
Musculoskeletal pain	1	1
Musculoskeletal stiffness	1	1
Myalgia	18	22

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
2	2		
		1	1
		1	1
		1	1
2	2	9	9
1	1		1
		1	1
		1	1
1	1	1	1
		1	1
		3	3
1	1		
		1	2
		2	2
1	1		
		2	2
4	4	5	5
1	1	1	1
6	7	8	8
		1	1
1	1	1	1
1	1	2	2
		1	1
		1	1
		1	1
		2	2
		1	1
		1	1
4	6	14	16

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myocardial infarction	1	1
Nasal congestion	1	1
Nasopharyngitis	1	1
Nausea	32	36
Neck pain	3	3
Negative thoughts	1	1
Nervousness	1	1
Nightmare	1	1
Off label use	3	3
Oral candidiasis	1	1
Oral papule	1	1
Oropharyngeal pain	7	7
Overdose	3	3
Oxygen saturation decreased	1	1
Pain	11	11
Pain in extremity	22	23
Pain in jaw	1	1
Pallor	2	2
Paraesthesia	2	2
Paralysis	1	1
Peripheral coldness	1	1
Peripheral swelling	3	3
Poor peripheral circulation	1	1
Poor quality sleep	1	1
Pre-existing condition improved	1	1
Presyncope	1	1
Primary headache associated with sexual activity	1	1
Product preparation issue	2	2
Product use issue	3	3
Pruritus	3	3
Pulseless electrical activity	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
1	1		
9	12	23	24
1	1	2	2
		1	1
1	1		
1	1		
2	2	1	1
		1	1
		1	1
3	3	4	4
3	3		
		1	1
4	4	7	7
6	7	16	16
		1	1
		2	2
1	1	1	1
		1	1
1	1		
1	1		
		1	1
		1	1
2	2		
2	2	1	1
1	1	2	2
		1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pyrexia	27	30
Rash	1	1
Rash erythematous		1
Rash pruritic	2	2
Respiration abnormal	1	1
Respiratory arrest	2	2
Restlessness	1	1
Rhinorrhoea	1	1
SARS-CoV-2 ant body test negative	1	1
SARS-CoV-2 test positive	1	1
Seizure	2	2
Sinusitis	1	1
Skin mass		1
Sleep disorder	1	1
Speech disorder	1	1
Spinal pain	1	1
Suspected COVID-19	3	3
Swelling	1	1
Swelling face	1	1
Swollen tongue	2	3
Tachycardia	1	1
Tenderness	1	1
Tension headache	1	1
Therapeutic response unexpected	1	1
Thirst	1	1
Throat tightness	1	1
Thrombocytopenia	2	2
Tremor	4	4
Unresponsive to stimuli	3	3
Urinary retention	1	1
Vaccination site bruising	2	2
Vaccination site discolouration	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	6	22	24
1	1		
	1		
1	1	1	1
		1	1
		2	2
1	1		
1	1		
1	1		
		1	1
		2	2
		1	1
	1		
1	1		
		1	1
		1	1
		3	3
		1	1
		1	1
1	1	1	2
		1	1
		1	1
1	1		
		1	1
		2	2
2	2	2	2
		3	3
		1	1
1	1	1	1
		1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	2	2			2	2
Vaccination site infection	1	1			1	1
Vaccination site mass	2	2	1	1	1	1
Vaccination site pain	14	18	4	8	10	10
Vaccination site reaction	1	1			1	1
Vaccination site swelling	1	2	1	2		
Vaccination site warmth	2	2			2	2
Vertigo	1	1			1	1
Vision blurred	1	1			1	1
Visual impairment	2	2			2	2
Vomiting	10	13	3	5	7	8
Vomiting psychogenic	1	1			1	1
Wheezing	1	1			1	1
Writer's cramp	1	1			1	1
	624	681	154	196	470	485

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions	1	1					1	1
Abdominal discomfort	2	2					2	2
Abdominal distension	1	1					1	1
Abdominal pain	7	8			2	3	5	5
Abdominal pain lower	2	2					2	2
Abdominal pain upper	6	6			3	3	3	3
Abnormal dreams	1	1			1	1		
Acidosis	2	2			1	1	1	1
Acute cardiac event	1	1					1	1
Acute kidney injury	5	5					5	5
Acute myocardial infarction	3	5					3	5
Acute pulmonary oedema	1	1					1	1
Acute respiratory failure	1	1					1	1
Age-related macular degeneration	1	1					1	1
Ageusia	3	3			1	1	2	2
Agitation	5	5			2	2	3	3
Alanine aminotransferase increased	1	1					1	1
Allergy to vaccine	2	2			2	2		
Altered state of consciousness	1	1					1	1
Anal incontinence	1	1					1	1
Anaphylactic reaction	5	5					5	5
Angioedema	3	5					3	5
Ankylosing spondylitis	1	1					1	1
Anosmia	1	1			1	1		
Anxiety	1	1					1	1
Aortic aneurysm rupture	1	1					1	1
Apathy	1	1					1	1
Aphasia	1	1					1	1
Aphonia	1	1					1	1
Arrhythmia		1						1
Arthralgia	37	38			8	8	29	30
Arthritis	5	5			1	1	4	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropathy	1	1
Aspiration	1	1
Asthenia	28	32
Asymptomatic COVID-19	1	1
Atrial fibrillation	9	11
Back pain	11	11
Balance disorder	11	13
Bedridden	2	2
Bile duct stone	1	1
Biliary sepsis	1	1
Bite	1	1
Bladder pain	1	1
Blindness	2	2
Blood alkaline phosphatase increased	1	1
Blood creatine phosphokinase increased	2	2
Blood electrolytes increased	1	1
Blood glucose increased	5	5
Blood lactic acid increased	2	2
Blood pressure decreased	2	2
Blood pressure increased	3	5
Blood pressure orthostatic abnormal	1	1
Blood pressure systolic increased	1	1
Blood sodium decreased	1	1
Blood urea increased	1	1
Body temperature abnormal	2	2
Body temperature decreased	1	1
Body temperature fluctuation	1	1
Body temperature increased	1	1
Bone pain	1	1
Bradycardia	1	1
Breath odour	1	1
Burning sensation	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		7	8	21	24
				1	1
				9	11
		3	3	8	8
1	1	3	3	8	10
				2	2
				1	1
				1	1
				1	1
				1	1
				1	1
				2	2
				1	1
		1	1	1	1
		1	1		
		2	2	3	3
		1	1	1	1
				2	2
		2	4	1	1
				1	1
				1	1
		1	1		
		1	1		
		1	1	1	1
				1	1
				1	1
				1	1
				1	1
		1	1		
				2	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cardiac arrest	8	10
Cardiac failure	2	2
Cardiac failure congestive	1	1
Cardiopulmonary failure	1	1
Cardio-respiratory arrest	1	1
Cellulitis	1	1
Central vision loss	1	1
Cerebellar infarction	1	1
Cerebellar stroke	1	1
Cerebral haemorrhage	2	2
Cerebral infarction	1	1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	14	16
Chest discomfort	5	5
Chest pain	11	14
Chills	53	55
Chromaturia	2	2
Circulatory collapse	8	8
Clinical death	1	1
Cognitive disorder	3	3
Cold sweat	3	5
Colitis ulcerative	1	1
Coma scale abnormal	2	2
Condition aggravated	5	5
Confusional state	21	21
Conjunctival haemorrhage	1	2
Constipation	1	1
Contusion	2	3
Coronary artery disease	1	1
Cough	16	17
COVID-19	23	23
COVID-19 pneumonia	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				8	10
				2	2
				1	1
				1	1
				1	1
				1	1
				1	1
				1	1
				1	1
				2	2
				1	1
				1	1
				14	16
		2	2	3	3
		3	4	8	10
		10	11	43	44
				2	2
				8	8
				1	1
				3	3
		1	1	2	4
				1	1
				2	2
				5	5
		6	6	15	15
				1	2
				1	1
				2	3
				1	1
		8	9	8	8
				23	23
				2	2

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
C-reactive protein increased	2	2
Crying	1	1
Culture negative	1	1
Cyanosis	1	1
Cystitis	1	1
Deafness	2	2
Death	37	37
Decreased appetite	31	31
Decreased interest	1	1
Deep vein thrombosis	4	4
Dehydration	4	4
Delirium	5	5
Dementia	2	2
Depressed level of consciousness	2	2
Depression	1	1
Dermatitis	2	2
Dermatitis allergic		1
Dermatitis bullous	1	1
Diabetes mellitus inadequate control	1	1
Diarrhoea	38	47
Diplopia	1	1
Discomfort	2	2
Disorientation	2	2
Disturbance in attention	1	2
Dizziness	40	47
Dizziness postural	5	6
Drug hypersensitivity	1	1
Drug ineffective	34	34
Dry mouth	2	2
Dry skin	1	1
Dry throat	1	1
Dysarthria	6	6

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
				1	1
				1	1
				1	1
				2	2
				37	37
		5	5	26	26
				1	1
				4	4
		1	1	3	3
				5	5
				2	2
				2	2
				1	1
		1	1	1	1
					1
				1	1
		3	9	35	38
		1	1		
				2	2
				2	2
			1	1	1
		9	11	31	36
			1	5	5
		1	1		
				34	34
				2	2
		1	1		
				1	1
				6	6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysgeusia	3	3
Dysphagia	3	4
Dysphonia	1	1
Dyspnoea	32	38
Dyspnoea exertional	1	2
Dysstasia	2	2
Electrocardiogram ST segment abnormal	1	1
Electrocardiogram ST segment elevation	1	1
Enteritis		1
Enuresis	1	1
Epilepsy	1	1
Epistaxis	2	3
Eructation	2	2
Erythema	11	12
Expired product administered		1
Eye allergy	1	1
Eye disorder	2	2
Eye infection	1	1
Eye pain	2	2
Eye pruritus	1	2
Eye swelling	5	5
Facial discomfort	1	1
Facial pain	2	2
Facial paralysis	7	7
Facial paresis	1	1
Faeces discoloured		1
Faeces pale	1	1
Fall	19	19
Fatigue	88	99
Fear	1	2
Feeding disorder	2	2
Feeling abnormal	7	7

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
		1	1	2	3
		1	1		
		7	8	25	30
			1	1	1
		1	1	1	1
				1	1
			1		
		1	1		
				1	1
		1	1		
				1	1
		1	1		
				2	2
		4	5	7	7
			1		
				1	1
				2	2
				1	1
				2	2
			1	1	1
		2	2	3	3
				1	1
				2	2
				7	7
				1	1
			1		
				1	1
		2	2	17	17
1	1	17	23	71	76
				1	2
		2	2		
1	1	3	3	4	4

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling cold	14	14
Feeling drunk	1	1
Feeling hot	7	9
Feeling of body temperature change	5	5
Fibrin D dimer increased	1	1
Flatulence	1	1
Fluid intake reduced	1	1
Flushing	2	3
Folliculitis	1	1
Frequent bowel movements	1	1
Gait disturbance	7	7
Gait inability	2	2
Gastritis	1	1
Gastroenteritis	1	2
Gastroenteritis viral	1	1
Gastrointestinal disorder	1	1
Gastrointestinal pain	1	2
Generalised tonic-clonic seizure	1	1
General physical health deterioration	1	1
Gingival pain	1	1
Glassy eyes	1	1
Glossodynia	1	1
Grip strength decreased	1	1
Groin pain	1	1
Guillain-Barre syndrome	1	1
Haematemesis	3	3
Haemoglobin decreased	1	1
Haemorrhage intracranial	2	2
Haemorrhagic stroke	2	2
Hallucination	8	8
Hallucination, visual	4	4
Hand-eye coordination impaired	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	4	10	10
				1	1
		3	5	4	4
		1	1	4	4
				1	1
				1	1
		2	2		1
				1	1
				1	1
		2	2	5	5
				2	2
				1	1
			1	1	1
				1	1
		1	1		
				1	2
				1	1
				1	1
		1	1		
				1	1
				1	1
		1	1		
		1	1		
				1	1
				3	3
		1	1		
				2	2
				2	2
				8	8
				4	4
				1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Headache	63	68
Head injury	1	1
Heart rate decreased	3	3
Heart rate increased	5	6
Hemiparesis	6	8
Hepatic artery embolism	1	1
Hepatic enzyme increased	1	1
Herpes zoster	2	2
Hot flush	1	1
Hyperacusis	1	1
Hyperhidrosis	13	13
Hyperpyrexia	1	1
Hypersensitivity	5	6
Hypersensitivity pneumonitis	1	1
Hypersomnia	4	4
Hypertension	4	4
Hypertonia	1	1
Hypoacusis	1	1
Hypoaesthesia	3	4
Hypoglycaemia	2	2
Hypokinesia	1	1
Hyponatraemia	1	1
Hypophagia	2	2
Hypopnoea	1	1
Hyporeflexia	1	1
Hypotension	8	10
Hypothermia	3	3
Hypoxia	3	3
Ill-defined disorder	1	1
Illness	11	11
Immobile	1	1
Inappropriate schedule of product administration	5	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		9	12	54	56
				1	1
				3	3
		1	1	4	5
				6	8
				1	1
		1	1		
				2	2
				1	1
				1	1
		2	2	11	11
				1	1
		1	1	4	5
				1	1
				4	4
				4	4
				1	1
		1	1		
				3	4
		1	1	1	1
				1	1
				1	1
				2	2
				1	1
				1	1
		1	2	7	8
				3	3
				3	3
				1	1
		4	4	7	7
				1	1
		5	5		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incontinence	1	1
Incorrect route of product administration	4	5
Infarction	1	1
Infection	4	4
Influenza	1	1
Influenza like illness	24	26
Inguinal mass	1	1
Insomnia	12	12
International normalised ratio increased	4	4
Ischaemic stroke	5	6
Joint effusion	1	1
Joint lock	1	1
Joint stiffness	3	3
Joint swelling	3	3
Lacrimation increased	1	1
Lacunar infarction	1	1
Lethargy	14	14
Leukaemia	1	1
Limb discomfort	4	4
Limb mass	1	1
Lip pain		1
Lip swelling	6	7
Livedo reticularis	1	1
Liver function test increased	1	1
Local reaction	1	1
Loss of consciousness	14	14
Loss of personal independence in daily activities	3	3
Lower limb fracture	1	1
Lower respiratory tract infection	7	7
Lung consolidation	1	1
Lung opacity	1	1
Lymphadenopathy	7	8

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		4	5		
				1	1
				4	4
				1	1
		4	5	20	21
				1	1
		5	5	7	7
				4	4
				5	6
				1	1
				1	1
		1	1	2	2
				3	3
		1	1		
				1	1
		4	4	10	10
				1	1
		2	2	2	2
		1	1		
			1		
		3	3	3	4
				1	1
				1	1
				1	1
				14	14
				3	3
				1	1
				7	7
				1	1
				1	1
		1	2	6	6

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymph node pain	1	1
Malaise	66	73
Mastication disorder	1	1
Melaena	1	1
Memory impairment	2	2
Mental fatigue	2	2
Mental impairment	1	1
Middle insomnia	1	1
Migraine	1	1
Migraine with aura	1	1
Miliaria	1	1
Mobility decreased	8	9
Monoplegia	1	1
Motion sickness	1	1
Mouth swelling		1
Mouth ulceration	1	1
Movement disorder	1	1
Multiple organ dysfunction syndrome	2	2
Muscle fatigue	2	2
Muscle rigidity	2	2
Muscle spasms	2	2
Muscle strain	1	1
Muscle twitching	2	2
Muscular weakness	12	13
Musculoskeletal chest pain	4	4
Musculoskeletal discomfort	1	1
Musculoskeletal stiffness	6	7
Myalgia	34	39
Myelitis	1	1
Myocardial infarction	10	11
Myocardial ischaemia	1	1
Narcolepsy	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		20	21	46	52
				1	1
				1	1
				2	2
		1	1	1	1
				1	1
				1	1
		1	1		
		4	4	4	5
				1	1
		1	1		
			1		
				1	1
				1	1
				2	2
				2	2
				2	2
		2	2		
				1	1
		1	1	1	1
		2	2	10	11
		1	1	3	3
		1	1		
		1	2	5	5
		9	12	25	27
				1	1
				10	11
				1	1
				1	1

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Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nasopharyngitis	2	2
Nausea	66	74
Neck pain	7	7
Nervousness	1	1
Night sweats	2	2
No adverse event	1	1
Nocturia	1	1
Obsessive-compulsive symptom	1	1
Ocular hyperaemia	1	1
Oedema	2	2
Oedema peripheral	1	1
Off label use	6	7
Oral mucosal blistering	1	1
Oral mucosal eruption	1	1
Oropharyngeal pain	7	7
Orthopnoea	1	1
Orthostatic hypotension	1	1
Oxygen saturation decreased	7	9
Pain	25	25
Pain in extremity	36	45
Pallor	4	6
Palpitations	2	2
Pancytopenia	1	1
Panic attack	1	1
Paraesthesia	9	10
Paraesthesia oral	1	4
Paralysis	2	2
Parotitis	2	2
Pericarditis	1	1
Periorbital swelling	1	1
Peripheral coldness	4	4
Peripheral ischaemia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
1	1	11	19	55	55
		3	3	4	4
		1	1		
		1	1	1	1
		1	1		
		1	1		
				1	1
				1	1
				2	2
				1	1
		6	7		
		1	1		
		1	1		
		1	1	6	6
		1	1		
				1	1
			1	7	8
		8	8	17	17
		12	19	24	26
				4	6
				2	2
				1	1
				1	1
		4	4	5	6
		1	4		
				2	2
				2	2
				1	1
		1	1		
				4	4
				1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Peripheral swelling	10	12
Petechiae	1	1
Petit mal epilepsy	2	2
Pharyngeal erythema	1	1
Pharyngeal inflammation	1	1
Pharyngeal oedema	1	1
Pharyngeal swelling	2	2
Photophobia	1	1
Pleural effusion	1	1
Pleuritic pain	1	1
Pneumonia	4	5
Pneumonia aspiration	3	3
Pneumonitis	1	1
Pollakiuria	1	1
Polyuria	1	1
Poor quality sleep	2	2
Posterior revers ble encephalopathy syndrome	1	1
Postoperative ileus	1	1
Posture abnormal	1	1
Presyncope	4	4
Primary cough headache	1	1
Productive cough	3	3
Product use issue	6	7
Prostatomegaly	1	1
Pruritus	16	21
Psoriasis	1	1
Psychotic behaviour	1	1
Pulmonary oedema	1	1
Pulse abnormal	1	1
Purpura	1	1
Pyrexia	67	70
Rash	15	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	4	8	8
				1	1
				2	2
				1	1
				1	1
		1	1	1	1
				1	1
				1	1
				4	5
				3	3
				1	1
		1	1		
		1	1		
		1	1	1	1
				1	1
				1	1
		1	1	3	3
				1	1
				3	3
		6	7		
		1	1		
		7	10	9	11
				1	1
				1	1
				1	1
		1	1		
		14	16	53	54
		10	11	5	6

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash erythematous	4	4
Rash macular	7	7
Rash maculo-papular	1	1
Rash papular	1	1
Rash pruritic	3	3
Rash vesicular	2	2
Red blood cell sedimentation rate increased	1	1
Regurgitation	1	1
Renal failure	1	1
Renal pain	1	1
Respiration abnormal		1
Respiratory rate increased	1	1
Restlessness	1	1
Retching	4	4
Rhabdomyolysis	1	1
Right ventricular enlargement	1	1
SARS-CoV-2 test positive	2	2
Sciatica	1	1
Seizure	7	7
Sensory disturbance	1	1
Sepsis	4	4
Severe acute respiratory syndrome	1	1
Sinus headache	1	1
Skin cancer	1	1
Skin discolouration	3	3
Skin erosion	2	2
Skin exfoliation	4	4
Skin irritation	2	2
Skin mass	1	1
Skin ulcer	1	1
Skin warm	2	2
Skin weeping	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3	1	1
		5	5	2	2
				1	1
		1	1		
		2	2	1	1
				2	2
				1	1
				1	1
				1	1
					1
				1	1
				1	1
		2	2	2	2
				1	1
		1	1		
				2	2
				1	1
				7	7
		1	1		
				4	4
				1	1
				1	1
		2	2	1	1
		1	1	1	1
		1	1	3	3
				2	2
				1	1
				1	1
		2	2		
				1	1

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Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sleep attacks	1	1
Sleep disorder	6	6
Small intestinal obstruction	1	1
Sneezing	2	2
Somnolence	15	16
Speech disorder	2	2
Stevens-Johnson syndrome	1	1
Stoma site extravasation		1
Stoma site haemorrhage		1
Stress	1	1
Stridor	1	1
Subarachnoid haemorrhage	1	1
Sudden death	7	7
Supraventricular tachycardia	1	1
Suspected COVID-19	7	7
Sweating fever	1	1
Swelling	1	1
Swelling face	7	8
Swelling of eyelid	1	1
Swollen tongue	3	5
Syncope	14	15
Synovitis	1	1
Tachycardia	2	2
Tachypnoea	1	1
Taste disorder	1	1
Temperature regulation disorder	1	1
Tenderness		1
Tendonitis	1	1
Tension headache	2	2
Thirst	1	1
Throat irritation	1	1
Throat tightness	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	2	4	4
				1	1
		1	1	1	1
		4	4	11	12
				2	2
				1	1
			1		
					1
		1	1		
				1	1
				1	1
				7	7
				1	1
				7	7
				1	1
				1	1
		1	1	6	7
				1	1
		1	2	2	3
				14	15
				1	1
				2	2
				1	1
				1	1
				1	1
			1		
				1	1
				2	2
		1	1		
		1	1		
				2	3

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Thrombocytopenia	1	1
Thrombocytosis	1	1
Thrombosis	3	3
Tinnitus	1	1
Toothache	1	1
Toxic epidermal necrolysis	1	1
Transient ischaemic attack	4	5
Tremor	19	22
Troponin increased	1	1
Tunnel vision	1	1
Unresponsive to stimuli	5	7
Upper gastrointestinal haemorrhage	2	2
Upper limb fracture	1	1
Urinary incontinence	2	2
Urinary retention	2	2
Urinary tract disorder	1	1
Urinary tract infection bacterial	1	1
Urosepsis	1	1
Urticaria	9	10
Vaccination site bruising	2	2
Vaccination site discolouration	1	1
Vaccination site discomfort	1	1
Vaccination site erythema	13	14
Vaccination site haemorrhage	1	2
Vaccination site induration	1	1
Vaccination site infection	1	1
Vaccination site inflammation	2	2
Vaccination site joint movement impairment	1	1
Vaccination site mass	1	1
Vaccination site movement impairment		1
Vaccination site oedema	1	1
Vaccination site pain	41	47

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				3	3
				1	1
		1	1		
				1	1
				4	5
		3	4	16	18
				1	1
				1	1
				5	7
				2	2
				1	1
				2	2
				2	2
				1	1
				1	1
		6	7	3	3
				2	2
				1	1
				1	1
		5	6	8	8
			1	1	1
				1	1
				1	1
				2	2
		1	1		
				1	1
			1		
				1	1
		15	19	26	28

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site pruritus	2	3
Vaccination site rash	3	3
Vaccination site swelling	9	10
Vaccination site ulcer	1	1
Vaccination site vesicles	1	1
Vaccination site warmth	4	5
Vasculitis	1	1
Ventricular f brillation		1
Vertigo	7	8
Vertigo positional	1	1
Viral infection	1	1
Vision blurred	9	11
Visual acuity reduced	1	1
Visual impairment	3	3
Vomiting	36	44
Weight decreased	1	1
Weight loss diet	1	1
Wheezing	2	3
	1	1
	2,080	2,279

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	3		
		2	2	1	1
		2	3	7	7
				1	1
				1	1
			1	4	4
				1	1
					1
		2	2	5	6
				1	1
		1	1		
		5	6	4	5
		1	1		
		1	1	2	2
		7	15	29	29
		1	1		
				1	1
			1	2	2
		1	1		
		4	4	1631	1729

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	2	2			2	2
Abdominal pain	2	5	1	3	1	2
Abdominal pain upper	6	6	3	3	3	3
Abnormal faeces		1		1		
Acute respiratory failure	1	1			1	1
Agitation	1	1	1	1		
Allergy to vaccine	2	2	1	1	1	1
Amnesia	1	1	1	1		
Anaphylactic reaction	2	3			2	3
Anger	1	1			1	1
Angina pectoris	1	1			1	1
Angioedema	1	1			1	1
Anosmia	2	2			2	2
Anticoagulation drug level increased	1	1			1	1
Anxiety	1	2			1	2
Arthralgia	23	26	7	10	16	16
Arthritis reactive	1	1			1	1
Asthenia	5	7	2	3	3	4
Asthma	1	1	1	1		
Atrial f brillation	1	1			1	1
Axillary pain	6	6	3	3	3	3
Back pain	4	5	2	3	2	2
Blood glucose decreased	1	1			1	1
Blood pressure decreased		1				1
Blood pressure increased	4	4	3	3	1	1
Body temperature fluctuation	1	1			1	1
Body temperature increased	2	2	1	1	1	1
Bone pain	3	3	2	2	1	1
Burning sensation	1	2			1	2
Cardiac arrest	2	2			2	2
Cerebral infarction		1				1
Cerebrovascular accident	1	1			1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest discomfort	1	3
Chest pain	9	10
Chills	31	40
Choking	1	1
Circulatory collapse	2	2
Circumstance or information capable of leading to medication error	2	3
Cold sweat	1	1
Consciousness fluctuating	1	1
Contraindicated product administered	1	1
Contusion	1	1
Coronavirus infection		2
Cough	5	5
COVID-19	72	77
Death	4	4
Decreased appetite	4	4
Delirium	1	1
Dermatitis	1	1
Dermatitis allergic	1	1
Diarrhoea	11	16
Discomfort	1	1
Disease recurrence	1	1
Dizziness	28	36
Dizziness postural	2	3
Drug eruption	2	2
Drug ineffective	76	88
Dry mouth	2	2
Dysgeusia	6	7
Dysphagia	1	1
Dyspnoea	12	18
Ear discomfort	1	1
Ear infection	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
3	4	6	6
13	19	18	21
		1	1
		2	2
2	3		
		1	1
		1	1
1	1		
1	1		
			2
4	4	1	1
		72	77
		4	4
1	1	3	3
		1	1
1	1		
1	1		
5	9	6	7
1	1		
1	1		
9	15	19	21
1	1	1	2
		2	2
		76	88
2	2		
4	5	2	2
		1	1
3	6	9	12
1	1		
		1	1

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	1
1	1		
		1	1
1	1	3	4
2	3	1	3
		1	1
2	2		
			1
1	1		
		1	1
1	1		
		1	1
1	1		
1	2		1
1	1	1	1
1	1		
46	55	21	27
4	6	1	4
3	5	2	2
1	1	1	
6	7	6	
	1		
2	4	1	2
	1		1
1	1	1	1
1	2		1
1	2		2
1	1	1	1
1	1	1	1
1	1		
72	85	34	42
1	1	1	
5	6	3	2

Ear pain 2 2

Eczema 1 1

Epilepsy 1 1

Epistaxis 4 5

Erythema 3 6

Euphoric mood 1 1

Exposure via breast milk 2 2

Extrasystoles 1

Eye disorder 1 1

Eye irritation 1 1

Eyelid irritation 1 1

Facial discomfort 1 1

Facial pain 1 2

Facial paralysis 1 1

Fall 1 1

Fatigue 46 55

Feeling abnormal 4 6

Feeling cold 3 5

Feeling drunk 1 1

Feeling hot 6 7

Feeling of body temperature change 1

Flushing 2 4

Formication 1

Generalised tonic-clonic seizure 1 1

Gingival pain 1 2

Haematemesis 1 2

Haemoptysis 1 1

Haemorrhage 1 1

Hair colour changes 1 1

Headache 72 85

Head injury 1 1

Heart rate increased 5 6

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster	2	3
Hot flush		1
Hyperacusis		1
Hyperaesthesia	1	1
Hyperglycaemia	1	1
Hyperhidrosis	1	6
Hypersensitivity	3	4
Hypertension	4	5
Hyperventilation	1	1
Hypoaesthesia	2	6
Hypoaesthesia oral	3	5
Hyporesponsive to stimuli	1	1
Hypotension	1	2
Illness	3	4
Inappropriate schedule of product administration	2	2
Increased upper airway secretion		1
Induration	1	1
Inflammation	2	2
Influenza	3	3
Influenza like illness	10	12
Injection related reaction	1	1
Injection site pain		1
Injury associated with device		1
Insomnia		1
Joint swelling	1	1
Lacrimation increased	1	1
Lacunar stroke	1	1
Lethargy	7	8
Limb discomfort	1	1
Lip swelling	1	1
Liquid product physical issue		2
Localised infection	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		
			1
	1		
		1	1
		1	1
	4	1	2
2	3	1	1
1	1	3	4
		1	1
	1	2	5
2	3	1	2
		1	1
		1	2
	1	3	3
2	2		
	1		
		1	1
		2	2
		3	3
7	9	3	3
1	1		
	1		
	1		
1	1		
		1	1
		1	1
6	7	1	1
1	1		
		1	1
	2		
		1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Loss of consciousness	1	1
Lower respiratory tract infection	1	1
Lymphadenopathy	14	18
Lymph node pain	1	3
Malaise	24	30
Mast cell activation syndrome	1	1
Maternal exposure during pregnancy	2	2
Memory impairment		1
Mental impairment		1
Migraine	7	8
Mobility decreased		1
Morning sickness	1	1
Mouth swelling	2	2
Muscular weakness	2	3
Musculoskeletal disorder	1	1
Musculoskeletal stiffness		1
Myalgia	31	36
Myocardial infarction	1	1
Nasal congestion	2	2
Nasal discomfort	1	1
Nasal dryness	1	1
Nasopharyngitis	1	2
Nausea	36	43
Neck pain	8	11
Nervousness	1	1
Neurogenic shock	1	1
Night sweats	1	1
No adverse event	1	1
Occupational exposure to product		1
Ocular hyperaemia	1	1
Off label use	2	3
Oral discomfort	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
8	11	6	7
1	3		
13	16	11	14
		1	1
		2	2
	1		
			1
5	6	2	2
	1		
		1	1
1	1	1	1
		2	3
		1	1
	1		
14	19	17	17
		1	1
1	1	1	1
		1	1
	1	1	1
17	21	19	22
5	8	3	3
		1	1
		1	1
		1	1
1	1		
	1		
		1	1
1	2	1	1
		1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral pain		1
Oral pruritus	1	1
Oropharyngeal pain	6	8
Oxygen saturation decreased		1
Pain	21	27
Pain in extremity	26	33
Pain of skin		1
Pallor		2
Palpitations	3	3
Papule	1	1
Paraesthesia	9	16
Paraesthesia oral	9	15
Paralysis	1	1
Parosmia	1	1
Peau d'orange	1	1
Peripheral coldness	2	2
Peripheral swelling	5	6
Pharyngeal swelling	2	2
Photophobia	1	2
Poor quality product administered	3	9
Presyncope	4	6
Productive cough	1	1
Product label confusion		1
Product packaging quantity issue		4
Product preparation error		3
Product temperature excursion issue	3	3
Product use issue	1	2
Pruritus	11	14
Pulmonary pain		1
Pulmonary thrombosis	1	1
Pyrexia	50	62
Rash	14	17

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	1		
5	7	1	1
			1
8	13	13	14
15	21	11	12
			1
	1		1
1	1	2	2
		1	1
4	7	5	9
8	13	1	2
		1	1
		1	1
1	1		
2	2		
2	2	3	4
2	2		
	1	1	1
3	9		
2	3	2	3
1	1		
	1		
	4		
	3		
3	3		
	1	1	1
6	7	5	7
	1		
		1	1
18	26	32	36
11	13	3	4

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash erythematous	3	5
Rash pruritic	3	4
Renal pain	1	1
Respiratory arrest	1	1
Retching	1	1
Rhinorrhoea		1
Salivary hypersecretion	1	1
SARS-CoV-2 test positive	2	7
Seizure	1	1
Serotonin syndrome	1	1
Sinus disorder	1	1
Sinus headache	1	1
Sinus pain	1	1
Skin warm	1	3
Sleep disorder	2	3
Sleep terror	1	1
Sneezing	1	1
Somnolence	1	2
Suspected COVID-19	5	5
Sweating fever	1	1
Swelling	4	5
Swelling face	2	2
Swollen tongue	3	3
Symphysiolysis	1	1
Syncope	6	7
Synovial rupture	1	1
Tachycardia	6	7
Tachypnoea	2	2
Taste disorder	1	1
Tension headache	1	1
Therapeutic response unexpected	1	1
Throat irritation	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2	1	3
2	2	1	2
		1	1
		1	1
1	1		
	1		
1	1		
		2	7
		1	1
		1	1
		1	1
		1	1
1	1		
1	1		2
1	2	1	1
		1	1
		1	1
	1	1	1
		5	5
		1	1
2	3	2	2
		2	2
1	1	2	2
		1	1
		6	7
1	1		
2	3	4	4
		2	2
1	1		
1	1		
1	1		
1	1		

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		1
		1	1
		1	2
1	1		
		1	1
1	4	3	3
		1	1
	3		
		2	2
		1	1
		1	1
		1	1
3	4	6	7
1	1	2	2
	1	1	1
1	1		
6	7	5	6
		1	1
	1		
1	1		
3	4	2	2
		1	1
22	28	10	10
2	2	1	1
3	3		
		1	1
8	9	6	7
3	4	4	4
	1	3	3
		1	1
1	3	2	2
		1	1

Throat tightness	1	2
Thrombocytopenia	1	1
Tinnitus	1	2
Tonsillar hypertrophy	1	1
Tonsillitis	1	1
Tremor	4	7
Trismus	1	1
Underdose		3
Unresponsive to stimuli	2	2
Urinary incontinence	1	1
Urinary retention	1	1
Urinary tract infection	1	1
Urticaria	9	11
Vaccination site bruising	3	3
Vaccination site cellulitis	1	2
Vaccination site discomfort	1	1
Vaccination site erythema	11	13
Vaccination site haemorrhage	1	1
Vaccination site hypoaesthesia		1
Vaccination site induration	1	1
Vaccination site mass	5	6
Vaccination site movement impairment	1	1
Vaccination site pain	32	38
Vaccination site paraesthesia	3	3
Vaccination site pruritus	3	3
Vaccination site rash	1	1
Vaccination site swelling	14	16
Vaccination site warmth	7	8
Vertigo	3	4
Viral tonsillitis	1	1
Vision blurred	3	5
Visual impairment	1	1

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2	8	11
	2		
1	1		
3	3		
430	611	664	774

Vomiting  
 Wheezing  
 Wrong product administered

1,094

1,385

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Country Where Event Occurred

**UNITED STATES**

Age Range

**Less than or equal to 17 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergy to vaccine		1		1
Exposure via breast milk	17	30	17	30
Increased appetite	1	1	1	1
Infantile vomiting	1	2	1	2
Infant irritability	1	3	1	3
Insomnia	1	1	1	1
Lethargy		1		1
Off label use	1	1	1	1
Poor feeding infant		1		1
Product administered to patient of inappropriate age	4	5	4	5
Pyrexia	2	3	2	3
Rash	1	2	1	2
Vaginal infection		1		1
	29	52	29	52

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	5	6	5	6		
Abdominal distension	1	1	1	1		
Abdominal pain	15	16	15	16		
Abdominal pain upper	12	15	11	14	1	1
Abnormal dreams	1	1	1	1		
Abortion spontaneous	1	1			1	1
Accidental exposure to product	1	1	1	1		
Accidental overdose	1	1	1	1		
Acne	1	1	1	1		
Ageusia	6	10	4	8	2	2
Agitation		1		1		
Allergy to vaccine	3	6	3	5		1
Alopecia	2	2	2	2		
Anaphylactic reaction	9	14			9	14
Anaphylactoid reaction		1				1
Angioedema	1	2			1	2
Anosmia	9	12	7	10	2	2
Anxiety	7	8	5	6	2	2
Aphasia		1		1		
Arrhythmia		1				1
Arthralgia	61	83	59	81	2	2
Arthritis	1	1	1	1		
Asthenia	40	48	35	43	5	5
Asymptomatic COVID-19		1				1
Axillary pain	8	9	8	9		
Back pain	25	32	23	30	2	2
Balance disorder	1	4	1	3		1
Blepharospasm	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure abnormal		1		1		
Blood pressure decreased	1	2	1	2		
Blood pressure increased	4	6	1	3	3	3

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Body temperature decreased	1	1
Body temperature increased	3	5
Bone pain	2	2
Breast pain	1	1
Cardiac disorder	1	2
Cerebrovascular accident		1
Chest discomfort	9	14
Chest pain	16	22
Chills	201	267
Chromaturia	2	2
Circumstance or information capable of leading to medication error	1	1
Cold sweat	5	8
Condition aggravated	5	5
Confusional state	2	2
Constipation	1	2
Contraindication to vaccination	1	1
Costovertebral angle tenderness	1	1
Cough	25	35
COVID-19	20	26
C-reactive protein increased	1	1
Crying	2	2
Cyanosis	1	2
Decreased appetite	7	9
Deep vein thrombosis	2	2
Dehydration	3	5
Depressed mood	1	1
Depression	1	1
Device breakage	1	1
Diarrhoea	29	41
Discomfort	4	6
Disease recurrence	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
3	5		
2	2		
1	1		
	1	1	1
			1
6	9	3	5
12	17	4	5
193	259	8	8
2	2		
1	1		
4	7	1	1
5	5		
2	2		
1	2		
1	1		
1	1		
20	29	5	6
1	1	19	25
		1	1
1	1	1	1
	1	1	1
6	8	1	1
		2	2
3	4		1
1	1		
		1	1
		1	1
28	39	1	2
2	4	2	2
2	2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Disturbance in attention		1
Dizziness	71	114
Dizziness postural	3	3
Drug hypersensitivity	1	1
Drug ineffective	33	53
Dry mouth	1	3
Dry skin		1
Dry throat	6	9
Dysgeusia	3	4
Dyskinesia	1	1
Dyspepsia	1	2
Dysphagia	6	8
Dysphemia		1
Dysphonia	4	4
Dyspnoea	34	46
Dysuria	1	1
Ear discomfort	3	6
Ear disorder	1	1
Ear pain	3	4
Ear swelling		2
Ejection fraction abnormal		1
Emotional disorder	1	1
Enlarged uvula	1	1
Eosinophil count increased	1	1
Epistaxis	2	2
Eructation	1	1
Erythema	9	15
Exposure during pregnancy	2	2
Exposure to SARS-CoV-2	2	2
Eye disorder	2	2
Eyelid ptosis		1
Eye pain	3	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
62	101	9	13
1	1	2	2
1	1		
		33	53
1	3		
	1		
5	7	1	2
3	4		
		1	1
1	2		
2	3	4	5
	1		
3	3	1	1
20	27	14	19
1	1		
3	6		
1	1		
3	4		
	2		
	1		
1	1		
		1	1
		1	1
2	2		
1	1		
7	13	2	2
1	1	1	1
2	2		
2	2		
			1
2	4	1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye swelling	1	2
Face injury	1	1
Face oedema		1
Facial pain	3	4
Facial paralysis	3	6
Facial paresis	2	2
Fall	2	2
Fatigue	153	225
Fear		1
Feeding disorder		1
Feeling abnormal	15	20
Feeling cold	6	8
Feeling hot	11	19
Feeling jittery	1	1
Feeling of body temperature change	1	1
Fluid imbalance	1	1
Flushing	10	17
Formication	1	1
Gait disturbance	1	1
Gastrointestinal disorder	1	1
Gingival blister	1	1
Gingival discolouration		1
Gingival discomfort		1
Gingival pain		2
Glassy eyes		1
Haematochezia	1	1
Headache	225	307
Head injury	1	1
Heart rate increased	23	38
Heart rate irregular	1	1
Hemiparesis		1
Herpes zoster	4	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
1	1		
			1
3	4		
		3	6
		2	2
2	2		
150	222	3	3
			1
	1		
14	17	1	3
6	8		
10	17	1	2
1	1		
1	1		
		1	1
5	10	5	7
1	1		
1	1		
1	1		
			1
			1
			2
	1		
		1	1
218	298	7	9
1	1		
19	31	4	7
1	1		
			1
4	4		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hot flush	9	11
Hyperacusis		1
Hyperaemia		1
Hyperaesthesia	1	2
Hyperhidrosis	23	31
Hyperpyrexia		1
Hypersensitivity	7	9
Hypersomnia	1	3
Hypertension	4	8
Hyperthermia	1	1
Hyperventilation		2
Hypoaesthesia	25	33
Hypoaesthesia oral	1	4
Hypopnoea	2	2
Hypotension	7	7
Illness	5	8
Immune thrombocytopenia		1
Impaired work ability	1	1
Inappropriate schedule of product administration	44	44
Incorrect dose administered	1	1
Incorrect route of product administration	1	2
Induration		1
Inflammation		1
Influenza	2	3
Influenza like illness	12	14
Injection site erythema	2	2
Injection site joint movement impairment	1	1
Injection site pain	1	2
Injection site rash	1	2
Injection site swelling	2	2
Injection site urticaria		1
Injury	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
7	9	2	2
	1		
	1		
1	2		
22	30	1	1
			1
4	6	3	3
1	3		
2	5	2	3
1	1		
	1		1
19	26	6	7
1	4		
2	2		
4	4	3	3
4	7	1	1
			1
1	1		
44	44		
1	1		
	1	1	1
	1		
			1
2	3		
12	14		
2	2		
		1	1
1	2		
1	2		
2	2		
	1		
1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Insomnia	6	8
Intranasal paraesthesia		1
Irritable bowel syndrome	1	1
Joint instability		1
Joint range of motion decreased	5	6
Joint stiffness	2	2
Joint swelling	1	2
Kidney infection	1	1
Lacrimation increased	1	1
Laryngeal oedema	1	1
Lethargy	5	6
Ligament injury	1	1
Limb discomfort	2	2
Lip erythema		1
Lip oedema		2
Lip swelling	5	9
Loss of consciousness	8	8
Loss of personal independence in daily activities	1	2
Lung disorder	1	1
Lymphadenopathy	61	76
Lymph node pain	8	9
Lymph node palpable	1	1
Macule	1	1
Malaise	37	59
Mass	1	1
Maternal exposure during pregnancy	6	10
Meningism	1	1
Menstrual disorder		1
Mental impairment	1	3
Migraine	16	19
Mobility decreased		2
Mouth swelling		2

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	7	1	1
	1		
1	1		
			1
3	4	2	2
2	2		
	1	1	1
		1	1
1	1		
		1	1
5	6		
1	1		
2	2		
	1		
	1		1
3	6	2	3
		8	8
1	2		
1	1		
58	73	3	3
8	9		
1	1		
1	1		
33	55	4	4
1	1		
6	10		
1	1		
	1		
		1	3
15	18	1	1
	2		
	2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Movement disorder	1	1
Mucosal disorder	1	1
Muscle discomfort		1
Muscle disorder	2	2
Muscle fatigue	2	2
Muscle spasms	5	6
Muscle tightness	6	6
Muscle twitching	1	1
Muscular weakness	5	5
Musculoskeletal chest pain	2	2
Musculoskeletal discomfort	1	1
Musculoskeletal disorder	1	2
Musculoskeletal pain		1
Musculoskeletal stiffness	8	10
Myalgia	105	138
Myocardial infarction		1
Myocardial necrosis marker increased		1
Nasal congestion	10	19
Nasal discomfort	1	2
Nasal dryness	1	2
Nasal injury	2	2
Nasal oedema		1
Nasopharyngitis	3	6
Nausea	136	189
Neck mass	1	1
Neck pain	14	19
Nervousness	3	4
Neuralgia	4	4
Neutrophil count increased	1	1
Nightmare	1	2
Night sweats	8	10
Ocular hyperaemia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
	1		
2	2		
2	2		
5	6		
6	6		
1	1		
5	5		
2	2		
1	1		
1	2		
	1		
8	10		
102	134	3	4
			1
			1
9	17	1	2
1	2		
1	2		
2	2		
			1
3	6		
130	181	6	8
1	1		
13	17	1	2
3	4		
4	4		
		1	1
1	2		
7	9	1	1
1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Off label use	20	25
Oral discomfort		1
Oral disorder	1	2
Oral herpes	2	2
Oral mucosal eruption		1
Oral pain	1	2
Oral pruritus		1
Oropharyngeal discomfort	2	3
Oropharyngeal pain	21	30
Overdose	2	4
Pain	146	195
Pain in extremity	66	98
Pain in jaw	2	2
Pain of skin	2	2
Palatal swelling	1	1
Pallor	1	1
Palpitations	16	24
Panic attack		1
Panic reaction	1	1
Paraesthesia	18	31
Paraesthesia oral	2	6
Paralysis	2	2
Paranasal sinus discomfort	3	3
Parosmia		1
Periarthritis	1	1
Periorbital swelling		1
Peripheral coldness	1	1
Peripheral swelling	7	11
Petechiae	1	1
Pharyngeal hypoaesthesia		2
Pharyngeal paraesthesia	1	3
Pharyngeal swelling	6	9

Spontaneous			
Nonserious		Serious	
I	C	I	C
20	25		
	1		
1	2		
2	2		
	1		
1	1		1
	1		
2	2		1
19	26	2	4
2	4		
141	189	5	6
66	98		
2	2		
2	2		
1	1		
1	1		
14	19	2	5
	1		
1	1		
14	26	4	5
1	5	1	1
		2	2
3	3		
	1		
		1	1
	1		
1	1		
7	10		1
1	1		
	2		
1	3		
4	5	2	4

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Photophobia	1	2
Photopsia	1	1
Photosensitivity reaction	1	2
Piloerection	2	3
Platelet count increased	2	2
Pleuritic pain	1	1
Pollakiuria	1	2
Polyuria	1	1
Poor quality product administered	1	1
Poor quality sleep	2	2
Postictal state		1
Premature rupture of membranes	1	1
Presyncope	4	7
Procedural pain	1	1
Product administered at inappropriate site	4	4
Product administration error	1	1
Product formulation issue		1
Product preparation error	1	3
Product preparation issue		1
Product temperature excursion issue	1	1
Product use issue	18	23
Pruritus	21	34
Pulmonary embolism	1	1
Pyrexia	213	281
Rash	23	38
Rash erythematous	3	6
Rash macular	2	3
Rash maculo-papular	1	1
Rash papular	4	4
Rash pruritic	4	9
Reaction to excipient	1	1
Renal pain	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
1	1		
1	2		
2	3		
		2	2
1	1		
1	2		
1	1		
1	1		
2	2		
	1		
		1	1
4	6		1
		1	1
3	3	1	1
1	1		
			1
1	3		
			1
1	1		
18	23		
16	29	5	5
		1	1
203	269	10	12
19	33	4	5
3	4		2
2	3		
1	1		
4	4		
4	8		1
1	1		
1	1		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory distress	1	1
Respiratory tract congestion		1
Restlessness	2	3
Retching	3	3
Rhinalgia		1
Rhinorrhoea	7	10
SARS-CoV-2 test false positive	1	1
SARS-CoV-2 test positive	14	27
Scar	1	1
Seasonal allergy	1	1
Seizure		2
Sensation of foreign body	4	5
Sensitive skin	2	2
Shock symptom		1
Sinus congestion	1	3
Sinusitis	1	1
Sinus tachycardia	1	1
Skin burning sensation	2	3
Skin discolouration		1
Skin disorder	1	3
Skin tightness		1
Sleep disorder	3	3
Slow response to stimuli		1
Sneezing	2	3
Snoring	1	1
Somnolence	4	4
Speech disorder	1	2
Spinal pain	1	2
Stomatitis	3	3
Stress	1	1
Suspected COVID-19		1
Suture related complication	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
	1		
1	2	1	1
3	3		
	1		
6	9	1	1
1	1		
		14	27
1	1		
1	1		
			2
2	2	2	3
2	2		
			1
1	3		
1	1		
		1	1
2	3		
	1		
1	3		
	1		
3	3		
	1		
2	3		
		1	1
4	4		
	1	1	1
1	2		
3	3		
1	1		
			1
		1	1

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling	7	11
Swelling face	4	10
Swelling of eyelid	3	3
Swollen tongue	4	5
Syncope	13	18
Tachycardia	18	31
Tachypnoea	1	2
Taste disorder	2	3
Tenderness	2	2
Thirst	2	2
Throat irritation	7	10
Throat tightness	8	13
Thrombocytopenia	1	1
Thrombotic thrombocytopenic purpura		1
Tinnitus	2	3
Tongue discomfort		1
Tongue disorder	1	1
Tongue pruritus	1	1
Tonsillar hypertrophy	1	1
Tonsillolith	1	1
Toothache	1	1
Tremor	9	15
Trismus	1	1
Tunnel vision		1
Underdose	2	5
Upper-airway cough syndrome	1	3
Upper respiratory tract congestion	1	1
Urticaria	30	40
Uterine haemorrhage	1	1
Vaccination site bruising	2	2
Vaccination site cellulitis		1
Vaccination site discomfort	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
7	11		
4	10		
3	3		
2	3	2	2
		13	18
11	20	7	11
1	1		1
2	3		
2	2		
2	2		
4	7	3	3
2	2	6	11
		1	1
			1
2	3		
	1		
		1	1
1	1		
1	1		
1	1		
9	14		1
1	1		
			1
2	5		
1	3		
1	1		
21	30	9	10
		1	1
2	2		
			1
1	2		

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Age Range

18 - 30 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site erythema	25	39	25	38		1
Vaccination site haemorrhage	1	2	1	2		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site hypoaesthesia	2	3	2	3		
Vaccination site induration	3	6	3	6		
Vaccination site infection	1	1	1	1		
Vaccination site inflammation	2	3	2	2		1
Vaccination site injury	1	1	1	1		
Vaccination site lymphadenopathy	2	2	2	2		
Vaccination site macule	1	1	1	1		
Vaccination site mass	5	5	5	5		
Vaccination site movement impairment		1		1		
Vaccination site nodule	1	1	1	1		
Vaccination site pain	104	162	103	161	1	1
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	2	4	2	4		
Vaccination site pruritus	12	14	12	14		
Vaccination site rash	5	7	5	7		
Vaccination site scab	1	1	1	1		
Vaccination site swelling	27	38	26	36	1	2
Vaccination site vesicles	1	2	1	2		
Vaccination site warmth	12	13	12	13		
Ventricular tachycardia		1				1
Vertigo	4	5	4	4		1
Viral rash		1		1		
Vision blurred	3	3	2	2	1	1
Visual impairment	1	1			1	1
Vomiting	42	57	42	56		1
Wheezing	2	4		1	2	3
White blood cell count increased	2	2			2	2
Wrong technique in product usage process	1	1	1	1		
	2,984	4,200	2627	3682	357	518

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	15	22	13	20	2	2
Abdominal distension	3	5	3	5		
Abdominal pain	9	15	8	14	1	1
Abdominal pain lower		4		2		2
Abdominal pain upper	18	22	17	21	1	1
Abdominal rigidity	1	1	1	1		
Abnormal dreams	4	6	4	6		
Abnormal sensation in eye	1	2	1	2		
Abortion spontaneous	4	4			4	4
Accidental exposure to product	1	2	1	2		
Accidental overdose	3	6	3	5		1
Accidental underdose	1	1	1	1		
Acne	1	2	1	2		
Acute disseminated encephalomyelitis	1	1			1	1
Acute myocardial infarction	1	1			1	1
Ageusia	12	22	10	19	2	3
Agitation	1	1	1	1		
Alanine aminotransferase increased	1	1			1	1
Allergy to vaccine	8	16	5	10	3	6
Alopecia	1	1	1	1		
Amnesia	1	1			1	1
Anaesthesia		1		1		
Anal incontinence	1	1	1	1		
Anaphylactic reaction	23	32			23	32
Anaphylactic shock	1	2			1	2
Anaphylactoid reaction	1	2			1	2
Angioedema	3	8			3	8
Anosmia	12	22	9	17	3	5
Anxiety	18	31	18	29		2
Aphasia	1	2		1	1	1
Appendicitis	2	4			2	4
Arrhythmia	2	2			2	2

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arteriospasm coronary	1	1
Arthralgia	203	261
Arthritis	5	5
Aspartate aminotransferase increased	1	1
Asthenia	81	117
Asthenopia	5	6
Asthma	7	9
Asymptomatic COVID-19		2
Atrial f brillation	1	1
Aura	1	1
Autoimmune disorder		3
Autonomic nervous system imbalance	1	1
Axillary mass	5	7
Axillary pain	24	29
Back pain	41	56
Balance disorder	9	13
Bedridden	2	2
Bilirubin urine present	1	1
Blepharospasm	2	3
Blindness	1	1
Blindness transient		1
Blister	3	7
Blood count abnormal		1
Blood glucose abnormal	1	1
Blood glucose decreased	1	1
Blood iron decreased	1	1
Blood potassium decreased	1	1
Blood pressure abnormal	1	2
Blood pressure decreased	2	4
Blood pressure diastolic decreased	1	1
Blood pressure diastolic increased	1	2
Blood pressure fluctuation		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
193	246	10	15
5	5		
1	1		
71	103	10	14
4	5	1	1
5	7	2	2
			2
		1	1
1	1		
			3
		1	1
4	5	1	2
23	28	1	1
37	50	4	6
8	11	1	2
2	2		
1	1		
2	3		
		1	1
			1
3	7		
	1		
1	1		
1	1		
		1	1
1	2		
1	2	1	2
1	1		
1	2		
	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood pressure increased	27	50
Blood pressure systolic increased	2	2
Blood thyroid stimulating hormone increased	1	1
Blood urine present	1	2
Body temperature abnormal	2	3
Body temperature decreased	1	1
Body temperature fluctuation	1	1
Body temperature increased	7	13
Bone pain	14	16
Bone swelling		1
Booster dose missed	1	1
Brachial plexopathy	1	1
Bradykinesia		1
Brain injury	2	2
Breast discomfort	1	1
Breast pain	5	5
Breast swelling	1	2
Breast tenderness	1	2
Breath odour	2	2
Bronchospasm	3	3
Burning sensation	23	35
Capillary nail refill test abnormal		1
Cardiac arrest	2	2
Cardiac disorder		1
Cardiac flutter	1	2
Cardiac valve sclerosis	1	1
Cardio-respiratory arrest	1	1
Cellulitis	1	1
Central nervous system lesion	1	1
Cerebral haemorrhage	2	2
Cerebrovascular accident	7	8
Cheilitis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
15	32	12	18
1	1	1	1
1	1		
1	2		
2	3		
1	1		
1	1		
7	13		
11	13	3	3
	1		
1	1		
		1	1
	1		
		2	2
1	1		
5	5		
1	2		
1	1		1
2	2		
2	2	1	1
19	29	4	6
	1		
		2	2
	1		
		1	2
		1	1
		1	1
1	1		
		2	2
		7	8
	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chest discomfort	50	80
Chest pain	44	62
Chills	468	614
Choking	1	1
Choking sensation	1	1
Chromaturia	1	2
Circulatory collapse	2	2
Circumstance or information capable of leading to medication error	1	1
Cognitive disorder	1	2
Cold sweat	10	17
Condition aggravated	11	18
Confusional state	9	11
Conjunctival irritation	1	1
Conjunctival oedema	1	1
Conjunctivitis	1	2
Constipation	2	2
Contusion	7	10
Coordination abnormal	1	1
Corneal oedema	1	1
Cough	51	81
COVID-19	68	99
COVID-19 pneumonia	1	1
C-reactive protein increased	1	1
Crying	4	6
Cyanosis	2	2
Cyst	1	1
Deafness	4	4
Deafness neurosensory	1	2
Deafness unilateral	1	2
Decreased appetite	30	40
Defaecation urgency		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
33	60	17	20
29	44	15	18
454	592	14	22
		1	1
		1	1
1	2		
		2	2
1	1		
1	1		1
7	14	3	3
9	14	2	4
8	10	1	1
1	1		
1	1		
1	2		
2	2		
7	10		
		1	1
1	1		
41	66	10	15
		68	99
		1	1
1	1		
4	6		
1	1	1	1
1	1		
		4	4
		1	2
		1	2
29	39	1	1
	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dehydration	7	10
Demyelinating polyneuropathy	1	1
Dental paraesthesia		1
Depressed level of consciousness	1	2
Depressed mood	1	1
Dermatitis	2	2
Dermatitis allergic	3	3
Dermatitis exfoliative	1	1
Diabetes mellitus		1
Diarrhoea	94	132
Dilatation ventricular	1	1
Discomfort	15	18
Disease recurrence	6	10
Disorientation	3	3
Dissociation	1	1
Disturbance in attention	7	11
Dizziness	185	297
Dizziness exertional	2	2
Dizziness postural	3	5
Drooling	1	1
Drug eruption		1
Drug hypersensitivity	3	3
Drug ineffective	110	160
Drug interaction	4	4
Dry eye	2	2
Dry mouth	10	20
Dry skin	1	1
Dry throat	7	10
Dysarthria	3	6
Dysgeusia	29	47
Dyskinesia	1	2
Dysmenorrhoea	2	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	8	2	2
		1	1
	1		
		1	2
		1	1
2	2		
2	2	1	1
		1	1
			1
90	126	4	6
		1	1
15	18		
5	9	1	1
2	2	1	1
1	1		
7	8		3
162	260	23	37
2	2		
3	5		
1	1		
	1		
3	3		
2	2	108	158
4	4		
2	2		
8	17	2	3
1	1		
5	7	2	3
1	4	2	2
28	45	1	2
1	1		1
2	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspepsia	5	6
Dysphagia	13	17
Dysphonia	6	10
Dyspnoea	94	134
Dyspnoea exertional	5	8
Dysstasia	3	4
Ear congestion	1	1
Ear discomfort	6	8
Ear disorder	2	2
Ear pain	18	25
Ear pruritus	1	1
Ear swelling	1	1
Eating disorder	1	3
Eczema		1
Electrocardiogram abnormal	3	3
Electrocardiogram QT prolonged		1
Emotional disorder		1
Enanthema		1
Enlarged uvula	2	2
Epicondylitis	2	2
Epinephrine increased		1
Epistaxis	5	9
Erythema	35	53
Erythema of eyelid	2	3
Exercise lack of	1	1
Exposure during pregnancy	3	6
Exposure to SARS-CoV-2	6	7
Exposure via skin contact	1	1
Extensive swelling of vaccinated limb		1
Extrasystoles		1
Extremity contracture	1	1
Eye contusion	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
5	6		
5	8	8	9
3	5	3	5
63	88	31	46
4	7	1	1
3	3		1
		1	1
6	8		
2	2		
17	24	1	1
1	1		
1	1		
1	3		
	1		
3	3		
			1
	1		
	1		
1	1	1	1
2	2		
	1		
5	9		
27	41	8	12
2	3		
1	1		
3	6		
4	5	2	2
1	1		
	1		
	1		
1	1		
1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye discharge		1
Eye disorder	6	9
Eye haemorrhage	1	3
Eye infection		1
Eye inflammation	1	2
Eye irritation	7	9
Eyelid irritation	1	1
Eyelid pain	2	2
Eyelid ptosis	1	1
Eyelid sensory disorder	1	1
Eyelids pruritus	1	3
Eye movement disorder	1	2
Eye oedema	2	2
Eye pain	18	24
Eye paraesthesia	1	1
Eye pruritus	4	9
Eye swelling	19	29
Face injury		1
Face oedema		1
Facet joint syndrome	1	1
Facial pain	9	13
Facial paralysis	21	27
Facial paresis	3	3
Fall	2	4
Fatigue	433	613
Fear	1	1
Feeding disorder		1
Feeling abnormal	70	100
Feeling cold	21	30
Feeling drunk	3	3
Feeling hot	55	89
Feeling jittery	2	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
5	8	1	1
		1	3
	1		
	1	1	1
7	9		
1	1		
2	2		
1	1		
1	1		
1	3		
1	1		1
2	2		
14	20	4	4
		1	1
3	8	1	1
17	27	2	2
			1
	1		
1	1		
7	10	2	3
	1	21	26
2	2	1	1
1	2	1	2
419	595	14	18
1	1		
	1		
65	93	5	7
20	28	1	2
2	2	1	1
46	75	9	14
2	4		1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling of body temperature change	5	8
Fibrin D dimer increased	1	1
Fine motor skill dysfunction	2	3
Flank pain	1	1
Flatulence	3	4
Flushing	41	77
Formication	2	2
Frequent bowel movements	1	1
Fungal infection	1	1
Gait disturbance	10	14
Gait inability	3	5
Gallbladder disorder	1	1
Gastric disorder		1
Gastric pH decreased	1	1
Gastritis	2	3
Gastrointestinal disorder	4	5
Gastrointestinal pain	2	2
Gastrointestinal sounds abnormal	1	1
Gastrointestinal viral infection	1	1
Gastroesophageal reflux disease	1	1
Gingival bleeding		1
Gingival pain	1	1
Glossitis		1
Glossodynia	2	3
Gout	3	3
Grip strength decreased	1	2
Groin pain	1	1
Grunting	1	1
Guillain-Barre syndrome	2	3
Haematochezia	1	1
Haematocrit decreased	1	1
Haemoglobin decreased	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	7	1	1
1	1		
2	3		
1	1		
3	4		
27	54	14	23
2	2		
1	1		
1	1		
9	13	1	1
3	4		1
		1	1
	1		
1	1		
2	3		
4	5		
2	2		
1	1		
1	1		
1	1		
	1		
1	1		
	1		
2	3		
3	3		
1	2		
1	1		
		1	1
		2	3
		1	1
1	1		
1	1	1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemoglobin increased	1	1
Haemolytic anaemia	1	1
Haemoptysis	1	1
Haemorrhage		2
Hallucination		1
Hallucination, auditory	2	2
Hallucination, visual	1	1
Hand-eye coordination impaired	1	1
Hangover	2	2
Headache	612	838
Head discomfort	12	16
Heart rate abnormal	1	2
Heart rate decreased	1	3
Heart rate increased	65	117
Heart rate irregular	1	4
Hemiparesis	1	1
Hemiplegia	1	1
Hepatic pain		1
Herpes simplex		1
Herpes virus infection	3	3
Herpes zoster	9	11
Hidradenitis		1
Hordeolum		1
Hot flush	17	27
Hunger		1
Hydrophobia	1	1
Hyperacusis	3	3
Hyperaesthesia	7	10
Hyperaesthesia teeth	1	1
Hyperhidrosis	56	84
Hypersensitivity	25	38
Hypersomnia	7	8

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
		1	1
			2
			1
		2	2
		1	1
		1	1
2	2		
581	799	31	39
12	15		1
1	2		
1	2		1
48	90	17	27
1	3		1
		1	1
		1	1
	1		
	1		
3	3		
8	10	1	1
	1		
	1		
15	23	2	4
	1		
1	1		
3	3		
6	9	1	1
1	1		
50	75	6	9
17	24	8	14
7	8		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypertension	19	33
Hypertensive crisis	1	2
Hypertensive emergency	1	1
Hyperventilation	2	3
Hypervigilance	1	1
Hypoacusis	1	1
Hypoaesthesia	100	149
Hypoaesthesia eye	1	1
Hypoaesthesia oral	33	47
Hypocalcaemia	1	1
Hypogeusia		1
Hypoglycaemia	2	3
Hypokalaemia	1	1
Hypokinesia	1	1
Hypomagnesaemia	1	1
Hyposmia		2
Hypotension	5	6
Hypothermia	1	1
Hypothyroidism	1	1
Hypotonia	1	1
Hypoxia		1
Illness	14	24
Immune-mediated arthritis		1
Immune system disorder		2
Immunodeficiency		1
Impaired driving ability		1
Impaired work ability	2	2
Impulsive behaviour	1	1
Inappropriate schedule of product administration	83	83
Incomplete course of vaccination	1	1
Incorrect dose administered	3	4
Incorrect route of product administration	12	18

Spontaneous			
Nonserious		Serious	
I	C	I	C
12	21	7	12
		1	2
		1	1
1	1	1	2
1	1		
1	1		
81	125	19	24
1	1		
24	36	9	11
		1	1
	1		
2	3		
		1	1
1	1		
		1	1
	2		
4	5	1	1
		1	1
		1	1
1	1		
			1
12	22	2	2
			1
			2
			1
	1		
2	2		
1	1		
83	83		
1	1		
3	4		
12	18		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased appetite	1	1
Increased upper airway secretion	3	3
Induration	1	1
Infection		1
Inflammation	4	8
Influenza	5	7
Influenza like illness	38	49
Inhibitory drug interaction	1	1
Initial insomnia	1	1
Injected limb mobility decreased	1	1
Injection site extravasation		1
Injection site hypoaesthesia		1
Injection site pain	3	5
Injection site rash	1	1
Insomnia	36	43
Irritability	5	6
Jaundice	1	1
Joint dislocation	1	1
Joint instability	1	1
Joint noise	1	1
Joint range of motion decreased	6	12
Joint stiffness	7	8
Joint swelling	6	10
Labyrinthitis		1
Lacrimation increased	3	4
Laryngeal oedema		1
Laryngitis	1	1
Laryngospasm	2	2
Laziness		1
Lethargy	18	24
Ligament injury	1	1
Limb discomfort	19	33

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
3	3		
1	1		
	1		
4	8		
5	7		
35	46	3	3
1	1		
1	1		
1	1		
	1		
	1		
3	5		
1	1		
34	41	2	2
4	5	1	1
1	1		
		1	1
		1	1
1	1		
5	11	1	1
7	7		1
5	9	1	1
			1
			1
1	1		
		2	2
	1		
18	23		1
1	1		
17	29	2	4

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Limb injury	2	3
Limb mass	1	1
Lip blister		1
Lip disorder	2	3
Lip erythema		1
Lip exfoliation	1	1
Lip injury	1	1
Lip oedema	1	1
Lip pain		2
Lip pruritus	2	4
Lip swelling	14	23
Livedo reticularis	1	2
Liver injury	1	1
Local reaction		1
Loss of consciousness	8	11
Loss of personal independence in daily activities	10	14
Loss of proprioception	1	1
Lower respiratory tract infection	1	1
Lung disorder	1	1
Lung infiltration		1
Lymphadenitis	3	4
Lymphadenopathy	164	203
Lymph gland infection	1	1
Lymph node pain	41	50
Lymphoedema	2	3
Malaise	108	155
Malnutrition		1
Mania	1	1
Mass	3	3
Mastitis		1
Maternal exposure during pregnancy	18	26
Memory impairment	3	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		
1	1		
	1		
2	3		
	1		
1	1		
1	1		
1	1		
	1		1
2	3		1
9	14	5	9
		1	2
		1	1
	1		
		8	11
8	11	2	3
		1	1
		1	1
1	1		
			1
3	4		
155	190	9	13
1	1		
38	47	3	3
2	3		
100	147	8	8
	1		
		1	1
3	3		
			1
17	25	1	1
1	2	2	3

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Meningitis		1
Menorrhagia	1	1
Menstrual disorder	4	4
Menstruation irregular	4	4
Mental disorder	1	1
Mental impairment	5	7
Metrorrhagia	3	3
Middle insomnia	7	8
Migraine	35	43
Migraine with aura	1	1
Mobility decreased	10	16
Mononeuropathy	1	1
Motion sickness	1	2
Mouth swelling	2	2
Mouth ulceration	1	2
Movement disorder	5	6
Muscle atrophy	1	1
Muscle contractions involuntary	1	1
Muscle discomfort	2	2
Muscle fatigue	2	4
Muscle spasms	29	35
Muscle strain	1	3
Muscle swelling	2	2
Muscle tightness	11	15
Muscle twitching	7	8
Muscular weakness	26	35
Musculoskeletal chest pain	3	6
Musculoskeletal discomfort	4	5
Musculoskeletal disorder	1	1
Musculoskeletal pain	3	4
Musculoskeletal stiffness	25	30
Myalgia	259	352

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	1		
4	4		
4	4		
1	1		
		5	7
3	3		
7	7		1
32	39	3	4
1	1		
9	14	1	2
		1	1
1	2		
1	1	1	1
1	2		
5	6		
1	1		
		1	1
2	2		
2	4		
23	29	6	6
1	3		
2	2		
10	14	1	1
6	7	1	1
17	25	9	10
3	6		
4	5		
		1	1
2	2	1	2
24	28	1	2
247	337	12	15

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myelitis transverse	1	1
Myocardial infarction	2	2
Myocardial necrosis marker increased	1	1
Myocarditis	1	1
Myopathy	1	1
Myopia	1	1
Myositis	2	2
Nasal congestion	34	49
Nasal discomfort		2
Nasal disorder		1
Nasal dryness	1	1
Nasal oedema	3	4
Nasopharyngitis	10	13
Nausea	266	389
Neck injury		1
Neck pain	56	73
Needle issue	2	3
Neoplasm skin	1	1
Nerve compression	2	2
Nervousness	2	11
Neuralgia	14	15
Neurological symptom	1	1
Neuropathy peripheral	6	7
Nightmare	1	1
Night sweats	17	23
Nipple pain	1	1
Nipple swelling		1
Nodule	1	1
Noninfective encephalitis	1	1
Nuchal rigidity	1	1
Nystagmus	2	2
Obstructive airways disorder	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		2	2
		1	1
		1	1
1	1		
1	1		
		2	2
30	44	4	5
	1		1
	1		
		1	1
3	4		
8	11	2	2
248	364	18	25
	1		
53	68	3	5
2	3		
1	1		
2	2		
2	10		1
13	14	1	1
		1	1
		6	7
1	1		
		1	
1	1		
		1	1
1	1		
1	1	1	1
1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Occupational exposure to SARS-CoV-2	2	2
Ocular discomfort	5	7
Ocular hyperaemia	5	8
Odynophagia	3	3
Oedema	2	3
Oedema peripheral	5	6
Off label use	73	93
Optic neuritis	1	1
Oral discomfort	2	5
Oral disorder	1	3
Oral herpes	1	3
Oral mucosal blistering		2
Oral mucosal eruption		2
Oral pain		2
Oral pruritus	2	3
Oropharyngeal discomfort	2	8
Oropharyngeal pain	63	97
Oropharyngeal swelling	1	1
Orthopnoea	1	1
Osteochondritis	1	1
Overdose	2	5
Oxygen saturation decreased	1	2
Pain	391	508
Painful respiration	2	3
Pain in extremity	224	317
Pain in jaw	10	16
Pain of skin	4	6
Pallor	6	11
Palmar erythema	3	3
Palpitations	46	78
Pancreatitis		1
Pancreatitis acute	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
2	4	3	3
5	8		
2	2	1	1
1	2	1	1
4	5	1	1
72	92	1	1
		1	1
2	4		1
1	3		
1	3		
	2		
	2		
	2		
2	3		
1	5	1	3
58	91	5	6
		1	1
1	1		
1	1		
2	5		
1	2		
374	482	17	26
2	3		
216	307	8	10
9	15	1	1
4	6		
4	7	2	4
2	2	1	1
31	55	15	23
			1
		1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panic attack	2	4
Panic reaction	2	3
Paraesthesia	109	161
Paraesthesia ear		1
Paraesthesia mucosal		1
Paraesthesia oral	39	65
Paralysis	1	1
Paranasal sinus discomfort	5	5
Paranoia		1
Parosmia	3	5
Pelvic pain	1	1
Periarthritis	1	1
Pericarditis	3	3
Periorbital swelling	2	5
Peripheral coldness	10	20
Peripheral swelling	34	52
Peroneal nerve palsy	1	1
Petechiae	6	6
Pharyngeal disorder	2	2
Pharyngeal erythema	4	4
Pharyngeal hypoesthesia	3	5
Pharyngeal oedema	1	1
Pharyngeal paraesthesia	5	9
Pharyngeal swelling	20	32
Pharyngitis		1
Pharyngitis streptococcal		1
Photophobia	5	8
Photopsia	1	1
Photosensitivity reaction	2	3
Piloerection	1	2
Platelet count decreased	1	1
Pleural effusion	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2	1	2
2	2		1
91	137	18	24
	1		
	1		
29	50	10	15
		1	1
5	5		
	1		
3	4		1
1	1		
1	1		
		3	3
2	4		1
10	19		1
34	51		1
		1	1
5	5	1	1
2	2		
3	3	1	1
1	2	2	3
		1	1
2	6	3	3
9	15	11	17
	1		
	1		
4	7	1	1
1	1		
2	3		
	1	1	1
		1	1
1	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pleuritic pain		1
Pneumonia	2	2
PO2 decreased	1	1
Pollakiuria	2	2
Polyneuropathy	1	1
Polyuria	1	1
Poor peripheral circulation	1	2
Poor quality product administered	1	2
Poor quality sleep	2	6
Post-traumatic stress disorder	1	1
Pressure of speech	1	1
Presyncope	15	22
Product administered at inappropriate site	5	9
Product confusion	1	1
Productive cough	3	4
Product leakage		1
Product preparation error	2	6
Product preparation issue	1	2
Product use issue	63	87
Pruritus	79	125
Psychomotor hyperactivity	1	1
Pulmonary pain	2	2
Pulse abnormal	4	4
Purpura	1	1
Pyrexia	472	614
Rash	82	123
Rash erythematous	15	21
Rash macular	11	18
Rash maculo-papular	4	4
Rash papular	6	7
Rash pruritic	14	22
Rash pustular		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
		2	2
1	1		
2	2		
		1	1
1	1		
	1	1	1
1	2		
2	6		
1	1		
		1	1
10	17	5	5
5	9		
1	1		
3	4		
	1		
2	5		1
1	2		
62	86	1	1
70	111	9	14
1	1		
2	2		
3	3	1	1
1	1		
453	582	19	32
70	101	12	22
12	15	3	6
10	16	1	2
4	4		
6	7		
12	20	2	2
	1		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash vesicular	2	2
Raynaud's phenomenon	1	2
Reaction to excipient	1	1
Rectal haemorrhage	1	1
Red blood cell count decreased	1	1
Red blood cells urine positive	1	1
Reduced facial expression		1
Renal disorder	1	1
Renal pain	3	4
Respiratory distress	2	2
Respiratory rate increased	1	4
Respiratory tract congestion	3	4
Restless legs syndrome	1	1
Restlessness	6	6
Retching	2	3
Rheumatoid arthritis		1
Rhinalgia	2	2
Rhinitis	1	1
Rhinorrhoea	31	42
Right ventricular dysfunction	1	1
Salivary hypersecretion	1	1
SARS-CoV-2 ant body test negative	2	2
SARS-CoV-2 test positive	37	55
Scab		1
Scleritis	1	1
Scratch	1	2
Screaming	1	1
Secretion discharge		1
Sedation	1	1
Seizure	3	4
Sensation of foreign body	4	9
Sensitive skin	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	1	1
1	2		
1	1		
		1	1
1	1		
1	1		
	1		
1	1		
3	4		
		2	2
1	3		1
3	4		
1	1		
5	5	1	1
2	3		
			1
2	2		
1	1		
26	37	5	5
		1	1
1	1		
2	2		
3	4	34	51
	1		
		1	1
1	2		
		1	1
	1		
1	1		
		3	4
2	4	2	5
3	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensory disturbance	1	3
Sensory loss	1	2
Sepsis	1	1
Serum sickness		1
Sinus congestion	3	4
Sinus disorder	2	4
Sinus headache	2	3
Sinusitis	2	7
Sinus pain	2	2
Sinus tachycardia	4	4
Skin burning sensation	4	4
Skin discolouration	6	7
Skin disorder	3	4
Skin exfoliation	3	3
Skin indentation	1	1
Skin injury	1	2
Skin irritation	3	3
Skin laceration	1	1
Skin lesion	1	1
Skin odour abnormal	1	1
Skin reaction	1	2
Skin swelling	2	2
Skin tightness	1	2
Skin warm	2	2
Sleep disorder	3	5
Sleep disorder due to a general medical condition		1
Sleep disorder due to general medical condition, insomnia type		1
Sleep paralysis	1	1
Sluggishness	3	3
Sneezing	4	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3		
1	2		
		1	1
			1
3	4		
2	4		
2	3		
2	7		
2	2		
2	2	2	2
4	4		
6	7		
3	3		1
2	2	1	1
1	1		
1	2		
3	3		
1	1		
1	1		
1	1		
1	1	1	1
2	2		
	1	1	1
2	2		
3	5		
	1		
	1		
1	1		
3	3		
4	5		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Somnolence	27	34
Speech disorder	5	6
Spinal pain	4	5
Sputum discoloured	1	1
Staring		1
Stevens-Johnson syndrome	1	1
Stomatitis	3	4
Strawberry tongue		1
Streptococcal infection		1
Stress		1
Stridor	1	1
Substance abuse	1	1
Sudden hearing loss	1	1
Supraventricular tachycardia		1
Suspected COVID-19	8	10
Swelling	39	46
Swelling face	25	38
Swelling of eyelid	4	9
Swollen tongue	13	22
Syncope	8	12
Syringe issue		1
Systemic lupus erythematosus	1	1
Systemic scleroderma		1
Tachycardia	53	88
Tachyphrenia	3	3
Tachypnoea	1	2
Taste disorder	3	8
Tenderness	5	9
Tendonitis	1	2
Tendon pain	1	1
Tension headache	2	3
Terminal insomnia	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
24	31	3	3
4	5	1	1
4	5		
		1	1
			1
		1	1
2	3	1	1
	1		
			1
	1		
		1	1
		1	1
		1	1
			1
1	1	7	9
36	43	3	3
20	30	5	8
4	9		
6	11	7	11
		8	12
	1		
		1	1
			1
36	63	17	25
3	3		
		1	2
2	7	1	1
5	9		
1	2		
1	1		
2	3		
1	2		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tetany	1	2
Thinking abnormal	1	1
Thirst	8	8
Throat clearing	1	2
Throat irritation	26	49
Throat tightness	22	39
Thrombocytopenia	1	1
Thrombosis	1	1
Thyroid disorder	1	1
Tinnitus	18	26
Tongue discolouration		1
Tongue discomfort	5	5
Tongue disorder	2	5
Tongue erythema	1	1
Tongue haemorrhage	1	1
Tongue movement disturbance	1	1
Tongue pruritus	2	2
Tonsillar hypertrophy		1
Tonsillitis	1	1
Toothache	3	6
Transient ischaemic attack	1	1
Tremor	34	48
Trigeminal neuralgia	2	2
Trigeminal neuritis	1	1
Trismus	1	1
Troponin increased	1	1
Tryptase increased	1	1
Tunnel vision	2	2
Type IV hypersensitivity reaction	2	2
Underdose	3	8
Undifferentiated connective tissue disease		1
Unresponsive to stimuli	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
1	1		
8	8		
1	1		1
20	39	6	10
11	21	11	18
		1	1
		1	1
1	1		
15	21	3	5
	1		
4	4	1	1
1	4	1	1
1	1		
1	1		
		1	1
2	2		
	1		
1	1		
3	6		
		1	1
29	41	5	7
1	1	1	1
1	1		
1	1		
		1	1
1	1		
		2	2
2	2		
3	8		
			1
		1	1

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Upper-airway cough syndrome	1	1
Upper respiratory tract congestion	1	5
Upper respiratory tract infection	1	1
Urinary incontinence		1
Urinary tract infection	1	2
Urine output increased	1	1
Urticaria	79	116
Uterine contractions during pregnancy	1	1
Uvulitis	1	1
Vaccination site bruising	7	11
Vaccination site coldness		2
Vaccination site discolouration	5	5
Vaccination site discomfort	3	5
Vaccination site erythema	63	85
Vaccination site haemorrhage	2	4
Vaccination site hyperaesthesia	1	1
Vaccination site hypersensitivity	1	1
Vaccination site hypoaesthesia	3	6
Vaccination site induration	6	11
Vaccination site inflammation	1	1
Vaccination site irritation	1	1
Vaccination site joint movement impairment	4	4
Vaccination site joint pain	2	2
Vaccination site lymphadenopathy	3	3
Vaccination site mass	13	13
Vaccination site movement impairment	7	12
Vaccination site nodule	4	5
Vaccination site pain	282	433
Vaccination site paraesthesia	3	8
Vaccination site pruritus	31	42
Vaccination site rash	7	13
Vaccination site reaction	2	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	4	1	1
1	1		
	1		
1	2		
1	1		
64	98	15	18
1	1		
1	1		
7	11		
	2		
5	5		
2	4	1	1
60	82	3	3
2	4		
1	1		
1	1		
3	6		
6	11		
1	1		
1	1		
3	3	1	1
1	1	1	1
3	3		
13	13		
7	12		
4	5		
272	421	10	12
2	7	1	1
30	41	1	1
7	13		
2	3		

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Age Range

31 - 50 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site scab	1	1	1	1		
Vaccination site swelling	60	84	58	82	2	2
Vaccination site ulcer	1	1	1	1		
Vaccination site urticaria	10	12	10	12		
Vaccination site vesicles	2	3	2	3		
Vaccination site warmth	32	42	31	41	1	1
Vaginal haemorrhage	2	3	1	2	1	1
Ventricular extrasystoles	1	3	1	3		
Ventricular tachycardia	1	1			1	1
Vertigo	19	25	19	23		2
Vertigo positional	1	2		1	1	1
Vision blurred	11	16	9	13	2	3
Visual impairment	6	11	6	10		1
Vomiting	75	106	71	99	4	7
Vomiting projectile	1	1	1	1		
Vulvovaginal mycotic infection	1	1	1	1		
Weight decreased	2	2	2	2		
Weight increased		2		2		
Wheezing	7	8	5	6	2	2
White blood cell count increased	1	2			1	2
Wrong product administered	2	2	2	2		
Wrong technique in product usage process	4	5	3	4	1	1
	8,748	12,426	7534	10692	1214	1734

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	12	17	12	17		
Abdominal distension	1	2		1	1	1
Abdominal pain	16	22	15	19	1	3
Abdominal pain lower	2	3	2	3		
Abdominal pain upper	12	14	11	13	1	1
Abdominal rigidity		1				1
Abnormal dreams	1	1	1	1		
Abnormal faeces	1	1	1	1		
Abnormal sensation in eye	1	1	1	1		
Accidental exposure to product	1	1	1	1		
Accidental overdose	2	2	2	2		
Acute myocardial infarction	1	1			1	1
Ageusia	18	23	18	22		1
Agitation	1	4	1	4		
Allergy to vaccine	3	7	2	4	1	3
Amnesia	3	4	2	3	1	1
Anaphylactic reaction	14	19			14	19
Anger	2	2	2	2		
Angioedema	1	1			1	1
Anosmia	11	17	11	16		1
Anxiety	8	13	7	12	1	1
Aphasia	3	3	1	1	2	2
Aphonia		1		1		
Aphthous ulcer	1	1	1	1		
Aptyalism		1		1		
Arrhythmia	1	1			1	1
Arthralgia	121	160	116	154	5	6
Arthritis	5	5	4	4	1	1
Arthropathy	1	3	1	3		
Asthenia	60	75	58	72	2	3
Asymptomatic COVID-19		1				1
Atrial f brillation	2	2	1	1	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Auricular swelling	1	1
Axillary mass		1
Axillary pain	9	9
Back pain	37	46
Balance disorder	5	6
Basal ganglia haemorrhage	1	2
Bedridden	3	3
Blepharochalasis	1	1
Blindness	1	1
Blister	3	3
Blood glucose fluctuation	1	1
Blood glucose increased	4	4
Blood potassium decreased	2	2
Blood pressure diastolic increased		1
Blood pressure fluctuation	1	1
Blood pressure increased	17	27
Blood pressure systolic increased	1	2
Blood sodium decreased	1	1
Blood thyroid stimulating hormone increased	1	1
Body temperature abnormal	1	1
Body temperature decreased	1	1
Body temperature increased	8	12
Bone pain	5	8
Brain oedema	1	1
Breast tenderness	1	1
Bronchospasm		1
Burning sensation	10	12
Cardiac disorder	1	1
Cardiac flutter	1	1
Cellulitis		1
Cerebral disorder		1
Cerebral haemorrhage	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	1		
9	9		
35	44	2	2
4	5	1	1
		1	2
3	3		
1	1		
		1	1
3	3		
1	1		
3	3	1	1
2	2		
			1
		1	1
11	16	6	11
		1	2
1	1		
1	1		
1	1		
8	12		
5	8		
		1	1
1	1		
	1		
9	10	1	2
1	1		
		1	1
			1
	1		
		1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cerebrovascular accident	1	2
Chest discomfort	26	35
Chest pain	11	14
Chills	258	343
Choking sensation	1	1
Circumoral swelling	1	1
Circumstance or information capable of leading to device use error	1	1
Circumstance or information capable of leading to medication error	2	2
Cognitive disorder	1	2
Cold sweat	3	4
Condition aggravated	8	10
Confusional state	3	4
Conjunctival haemorrhage	1	1
Conjunctivitis	1	1
Conjunctivitis viral	1	1
Contusion	2	3
Coordination abnormal	1	1
Costochondritis	1	1
Cough	47	67
COVID-19	61	77
C-reactive protein increased	2	2
Crying	1	1
Crystal urine	1	1
Cyst	1	1
Deafness	2	3
Deafness neurosensory	1	1
Deafness unilateral		1
Death	3	3
Decreased appetite	17	20
Deep vein thrombosis	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
19	24	7	11
9	11	2	3
245	327	13	16
		1	1
1	1		
1	1		
2	2		
1	2		
3	4		
8	9		1
2	3	1	1
		1	1
1	1		
1	1		
2	3		
1	1		
		1	1
42	56	5	11
1	2	60	75
2	2		
1	1		
1	1		
		2	3
		1	1
			1
		3	3
17	19		1
		2	2

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dehydration	1	1
Delirium	1	1
Depersonalisation/derealisation disorder	1	1
Depressed mood	1	2
Depression	2	2
Dermatitis	1	1
Dermatitis allergic	1	1
Dermatitis contact	1	1
Diabetes mellitus	1	1
Diarrhoea	54	71
Diarrhoea haemorrhagic		1
Diplopia	1	1
Discomfort	7	12
Disease progression	1	1
Disease recurrence	8	10
Disorientation	1	1
Dissociation	1	1
Disturbance in attention	5	6
Dizziness	110	164
Dizziness postural	3	3
Drug hypersensitivity	2	3
Drug ineffective	81	104
Drug interaction	1	1
Dry eye	1	1
Dry mouth	6	11
Dry throat	1	1
Dysaesthesia		1
Dysarthria	1	1
Dysgeusia	20	33
Dyslexia		1
Dyspepsia	5	7
Dysphagia	4	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
1	1		
1	2		
1	1	1	1
1	1		
1	1		
		1	1
52	69	2	2
			1
		1	1
7	12		
1	1		
7	9	1	1
1	1		
		1	1
4	5	1	1
101	143	9	21
3	3		
2	3		
1	1	80	103
1	1		
1	1		
5	10	1	1
1	1		
	1		
1	1		
19	32	1	1
	1		
5	7		
3	4	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysphonia	3	5
Dyspnoea	45	58
Dyspnoea exertional	2	2
Dysstasia	1	1
Dystonia	1	1
Dysuria		1
Ear congestion	1	1
Ear discomfort	1	1
Ear pain	8	12
Ear pruritus	2	2
Ear swelling	1	2
Eating disorder	1	3
Eczema		1
Emotional disorder	1	2
Emotional distress	1	1
Encephalopathy	1	1
Energy increased	1	1
Enlarged uvula		1
Eosinophilia	1	1
Episcleritis	2	2
Epistaxis	4	4
Erythema	28	42
Exposure to SARS-CoV-2	4	8
Exposure via skin contact	1	1
Eye contusion	1	1
Eye discharge		1
Eye disorder	2	3
Eye haemorrhage	2	2
Eye inflammation	2	2
Eye irritation	3	4
Eyelid disorder		1
Eyelids pruritus	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2	2	3
31	39	14	19
1	1	1	1
1	1		
		1	1
	1		
1	1		
1	1		
8	12		
2	2		
1	2		
1	2		1
	1		
1	2		
		1	1
		1	1
1	1		
			1
1	1		
2	2		
4	4		
26	39	2	3
1	5	3	3
1	1		
1	1		
	1		
2	2		1
		2	2
1	1	1	1
3	3		1
	1		
		1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Eye pain	9	11
Eye pruritus	1	3
Eye swelling	6	7
Face injury	1	1
Facial discomfort		2
Facial nerve disorder	1	1
Facial pain	2	2
Facial paralysis	8	10
Fall	1	4
Fatigue	263	341
Fear	2	3
Febrile convulsion	1	1
Feeding disorder	1	1
Feeling abnormal	41	58
Feeling cold	18	24
Feeling drunk	1	1
Feeling hot	23	33
Feeling jittery	2	2
Feeling of body temperature change	2	3
Fibrin D dimer increased		1
Fine motor skill dysfunction	1	1
Flank pain	2	2
Flatulence	2	2
Fluid intake reduced	1	1
Flushing	19	41
Food aversion	1	1
Foreign body aspiration		1
Fracture		1
Freezing phenomenon		1
Frequent bowel movements	2	2
Frostbite	1	1
Frustration tolerance decreased		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
9	11		
	1	1	2
4	5	2	2
1	1		
	2		
1	1		
2	2		
		8	10
1	3		1
253	329	10	12
2	3		
		1	1
1	1		
37	53	4	5
16	22	2	2
1	1		
22	31	1	2
1	1	1	1
2	3		
	1		
1	1		
2	2		
2	2		
1	1		
17	35	2	6
1	1		
			1
			1
	1		
2	2		
1	1		
	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gait disturbance	8	14
Gait inability	4	4
Gallbladder disorder		1
Gastric disorder	1	1
Gastrointestinal disorder	4	5
Gastrointestinal pain	1	2
Gastroesophageal sphincter insufficiency	1	1
Gingival bleeding	2	3
Gingival disorder	1	1
Gingival erythema	2	2
Gingival pain	2	2
Gingival swelling	3	3
Glossitis	1	1
Glossodynia		1
Groin pain	2	2
Haemoptysis	1	1
Haemorrhage	1	1
Haemorrhage intracranial	1	1
Haemorrhagic stroke	1	1
Haemorrhoids	1	1
Hallucination	1	1
Headache	333	469
Head discomfort	7	12
Head injury	2	2
Head titubation	1	1
Heart rate decreased		1
Heart rate increased	29	44
Heart rate irregular	1	1
Hemiparesis	1	1
Hepatic enzyme increased	1	1
Herpes virus infection		1
Herpes zoster	9	11

Spontaneous			
Nonserious		Serious	
I	C	I	C
6	11	2	3
4	4		
	1		
1	1		
3	4	1	1
1	2		
		1	1
2	3		
1	1		
2	2		
2	2		
3	3		
1	1		
	1		
2	2		
1	1		
		1	1
		1	1
		1	1
1	1		
		1	1
313	441	20	28
6	11	1	1
2	2		
1	1		
	1		
21	35	8	9
1	1		
		1	1
1	1		
	1		
9	11		

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## Age Range

## 51 - 64 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Hidradenitis	1	1
Hordeolum	1	2
Hot flush	8	11
Hunger	2	3
Hyperaesthesia	3	3
Hyperaesthesia teeth	1	1
Hyperglycaemia	2	2
Hyperhidrosis	30	38
Hypersensitivity	10	15
Hypersomnia	7	9
Hypertension	10	14
Hypertensive emergency		1
Hypertonia		1
Hyperventilation	1	2
Hypoacusis	2	5
Hypoaesthesia	33	51
Hypoaesthesia oral	13	21
Hypogeusia	1	1
Hypokinesia	2	2
Hypophagia	2	2
Hyposmia	1	1
Hypothyroidism	1	1
Illness	15	21
Illness anxiety disorder	1	1
Immune thrombocytopenia	1	1
Immunodeficiency	1	1
Impaired driving ability	1	1
Impaired work ability	2	4
Inappropriate schedule of product administration	36	37
Incoherent	1	1
Incorrect dose administered	1	1
Incorrect route of product administration	3	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	2		
8	11		
2	3		
3	3		
1	1		
1	1	1	1
29	35	1	3
9	11	1	4
6	8	1	1
5	6	5	8
			1
	1		
1	2		
2	5		
28	43	5	8
11	18	2	3
1	1		
2	2		
2	2		
1	1		
		1	1
14	20	1	1
1	1		
		1	1
		1	1
1	1		
2	4		
36	37		
		1	1
1	1		
2	3	1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Increased upper airway secretion		1
Inflammation	2	2
Inflammatory pain	1	1
Influenza	3	8
Influenza B virus test positive	1	1
Influenza like illness	27	38
Initial insomnia	1	1
Injection site pain	3	4
Insomnia	12	16
International normalised ratio increased	1	1
Intervertebral disc protrusion	1	1
Intestinal obstruction		1
Intrusive thoughts	1	1
Irregular sleep wake rhythm disorder		1
Irritability	2	2
Jaundice	1	1
Joint dislocation		1
Joint effusion	1	1
Joint range of motion decreased	1	2
Joint stiffness		1
Joint swelling	5	9
Labile hypertension	1	1
Lacrimation increased	2	2
Laryngitis		1
Lethargy	8	11
Limb discomfort	5	9
Limb injury	1	1
Lip blister	1	1
Lip erythema	1	1
Lipids increased		1
Lip injury	1	1
Lip pruritus	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
2	2		
1	1		
3	8		
1	1		
26	36	1	2
1	1		
2	3	1	1
12	16		
		1	1
1	1		
			1
1	1		
	1		
2	2		
1	1		
			1
1	1		
1	2		
	1		
4	8	1	1
1	1		
1	1	1	1
	1		
7	10	1	1
5	9		
1	1		
1	1		
1	1		
	1		
		1	1
1	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip swelling	14	18
Livedo reticularis	1	1
Liver function test abnormal	1	1
Localised oedema	1	2
Loss of consciousness	6	8
Loss of personal independence in daily activities	7	7
Lower respiratory tract congestion		1
Lymphadenitis	1	1
Lymphadenopathy	49	58
Lymph node pain	15	17
Lymphoedema	3	3
Malaise	89	132
Mass	1	1
Memory impairment	3	4
Mental fatigue	1	1
Mental impairment	2	2
Middle insomnia	2	3
Migraine	23	27
Mobility decreased	1	1
Motion sickness	1	1
Motor dysfunction	2	2
Mouth swelling	1	3
Movement disorder	6	7
Muscle discomfort	2	2
Muscle spasms	18	24
Muscle tightness	5	7
Muscle twitching	4	5
Muscular weakness	12	14
Musculoskeletal chest pain	3	6
Musculoskeletal discomfort	6	9
Musculoskeletal stiffness	16	17
Myalgia	125	172

Spontaneous			
Nonserious		Serious	
I	C	I	C
11	13	3	5
1	1		
		1	1
1	2		
		6	8
7	7		
	1		
1	1		
43	50	6	8
14	16	1	1
3	3		
86	127	3	5
1	1		
2	3	1	1
1	1		
		2	2
2	3		
21	25	2	2
1	1		
1	1		
1	1	1	1
1	1		2
6	7		
2	2		
17	23	1	1
5	6		1
4	5		
12	13		1
3	6		
5	8	1	1
15	16	1	1
121	166	4	6

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mydriasis	1	1
Myocardial infarction	1	2
Nasal congestion	13	20
Nasal discomfort	1	1
Nasal oedema	1	1
Nasopharyngitis	13	18
Nausea	171	230
Neck pain	31	36
Nephrolithiasis	1	1
Nerve compression	1	1
Nervousness	6	8
Neuralgia	2	3
Neuropathy peripheral	2	2
Nightmare	1	1
Night sweats	5	7
Nipple pain	1	1
Nuchal rigidity		1
Occupational exposure to SARS-CoV-2	2	2
Ocular discomfort	2	2
Ocular hyperaemia	5	7
Odynophagia	1	1
Oedema	2	2
Oedema peripheral	1	1
Off label use	12	13
Oral candidiasis	1	2
Oral discomfort		1
Oral disorder	1	1
Oral herpes	3	5
Oral mucosal blistering	1	1
Oral mucosal eruption	2	2
Oral mucosal erythema	1	2
Oral pain	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	2
11	18	2	2
1	1		
1	1		
13	18		
161	213	10	17
30	35	1	1
		1	1
1	1		
6	8		
2	3		
		2	2
1	1		
4	6	1	1
1	1		
	1		
2	2		
2	2		
5	7		
1	1		
2	2		
1	1		
12	13		
1	2		
	1		
1	1		
2	4	1	1
1	1		
2	2		
1	2		
2	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral pruritus		1
Oral viral infection		1
Organising pneumonia		1
Oropharyngeal pain	20	35
Orthostatic heart rate response increased	1	1
Overdose	3	5
Overweight	1	1
Oxygen saturation decreased	5	5
Pain	226	288
Pain in extremity	156	207
Pain in jaw	6	8
Pain of skin		1
Palatal disorder	1	1
Palatal swelling	1	2
Pallor	5	5
Palmar erythema		1
Palpitations	17	28
Panic attack		1
Panic reaction	1	1
Papule	1	1
Paraesthesia	38	64
Paraesthesia oral	13	21
Paralysis	1	1
Paranasal sinus discomfort	1	3
Parosmia	1	4
Periorbital discomfort		1
Periorbital oedema		1
Periorbital swelling	1	4
Peripheral coldness	2	4
Peripheral swelling	24	34
Peroneal nerve palsy		1
Pertussis		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
	1		
			1
18	32	2	3
1	1		
3	5		
1	1		
2	2	3	3
212	274	14	14
154	202	2	5
5	7	1	1
	1		
1	1		
1	1		1
5	5		
	1		
16	23	1	5
	1		
1	1		
1	1		
31	53	7	11
12	19	1	2
		1	1
1	3		
1	4		
	1		
1	3		1
2	4		
22	31	2	3
	1		
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Petechiae	2	2
Pharyngeal hypoaesthesia	1	1
Pharyngeal inflammation	1	1
Pharyngeal oedema	1	1
Pharyngeal paraesthesia	2	3
Pharyngeal swelling	7	11
Photophobia	5	6
Photopsia	1	1
Photosensitivity reaction	1	2
Platelet count decreased	1	1
Pneumonia	2	2
Pneumonitis	1	1
PO2 decreased	1	1
Pollakiuria	3	3
Polymyalgia rheumatica	1	1
Polyuria	1	1
Poor quality product administered	1	1
Poor quality sleep	4	5
Postural orthostatic tachycardia syndrome	1	1
Pre-existing condition improved	1	1
Presyncope	7	10
Procedural pain	1	2
Product administered at inappropriate site	3	6
Productive cough	2	4
Product preparation error	2	3
Product preparation issue	1	1
Product use issue	13	17
Pruritus	50	83
Pruritus genital	1	1
Psychiatric symptom	1	1
Psychomotor hyperactivity	1	1
Pulmonary congestion		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
		1	1
1	1		
		1	1
	1	2	2
6	9	1	2
5	6		
1	1		
1	2		
		1	1
		2	2
1	1		
		1	1
3	3		
		1	1
1	1		
1	1		
4	5		
1	1		
1	1		
5	6	2	4
1	2		
3	6		
2	4		
2	3		
1	1		
13	17		
43	73	7	10
		1	1
1	1		
		1	1
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pulmonary oedema		1
Pulse abnormal	1	3
Pupillary disorder	1	1
Pustule		1
Pyrexia	265	344
Rash	46	64
Rash erythematous	9	13
Rash macular	7	8
Rash maculo-papular	2	4
Rash papular	2	4
Rash pruritic	5	6
Rash vesicular	1	1
Red blood cell sedimentation rate increased	1	1
Renal pain	2	2
Respiratory distress	3	3
Respiratory rate decreased		1
Respiratory rate increased	1	1
Respiratory symptom		1
Respiratory tract congestion	2	2
Restless legs syndrome	1	1
Restlessness	1	2
Retching	2	3
Rhinalgia	1	1
Rhinorrhoea	16	22
Rosacea	1	1
Salivary gland pain	1	1
SARS-CoV-2 ant body test negative	1	1
SARS-CoV-2 ant body test positive	1	2
SARS-CoV-2 test positive	19	24
Scratch	1	1
Screaming	1	1
Seizure	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
1	3		
1	1		
			1
245	322	20	22
40	55	6	9
7	11	2	2
7	7		1
2	4		
2	4		
5	6		
1	1		
1	1		
2	2		
		3	3
			1
		1	1
			1
2	2		
1	1		
	1	1	1
1	2	1	1
1	1		
16	22		
1	1		
1	1		
1	1		1
		19	24
		1	1
1	1		
		1	1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sensation of foreign body	2	3
Sensitisation	1	1
Sensitive skin	1	1
Sensory disturbance	1	1
Sensory loss	3	3
Serotonin syndrome	1	1
Sinus congestion	8	9
Sinus disorder	3	4
Sinus headache		2
Sinusitis	1	3
Sinus pain	2	3
Sinus tarsi syndrome	1	1
Skin burning sensation	2	3
Skin discolouration	1	2
Skin disorder	2	3
Skin irritation	2	2
Skin reaction	1	1
Skin swelling	1	1
Sleep disorder	4	4
Sleep disorder due to a general medical condition	1	1
Sleep talking	1	1
Sluggishness	3	4
Small intestinal obstruction		1
Sneezing	9	11
Snoring		1
Soft tissue swelling		1
Somnolence	14	25
Speech disorder	4	5
Spinal pain	1	1
Sputum discoloured	1	1
Staphylococcal skin infection		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		
1	1		
1	1		
1	1		
3	3		
		1	1
7	8	1	1
3	4		
	2		
1	3		
2	3		
1	1		
2	3		
2	2		
1	1		
1	1		
4	4		
1	1		
1	1		
3	4		
			1
9	11		
	1		
	1		
13	24	1	1
4	5		
1	1		
1	1		
			1

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Status asthmaticus	1	1
Stiff tongue		1
Stomatitis	4	4
Stress	2	3
Stridor	2	3
Sunburn	1	1
Supraventricular tachycardia	1	2
Suspected COVID-19	5	7
Swelling	21	28
Swelling face	13	22
Swelling of eyelid	1	3
Swollen tongue	7	11
Syncope	1	2
Tachycardia	10	15
Tachyphrenia	1	1
Taste disorder	4	7
Tearfulness	1	1
Tenderness	1	1
Tendonitis	1	1
Tendon pain	1	1
Tenosynovitis		1
Tension headache	1	1
Therapeutic response unexpected	3	3
Thinking abnormal	1	2
Thirst	3	5
Throat irritation	9	11
Throat tightness	14	20
Thrombocytopenia	1	1
Thyroid disorder	1	1
Tinnitus	18	23
Tongue blistering	1	1
Tongue coated		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
			1
4	4		
2	3		
		2	3
1	1		
		1	2
1	1	4	6
16	21	5	7
11	18	2	4
1	3		
4	6	3	5
		1	2
8	9	2	6
1	1		
4	7		
1	1		
1	1		
		1	1
1	1		
	1		
1	1		
3	3		
1	2		
3	5		
7	9	2	2
7	10	7	10
		1	1
1	1		
12	17	6	6
1	1		
	1		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tongue discolouration	2	2
Tongue discomfort	1	3
Tongue disorder		1
Tongue dry		1
Tongue erythema	1	1
Tongue injury	1	1
Tongue oedema	1	1
Tongue pruritus	2	2
Tongue ulceration	1	1
Toothache	1	2
Tracheomalacia		1
Transient ischaemic attack	1	2
Tremor	30	38
Trismus	1	1
Underdose	4	7
Unresponsive to stimuli	1	1
Upper-airway cough syndrome	3	5
Upper respiratory tract congestion	7	12
Urge incontinence		1
Urinary tract infection	3	3
Urticaria	30	39
Vaccination site bruising	4	5
Vaccination site cellulitis	3	3
Vaccination site discomfort	2	3
Vaccination site erythema	34	42
Vaccination site haemorrhage	2	3
Vaccination site hypoaesthesia	3	3
Vaccination site induration	2	4
Vaccination site infection	2	2
Vaccination site inflammation	3	3
Vaccination site irritation	1	1
Vaccination site joint movement impairment	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
1	3		
	1		
	1		
1	1		
1	1		
		1	1
2	2		
1	1		
1	2		
			1
		1	2
25	31	5	7
1	1		
4	7		
		1	1
3	5		
7	12		
	1		
2	2	1	1
19	25	11	14
4	5		
2	2	1	1
2	3		
34	42		
2	3		
3	3		
2	4		
2	2		
3	3		
1	1		
2	2		

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Age Range

51 - 64 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site joint pain	1	1	1	1		
Vaccination site macule		1		1		
Vaccination site mass	6	7	6	7		
Vaccination site movement impairment	7	11	7	11		
Vaccination site nodule	2	2	2	2		
Vaccination site pain	181	253	180	252	1	1
Vaccination site pallor	1	1	1	1		
Vaccination site paraesthesia	3	3	3	3		
Vaccination site pruritus	14	20	13	19	1	1
Vaccination site rash	2	4	2	4		
Vaccination site reaction	1	2	1	2		
Vaccination site swelling	32	35	32	35		
Vaccination site urticaria		3		3		
Vaccination site vesicles	1	1	1	1		
Vaccination site warmth	15	17	15	17		
Vaginal haemorrhage	2	2	1	1	1	1
Varicella zoster virus infection		1		1		
Ventricular extrasystoles		3		1		2
Vertigo	16	22	16	22		
Vision blurred	14	22	11	16	3	6
Visual field defect	1	1	1	1		
Visual impairment	1	2	1	2		
Vomiting	36	57	30	49	6	8
Vulvovaginal pruritus	1	1			1	1
Vulvovaginal rash	1	1			1	1
Vulvovaginal swelling	1	1			1	1
Weight decreased	8	10	5	7	3	3
Wheezing	6	11	3	5	3	6
Wound	2	2	2	2		
Wound haemorrhage	1	1			1	1
Wrong technique in product usage process	1	2	1	2		
	4,894	6,678	4267	5803	627	875

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	4	4	4		
Abdominal distension	1	2	1	2		
Abdominal pain	5	6	5	6		
Abdominal pain upper	2	5	1	4	1	1
Abnormal dreams	1	1	1	1		
Accidental exposure to product	1	1			1	1
Accidental overdose		1		1		
Acne	1	1	1	1		
Acoustic neuritis		1				1
Acute myocardial infarction	1	1			1	1
Adnexa uteri pain	1	1	1	1		
Ageusia	3	4	3	4		
Agitation	1	1	1	1		
Allodynia	1	1	1	1		
Amnesia	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anosmia	4	5	4	5		
Aphasia	1	1	1	1		
Appendicitis	2	2			2	2
Arthralgia	38	50	37	49	1	1
Arthritis	4	5	4	5		
Arthropod bite	2	2	2	2		
Asthenia	27	34	24	31	3	3
Asthenopia	1	2	1	2		
Asthma	1	1	1	1		
Ataxia		1				1
Atrial f brillation	3	3			3	3
Autoimmune thyroiditis	1	1			1	1
Axillary pain	1	2	1	2		
Back pain	9	11	9	11		
Balance disorder	5	5	5	5		
Bedridden	1	1	1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blindness		1
Blister	4	4
Blood disorder	1	1
Blood glucose increased	3	4
Blood pressure decreased	1	1
Blood pressure fluctuation	1	1
Blood pressure increased	3	4
Blood urine present	2	2
Body height decreased	2	3
Body temperature abnormal	1	1
Body temperature increased	7	8
Bone pain	3	4
Bone swelling	2	2
Bowel movement irregularity	1	1
Bradycardia	1	1
Breast discomfort	1	1
Breast pain	2	2
Bronchitis	1	2
Burning sensation	2	3
Burn oral cavity	1	1
Cardiac arrest	3	3
Cardiac discomfort		1
Cardiac disorder	1	1
Cardio-respiratory arrest	1	1
Cellulitis	1	1
Cerebrovascular accident	5	5
Chalazion	1	1
Chapped lips	1	1
Chest discomfort	5	5
Chest pain	4	5
Chills	94	113
Choking	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
4	4		
1	1		
2	3	1	1
1	1		
1	1		
2	3	1	1
2	2		
2	3		
1	1		
7	8		
2	3	1	1
2	2		
1	1		
		1	1
1	1		
2	2		
1	2		
2	3		
		1	1
	1		
1	1		
		1	1
		1	1
		5	5
1	1		
1	1		
4	4	1	1
2	3	2	2
88	106	6	7
		2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chromaturia	1	1
Circumstance or information capable of leading to medication error	8	9
Cluster headache	1	1
Communication disorder		1
Condition aggravated	6	7
Confusional state	3	4
Conjunctivitis allergic	1	1
Contraindication to vaccination	1	1
Contrast media allergy	1	1
Contusion	4	4
Cough	20	27
COVID-19	24	25
COVID-19 pneumonia	1	1
Crying	1	1
Cystitis	1	1
Deafness	2	2
Deafness neurosensory	1	2
Death	3	3
Decreased appetite	10	13
Dehydration	3	3
Delirium		1
Dental paraesthesia		1
Dental restoration failure	1	1
Dermatitis contact	1	1
Diabetes mellitus	1	1
Diarrhoea	32	40
Diplopia	1	1
Discomfort	4	4
Disease recurrence	2	2
Disorientation	1	2
Disturbance in attention	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
8	9		
1	1		
	1		
5	5	1	2
3	3		1
1	1		
1	1		
1	1		
4	4		
20	27		
		24	25
		1	1
1	1		
		1	1
		2	2
		1	2
		3	3
8	10	2	3
3	3		
			1
	1		
1	1		
1	1		
		1	1
31	39	1	1
1	1		
4	4		
2	2		
1	2		
1	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dizziness	48	66
Dizziness postural	1	1
Drug ineffective	38	40
Dry mouth	1	2
Dry skin	1	1
Dry throat	1	1
Dysgeusia	5	6
Dyskinesia	1	1
Dysphagia	2	3
Dysphonia	2	3
Dyspnoea	16	19
Dysstasia	1	1
Ear discomfort	1	2
Ear pain	2	3
Eating disorder	1	1
Ecchymosis	1	1
Emotional disorder	1	1
Energy increased	1	1
Eosinophil count increased	1	1
Epistaxis	3	3
Erythema	13	14
Erythema of eyelid	1	1
Exposure via skin contact	1	1
Eye contusion	1	1
Eye disorder	1	1
Eyelid disorder	1	1
Eyelid function disorder		1
Eyelid oedema	2	2
Eye oedema	1	1
Eye pain	1	2
Eye pruritus	1	1
Eye swelling	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
44	60	4	6
1	1		
		38	40
1	2		
1	1		
1	1		
5	6		
1	1		
2	3		
2	3		
11	13	5	6
		1	1
1	1		1
2	3		
1	1		
1	1		
1	1		
1	1		
		1	1
3	3		
13	14		
1	1		
		1	1
1	1		
	1		
2	2		
1	1		
1	2		
1	1		
2	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial pain	3	3
Facial paralysis	6	7
Faeces discoloured	1	1
Faeces soft	1	1
Fall	3	4
Fatigue	92	115
Fear	2	3
Feeding disorder	3	3
Feeling abnormal	26	29
Feeling cold	11	13
Feeling drunk	2	2
Feeling hot	10	11
Feeling jittery	1	1
Feeling of body temperature change	4	4
Flatulence	1	1
Flushing	2	3
Food poisoning		1
Fungal infection	1	1
Gait disturbance	9	9
Gait inability	3	3
Gastroenteritis viral		1
Gastrointestinal pain	2	2
Gastrointestinal sounds abnormal	1	1
Gastrooesophageal reflux disease	1	1
Giant cell arteritis	1	1
Gingival pain	1	1
Glossitis	1	1
Glossodynia	1	1
Gout	1	1
Haematochezia	1	1
Haemorrhage	1	1
Hallucination, visual	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3		
		6	7
1	1		
1	1		
1	2	2	2
89	111	3	4
2	3		
2	2	1	1
26	29		
11	13		
2	2		
10	11		
1	1		
4	4		
1	1		
2	3		
	1		
1	1		
7	7	2	2
2	2	1	1
			1
2	2		
1	1		
1	1		
1	1		
1	1		
1	1		
		1	1
		1	1
		1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Headache	141	166
Head discomfort	2	2
Head injury	1	2
Heart rate abnormal	1	1
Heart rate decreased	1	1
Heart rate increased	10	11
Heart rate irregular	1	1
Herpes simplex	2	2
Herpes zoster	2	3
Hiccups		1
Hot flush	1	1
Hyperacusis		1
Hyperaesthesia	1	1
Hyperglycaemia	1	1
Hyperhidrosis	13	16
Hypersensitivity	5	5
Hypersomnia	2	3
Hypertension	3	5
Hypertensive emergency		1
Hyperventilation	1	1
Hypoacusis	2	2
Hypoaesthesia	7	7
Hypoaesthesia oral	4	6
Hypoglycaemia	1	1
Hypopnoea	1	1
Hypotension	2	2
Hypoxia		1
Illness	13	13
Inappropriate schedule of product administration	16	17
Incision site haemorrhage	1	1
Incomplete course of vaccination	2	2
Incontinence	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
135	159	6	7
2	2		
	1	1	1
1	1		
1	1		
8	9	2	2
1	1		
2	2		
2	3		
	1		
1	1		
			1
1	1		
		1	1
12	15	1	1
4	4	1	1
2	3		
3	5		
			1
1	1		
2	2		
6	6	1	1
3	5	1	1
1	1		
		1	1
1	1	1	1
			1
13	13		
16	17		
		1	1
2	2		
1	1		1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Incorrect dose administered	1	1
Incorrect route of product administration	4	4
Increased bronchial secretion		1
Influenza	2	3
Influenza like illness	16	20
Initial insomnia		1
Injected limb mobility decreased	1	1
Injection site pain	1	3
Injection site swelling	1	1
Insomnia	8	11
International normalised ratio decreased	1	1
Intranasal paraesthesia	1	1
Irritability postvaccinal	1	1
Joint range of motion decreased	2	2
Joint swelling	2	3
Laryngeal pain	1	1
Lethargy	9	11
Leukocytosis	2	2
Limb discomfort	6	6
Lip swelling	2	2
Loss of consciousness	7	7
Loss of personal independence in daily activities	1	1
Lymphadenopathy	12	15
Lymph node pain	2	5
Malaise	45	53
Maternal exposure during pregnancy	1	1
Mechanical urticaria		1
Memory impairment	2	2
Mental disorder	1	1
Mental impairment	1	1
Middle insomnia	3	3
Migraine	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
4	4		
	1		
1	1	1	2
16	20		
	1		
1	1		
1	3		
1	1		
8	11		
1	1		
1	1		
1	1		
2	2		
2	3		
1	1		
9	11		
1	1	1	1
6	6		
1	1	1	1
		7	7
1	1		
12	15		
2	5		
40	48	5	5
1	1		
	1		
2	2		
1	1		
		1	1
3	3		
1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mixed connective tissue disease	1	1
Monocyte count increased	1	1
Movement disorder	2	2
Mucosal disorder	1	1
Muscle spasms	4	4
Muscle tightness	2	3
Muscle twitching	1	1
Muscular weakness	2	3
Musculoskeletal chest pain		1
Musculoskeletal discomfort	1	1
Musculoskeletal disorder	1	1
Musculoskeletal pain	1	1
Musculoskeletal stiffness	6	9
Myalgia	43	54
Nasal congestion	7	10
Nasopharyngitis	4	6
Nausea	71	85
Neck pain	12	14
Nervousness	4	5
Nightmare	1	1
Nipple pain		1
Nipple swelling		1
Nodal rhythm	1	1
Occipital neuralgia	1	1
Ocular hyperaemia	1	1
Odynophagia	1	1
Oedema peripheral	1	1
Off label use	8	10
Oligodipsia	1	1
Oral pain	1	1
Oral pruritus	2	2
Oropharyngeal pain	2	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1		
2	2		
1	1		
3	3	1	1
2	3		
1	1		
2	3		
	1		
1	1		
1	1		
1	1		
5	8	1	1
39	49	4	5
7	10		
4	6		
67	81	4	4
12	14		
4	5		
1	1		
	1		
1	1		
1	1		
1	1		
1	1		
1	1		
8	10		
		1	1
1	1		
2	2		
2	5		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Orthostatic hypotension	1	1
Oxygen saturation decreased	1	1
Pain	63	78
Pain in extremity	87	103
Pain in jaw	3	3
Pain of skin	1	1
Palpitations	3	4
Paraesthesia	5	8
Paraesthesia oral	4	6
Paralysis	1	1
Paranasal sinus discomfort	1	1
Paranoia	1	1
Parosmia	2	2
Penile haemorrhage	1	1
Pericardial effusion	1	1
Periorbital swelling	2	2
Peripheral coldness		2
Peripheral swelling	12	14
Pharyngeal swelling	5	6
Phlebitis	1	1
Photophobia	1	1
Pleural effusion	1	1
Pneumonia	1	1
Polydipsia	1	1
Poor quality product administered	1	1
Poor quality sleep	1	2
Post procedural haemorrhage	1	1
Post-traumatic stress disorder		1
Presyncope	2	2
Product administered at inappropriate site	2	3
Product administration error	1	1
Productive cough	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
1	1		
59	74	4	4
85	101	2	2
3	3		
1	1		
3	4		
5	8		
4	6		
		1	1
1	1		
1	1		
2	2		
		1	1
		1	1
2	2		
	2		
12	14		
3	3	2	3
1	1		
1	1		
		1	1
		1	1
1	1		
1	1		
1	2		
		1	1
	1		
2	2		
2	3		
1	1		
2	2		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Product preparation error	1	2
Product use issue	12	14
Pruritus	29	30
Psoriasis		1
Pulmonary congestion	1	1
Pulmonary pain		1
Pulse abnormal	1	1
Pyrexia	81	96
Rash	20	21
Rash erythematous	3	3
Rash macular	1	1
Rash papular	2	2
Rash pruritic	7	7
Rash vesicular	2	2
Red blood cell sedimentation rate increased	1	1
Respiratory distress		2
Respiratory rate increased	1	1
Respiratory tract congestion	1	1
Restlessness	1	1
Rheumatoid arthritis	1	1
Rhinitis	1	2
Rhinorrhoea	5	5
Salivary hypersecretion	1	1
SARS-CoV-1 test positive	1	1
SARS-CoV-2 test positive	8	9
Sciatica	1	1
Seasonal allergy	1	1
Seizure	1	1
Sensation of foreign body	2	2
Sensory disturbance	1	1
Sensory loss	1	1
Sepsis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
11	13	1	1
27	28	2	2
	1		
		1	1
	1		
		1	1
76	90	5	6
18	19	2	2
3	3		
1	1		
2	2		
7	7		
2	2		
1	1		
			2
		1	1
1	1		
1	1		
		1	1
1	2		
5	5		
1	1		
		1	1
		8	9
1	1		
1	1		
		1	1
2	2		
1	1		
1	1		
		1	1

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Sinus disorder	1	1
Sinus headache	1	1
Sinusitis	1	1
Sinus pain	2	2
Skin burning sensation	2	2
Skin discolouration	1	1
Skin disorder	1	1
Skin laceration		1
Skin lesion	1	1
Skin mass	1	1
Skin swelling	1	1
Sleep disorder	4	5
Sleep disorder due to a general medical condition	1	1
Sleep disorder due to general medical condition, insomnia type	1	1
Sneezing	1	3
Somatic symptom disorder	1	1
Somnolence	11	17
Speech disorder	1	2
Spinal fusion surgery	1	1
Spinal pain	1	1
Streptococcus test positive		1
Stress	2	2
Sudden death	1	1
Sudden hearing loss	1	1
Suffocation feeling		1
Superficial vein prominence	1	1
Supraventricular extrasystoles	1	1
Suspected COVID-19	4	5
Swelling	4	5
Swelling face	12	12

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
1	1		
2	2		
2	2		
1	1		
1	1		
	1		
1	1		
1	1		
1	1		
3	3	1	2
1	1		
1	1		
1	3		
1	1		
10	16	1	1
1	2		
		1	1
1	1		
	1		
2	2		
		1	1
		1	1
	1		
1	1		
		1	1
	1	4	4
4	5		
10	10	2	2

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling of eyelid	3	3
Swollen tongue	2	3
Syncope	1	2
Taste disorder	2	4
Temperature intolerance	1	1
Tenderness	1	2
Tension headache	1	1
Therapeutic response unexpected	2	2
Thinking abnormal		1
Thirst	1	1
Throat irritation	3	4
Throat tightness	3	3
Tic	1	1
Tinnitus	3	5
Tongue discomfort		1
Tongue disorder	1	2
Tongue erythema	1	1
Tongue haematoma		1
Tongue pruritus	1	2
Toothache	2	3
Transient global amnesia	1	1
Tremor	7	9
Trigeminal nerve disorder		1
Troponin increased	1	1
Underdose	5	5
Upper-airway cough syndrome	1	2
Urinary tract infection		1
Urticaria	11	14
Vaccination site bruising	3	3
Vaccination site discomfort	1	2
Vaccination site erythema	20	25
Vaccination site hypoaesthesia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3		
2	3		
		1	2
2	4		
1	1		
1	2		
1	1		
2	2		
	1		
1	1		
3	4		
2	2	1	1
1	1		
3	4		1
	1		
1	2		
1	1		
	1		
1	2		
2	3		
1	1		
6	8	1	1
	1		
		1	1
5	5		
1	2		
	1		
10	13	1	1
3	3		
1	2		
19	24	1	1
1	1		

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Age Range

65 - 79 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site induration	1	1	1	1		
Vaccination site infection	1	1	1	1		
Vaccination site macule	1	1	1	1		
Vaccination site mass	4	4	3	3	1	1
Vaccination site movement impairment	2	3	2	3		
Vaccination site nodule		1		1		
Vaccination site oedema		1		1		
Vaccination site pain	69	92	68	91	1	1
Vaccination site pruritus	10	11	10	11		
Vaccination site rash	2	3	2	3		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	15	18	15	18		
Vaccination site urticaria	2	3	2	3		
Vaccination site vesicles	1	1	1	1		
Vaccination site warmth	9	9	8	8	1	1
Vaginal haemorrhage	1	1			1	1
Varicose vein	1	1	1	1		
Vascular pain	1	1	1	1		
Vein discolouration	1	1	1	1		
Ventricular f brillation	1	1			1	1
Vertigo	3	5	3	5		
Vision blurred	9	9	8	8	1	1
Visual impairment	2	2	2	2		
Vomiting	18	25	18	25		
Weight decreased	2	3	2	3		
Weight increased	1	1	1	1		
Wrong technique in product usage process	1	1	1	1		
	2,019	2,451	1763	2161	256	290

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	1	2	1	1		1
Abdominal pain upper	4	4	4	4		
Abnormal behaviour	1	1			1	1
Acarodermatitis	1	1	1	1		
Aggression	1	1	1	1		
Anger	1	1	1	1		
Anxiety	2	2	1	1	1	1
Arthralgia	14	14	14	14		
Arthritis	1	1	1	1		
Asthenia	12	12	11	11	1	1
Atrial f brillation	1	1			1	1
Back pain	3	3	3	3		
Bedridden	1	1			1	1
Blood creatinine increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	2	3	1	1	1	2
Blood pressure systolic increased	1	1			1	1
Body height decreased	3	3	3	3		
Body temperature increased	1	1	1	1		
Bone pain	1	1	1	1		
Bowel movement irregularity	1	1	1	1		
Bronchitis	1	1	1	1		
Burning sensation	3	3	3	3		
Cardiac arrest	1	1			1	1
Cellulitis	1	1			1	1
Chest discomfort	1	1	1	1		
Chest pain	1	1	1	1		
Chills	10	11	10	11		
Cholecystitis	1	1			1	1
Circumstance or information capable of leading to medication error	2	3	2	3		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cold sweat	1	1
Condition aggravated	1	1
Confusional state	2	2
Contusion	1	1
Cough	4	4
COVID-19	9	10
Crying	1	1
Death	8	9
Decreased appetite	2	2
Deep vein thrombosis	1	1
Delirium	2	2
Delusional perception	2	2
Depressed mood	1	1
Dermatitis	1	1
Dermatitis contact	1	1
Diarrhoea	8	9
Diet refusal	1	1
Diplopia	1	1
Discomfort	1	1
Disease recurrence	1	1
Dizziness	20	21
Drug ineffective	12	13
Dry mouth	1	1
Dysphagia	1	1
Dyspnoea	8	9
Dysstasia	1	1
Ear pain	2	2
Eating disorder	3	3
Epistaxis	1	1
Erythema	2	2
Erythema of eyelid	1	1
Extrasystoles	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
2	2		
1	1		
4	4		
		9	10
1	1		
		8	9
2	2		
		1	1
		2	2
1	1	1	1
1	1		
1	1		
8	9		
		1	1
1	1		
1	1		
18	18	2	3
		12	13
1	1		
		1	1
6	7	2	2
1	1		
2	2		
2	2	1	1
		1	1
2	2		
1	1		
1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total #	Cumulative Total #	Spontaneous			
	Spontaneous AE	Spontaneous AE	Nonserious		Serious	
			I	C	I	C
Eye pain	1	1	1	1		
Face injury	1	1	1	1		
Fall	3	3	2	2	1	1
Fatigue	19	19	18	18	1	1
Feeding disorder	1	1	1	1		
Feeling abnormal	8	8	8	8		
Feeling cold	2	2	2	2		
Feeling hot	6	6	6	6		
Feeling of body temperature change	1	1	1	1		
Flushing	1	1	1	1		
Gait disturbance	5	5	5	5		
Gait inability	1	1			1	1
General physical health deterioration	1	1			1	1
Haematochezia	1	1			1	1
Haemoptysis	2	2	1	1	1	1
Haemorrhage	1	1			1	1
Headache	19	20	18	19	1	1
Head injury	1	1			1	1
Heart rate increased	3	3	3	3		
Heart rate irregular	1	1	1	1		
Herpes zoster	1	1	1	1		
Hunger	1	1	1	1		
Hyperhidrosis	3	3	3	3		
Hypersensitivity	2	2	2	2		
Hypersomnia	3	3	2	2	1	1
Hypertension	1	2			1	2
Hypoacusis	4	4	4	4		
Illness	4	4	4	4		
Inappropriate schedule of product administration	10	10	10	10		
Injection site erythema	1	1	1	1		
Injection site pain	1	1	1	1		
Insomnia	8	8	8	8		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
International normalised ratio increased	1	1
Joint stiffness	1	1
Joint swelling	2	2
Lacrimation increased	1	1
Laziness	1	1
Lethargy	1	1
Leukocytosis	1	1
Ligament sprain	1	1
Limb discomfort	2	2
Lip dry	1	1
Lip swelling	4	4
Loss of consciousness	1	1
Lymphadenopathy	1	1
Malaise	12	12
Memory impairment	1	1
Mental disorder	1	1
Muscle spasms	1	1
Muscle tightness	1	1
Musculoskeletal disorder	2	2
Musculoskeletal stiffness		1
Mutism	1	1
Myalgia	5	5
Myocardial infarction	2	2
Nasal congestion	2	2
Nasopharyngitis	1	1
Nausea	17	18
Neck pain	5	5
Neuropathy peripheral	1	1
Nightmare	1	1
Nocturia	1	1
Off label use	3	3
Oral discomfort	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
2	2		
1	1		
1	1		
1	1		
1	1		
1	1		
1	1		
1	1	1	1
1	1		
4	4		
		1	1
1	1		
10	10	2	2
1	1		
		1	1
1	1		
1	1		
1	1	1	1
	1		
		1	1
5	5		
		2	2
2	2		
1	1		
17	17		1
5	5		
		1	1
1	1		
1	1		
3	3		
1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oral herpes	1	1
Oropharyngeal discomfort	1	1
Overdose	1	1
Oxygen saturation decreased	2	2
Pain	11	13
Pain in extremity	20	20
Pain of skin	1	1
Palpitations	2	2
Parosmia	1	1
Periorbital swelling	1	1
Peripheral swelling	4	4
Pharyngeal erythema	1	1
Pharyngeal swelling	1	1
Pneumonia	2	2
Pollakiuria	1	1
Polydipsia	1	1
Poor quality product administered	2	2
Poor quality sleep	1	1
Presyncope		1
Productive cough	1	1
Product preparation error	3	3
Product use issue	3	3
Pruritus	11	11
Pulmonary congestion	1	1
Pyrexia	13	15
Rash	3	3
Rash erythematous	1	1
Rash macular	1	1
Rash pruritic	1	1
Rash vesicular	1	1
Renal disorder	1	1
Renal impairment	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1		
1	1		
2	2		
11	13		
19	19	1	1
1	1		
2	2		
1	1		
1	1		
4	4		
1	1		
1	1		
		2	2
1	1		
1	1		
2	2		
1	1		
			1
1	1		
3	3		
3	3		
11	11		
		1	1
13	15		
3	3		
1	1		
1	1		
1	1		
1	1		
1	1		
		1	1

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory arrest	2	2
Respiratory failure	1	1
Restlessness	1	1
Rhinorrhoea	2	2
SARS-CoV-2 test positive	2	2
Sensation of foreign body	1	1
Skin burning sensation	1	1
Skin discolouration	1	1
Skin exfoliation	1	1
Skin reaction	1	1
Sleep disorder	2	2
Sneezing	2	2
Somnolence	4	4
Speech disorder	1	1
Sunburn	1	1
Suspected COVID-19	1	1
Swelling	3	3
Swelling face	1	1
Swelling of eyelid	2	2
Swollen tongue	2	2
Tachycardia	1	1
Tenderness	1	1
Terminal insomnia	1	1
Thinking abnormal	2	2
Throat tightness	2	2
Thrombosis	1	1
Tongue discomfort	1	1
Transient ischaemic attack	1	1
Tremor	1	1
Ulcer	1	1
Unresponsive to stimuli	1	1
Upper respiratory tract congestion	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	2
		1	1
1	1		
2	2		
		2	2
1	1		
1	1		
1	1		
1	1		
1	1		
2	2		
2	2		
3	3	1	1
1	1		
1	1		
		1	1
3	3		
1	1		
2	2		
1	1	1	1
		1	1
1	1		
1	1		
2	2		
2	2		
		1	1
1	1		
		1	1
1	1		
		1	1
1	1		

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Age Range

Greater than or equal to 80 years

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary incontinence	1	1	1	1		
Urinary retention	1	1			1	1
Urticaria	4	4	4	4		
Vaccination site bruising	2	2	2	2		
Vaccination site discolouration	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	7	7	7	7		
Vaccination site mass	1	1			1	1
Vaccination site pain	18	18	17	17	1	1
Vaccination site pruritus	3	3	2	2	1	1
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	2	2	2	2		
Vertigo	1	1	1	1		
Vision blurred	3	3	3	3		
Visual impairment	1	1	1	1		
Vomiting	5	6	5	6		
Weight increased	1	1	1	1		
	566	586	472	483	94	103

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	4	5	4	5		
Abdominal distension	2	2	2	2		
Abdominal pain	5	7	5	7		
Abdominal pain upper	12	13	12	13		
Abnormal dreams	1	1	1	1		
Abnormal sensation in eye	2	2	2	2		
Abortion spontaneous	1	1			1	1
Accidental exposure to product	6	10	6	10		
Accidental overdose	2	15	2	15		
Accidental underdose		1		1		
Acute kidney injury	1	1			1	1
Adverse event	1	1	1	1		
Ageusia	3	6	2	4	1	2
Aggression	1	1	1	1		
Allergy to vaccine	4	6	3	5	1	1
Anaesthesia		1		1		
Anaphylactic reaction	10	20			10	20
Anaphylactic shock		1				1
Anger	1	1	1	1		
Angioedema		1				1
Animal bite	1	1	1	1		
Anosmia	6	9	5	7	1	2
Anxiety	9	11	9	11		
Aphasia		1		1		
Aphonia	1	1	1	1		
Aphthous ulcer	2	2	2	2		
Arthralgia	51	64	49	62	2	2
Arthritis	1	1	1	1		
Arthropathy	2	2	2	2		
Arthropod bite	2	2	2	2		
Asthenia	20	29	20	29		
Asthenopia	1	1	1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Asthma	1	1
Asymptomatic COVID-19	1	1
Autoimmune disorder	1	1
Axillary mass	1	2
Axillary pain	3	4
Back pain	23	30
Balance disorder	1	1
Bladder discomfort	1	1
Blindness	1	1
Blister	2	4
Blood glucose abnormal	1	1
Blood glucose decreased	2	3
Blood glucose increased	3	3
Blood pressure decreased	1	3
Blood pressure increased	6	7
Blood pressure systolic increased	1	1
Blood testosterone decreased	1	1
Body temperature abnormal	2	3
Body temperature decreased	3	4
Body temperature increased	5	7
Bone pain	4	6
Bone swelling		1
Booster dose missed	1	1
Brain oedema	1	1
Breast mass	1	1
Breast milk discolouration	1	1
Breast pain	1	1
Breast swelling	1	1
Bronchitis	1	2
Burning sensation	3	4
Cardiac arrest	1	1
Cardiac disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
		1	1
1	2		
3	4		
22	28	1	2
1	1		
1	1		
		1	1
2	4		
1	1		
1	2	1	1
3	3		
1	3		
4	4	2	3
1	1		
1	1		
2	3		
3	3		1
5	7		
4	6		
	1		
1	1		
		1	1
1	1		
1	1		
1	1		
1	1		1
3	4		
		1	1
	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Chapped lips	1	1
Chest discomfort	9	12
Chest pain	4	6
Chillblains	1	1
Chills	129	164
Chromaturia	1	1
Circulatory collapse	1	1
Circumstance or information capable of leading to medication error	24	31
Coagulopathy	1	1
Cognitive disorder		1
Cold sweat	5	5
Colitis ulcerative	1	1
Coma	1	1
Condition aggravated	6	8
Confusional state		1
Conjunctivitis	1	1
Conjunctivitis allergic	1	1
Contraindicated product administered	1	1
Contusion	1	2
Coronavirus test positive	1	1
Cough	17	27
COVID-19	193	230
C-reactive protein increased	1	1
Crying	1	1
Cyanosis	2	2
Deafness	1	3
Death	15	15
Decreased appetite	3	6
Deep vein thrombosis	1	1
Dehydration	2	4
Dental restoration failure	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
6	8	3	4
4	4		2
1	1		
129	162		2
1	1		
		1	1
24	31		
		1	1
		1	1
5	5		
		1	1
		1	1
5	7	1	1
1	1		
1	1		
1	1		
1	2		
		1	1
16	26	1	1
		193	230
1	1		
1	1		
2	2		
		1	3
		15	15
3	6		
		1	1
1	3	1	1
1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Depressed mood	2	3
Dermatitis	1	1
Dermatitis contact	1	1
Diabetes mellitus	2	2
Diarrhoea	28	35
Diastolic hypotension		1
Diplopia	1	1
Discomfort	5	6
Disorientation	1	2
Disturbance in attention	2	4
Dizziness	55	80
Drug hypersensitivity	3	4
Drug ineffective	289	357
Drug interaction	2	2
Dry mouth	3	3
Dry throat	1	3
Dysarthria		1
Dysgeusia	14	17
Dyskinesia		1
Dysmenorrhoea	1	1
Dyspepsia	4	5
Dysphagia	5	6
Dysphonia	1	4
Dyspnoea	13	21
Dysstasia	3	3
Dysuria	2	2
Ear discomfort	2	3
Ear disorder	1	1
Ear infection	1	2
Ear neoplasm	1	1
Ear pain	2	3
Ear pruritus	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3		
1	1		
1	1		
		2	2
28	35		
			1
1	1		
5	6		
1	2		
2	4		
51	75	4	5
3	3		1
		289	357
2	2		
3	3		
1	3		
	1		
14	17		
	1		
1	1		
4	5		
3	4	2	2
	1	1	3
10	15	3	6
1	1	2	2
2	2		
2	3		
1	1		
1	2		
1	1		
2	2		1
1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Epistaxis	3	3
Erythema	15	20
Escherichia infection	1	1
Euphoric mood	1	1
Expired product administered	1	1
Exposure during pregnancy	7	7
Exposure to SARS-CoV-2	24	26
Exposure via breast milk	24	41
Exposure via eye contact	1	2
Exposure via skin contact	7	10
Eye allergy	1	1
Eye contusion	1	1
Eye discharge	1	1
Eye disorder	1	1
Eye haemorrhage	1	1
Eye irritation	5	6
Eye oedema	1	1
Eye pain	1	2
Eye pruritus	5	5
Eye swelling	5	6
Facial asymmetry		1
Facial pain	2	2
Facial paralysis	12	17
Fall	4	4
Fatigue	131	178
Fear	1	2
Febrile neutropenia	1	1
Feeding disorder	2	2
Feeling abnormal	29	40
Feeling cold	13	16
Feeling drunk	1	1
Feeling hot	14	17

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3		
14	19	1	1
		1	1
1	1		
1	1		
7	7		
18	20	6	6
24	41		
1	2		
7	10		
1	1		
1	1		
1	1		
		1	1
		1	1
5	6		
1	1		
1	2		
5	5		
5	6		
	1		
2	2		
		12	17
3	3	1	1
131	177		1
1	2		
		1	1
2	2		
29	39		1
13	16		
1	1		
12	15	2	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Feeling jittery	3	3
Feeling of body temperature change	1	2
Fibrin D dimer increased	1	1
Fibromyalgia	1	1
Flatulence		1
Flushing	10	21
Food allergy		1
Frustration tolerance decreased	1	1
Fungal infection	1	1
Furuncle	1	1
Gait disturbance	4	4
Gait inability	2	2
Gastrointestinal disorder	3	6
Gastrointestinal pain	1	1
Gastroesophageal reflux disease	1	1
Gingival swelling	3	3
Glare	1	1
Glassy eyes	1	1
Glaucoma	2	2
Glossodynia	1	1
Gout	1	1
Haematochezia	2	3
Haematuria		1
Haemoptysis	3	3
Hangover	2	3
Headache	195	245
Head discomfort	1	1
Heart rate decreased		2
Heart rate increased	25	32
Herpes virus infection	1	1
Herpes zoster	7	8
Hiccups	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3		
1	2		
		1	1
		1	1
	1		
7	17	3	4
	1		
1	1		
1	1		
1	1		
3	3	1	1
2	2		
3	6		
1	1		
1	1		
3	3		
1	1		
1	1		
		2	2
1	1		
1	1		
		2	3
			1
3	3		
2	3		
193	240	2	5
1	1		
	1		1
22	27	3	5
1	1		
7	8		
2	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hordeolum		1
Hot flush	2	5
Hyperhidrosis	4	8
Hypersensitivity	12	22
Hypersomnia	2	4
Hypertension	7	9
Hyperventilation	1	1
Hypoacusis	3	3
Hypoaesthesia	14	19
Hypoaesthesia eye	1	1
Hypoaesthesia oral	8	8
Hypogeusia	2	3
Hypokinesia	2	3
Hyposmia		1
Hypotension	1	2
Hypotonia	1	1
Illness	21	25
Immune thrombocytopenia	1	1
Impaired driving ability	1	1
Inappropriate schedule of product administration	78	82
Incomplete course of vaccination	5	5
Incorrect dose administered	4	6
Incorrect route of product administration	23	36
Induration	1	1
Infection	2	2
Infection parasitic	1	1
Inflammation	2	3
Influenza	10	11
Influenza like illness	24	31
Infrequent bowel movements	1	1
Injection site extravasation	1	1
Injection site pain	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
2	5		
4	8		
12	20		2
2	4		
4	6	3	3
		1	1
3	3		
14	18		1
1	1		
8	8		
2	3		
2	3		
	1		
	1	1	1
1	1		
21	25		
		1	1
1	1		
78	82		
5	5		
4	6		
22	35	1	1
		1	1
2	2		
1	1		
2	3		
10	11		
24	31		
1	1		
1	1		
1	1		

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
13	16		
1	1		
1	1		
1	1		
1	1		
1	1		
	1		
9	10		
8	10	1	1
1	1		
		1	1
1	1		
1	1		
1	1		
1	1		
4	4		
5	5		
1	1		
		1	4
3	3		
		1	1
2	3		
39	45	1	1
5	7		
1	2		
61	81	1	2
1	1		
23	34		
1	1		
		1	1
4	4		
4	4		

Insomnia	13	16
Intentional product misuse	1	1
International normalised ratio increased	1	1
Intraocular pressure increased	1	1
Irritability	1	1
Joint swelling	1	1
Lacrimation increased		1
Lethargy	9	10
Limb discomfort	9	11
Limb injury	1	1
Limb mass	1	1
Lip blister	1	1
Lip oedema	1	1
Lip pain	1	1
Lip pruritus	1	1
Lip swelling	4	4
Liquid product physical issue	5	5
Localised infection	1	1
Loss of consciousness	1	4
Loss of personal independence in daily activities	3	3
Lung neoplasm malignant	1	1
Lymphadenitis	2	3
Lymphadenopathy	40	46
Lymph node pain	5	7
Lymphoedema	1	2
Malaise	62	83
Maternal exposure during breast feeding	1	1
Maternal exposure during pregnancy	23	34
Maternal exposure timing unspecified	1	1
Meningitis viral	1	1
Menstrual disorder	4	4
Menstruation irregular	4	4

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mental disorder		1
Mental impairment		1
Metrorrhagia		1
Microembolism	1	1
Micturition urgency	1	1
Middle insomnia	2	2
Migraine	7	10
Mobility decreased	3	3
Motor dysfunction	1	1
Mouth swelling		1
Movement disorder	5	5
Mucous stools		1
Multiple organ dysfunction syndrome	1	1
Muscle spasms	7	7
Muscle tightness	2	3
Muscle twitching	1	1
Muscular weakness	4	6
Musculoskeletal chest pain	3	4
Musculoskeletal discomfort	4	4
Musculoskeletal pain	2	3
Musculoskeletal stiffness	6	6
Myalgia	57	77
Myocardial infarction	1	2
Nasal congestion	15	26
Nasal discomfort	1	1
Nasal oedema	1	1
Nasopharyngitis	11	14
Nausea	69	85
Neck mass	4	4
Neck pain	16	17
Needle issue	1	3
Nerve compression	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
			1
	1		
		1	1
1	1		
2	2		
7	10		
2	2	1	1
		1	1
	1		
5	5		
	1		
		1	1
7	7		
2	3		
1	1		
3	5	1	1
3	4		
4	4		
2	3		
6	6		
57	77		
		1	2
15	26		
1	1		
1	1		
11	14		
68	84	1	1
4	4		
16	17		
1	3		
3	3		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nerve injury		1
Nervousness	3	4
Nervous system disorder	1	1
Neuralgia	2	2
Neuritis	1	1
Neuropathy peripheral	2	2
Nightmare	1	1
Night sweats	4	4
No adverse event	4	4
Noninfective gingivitis	1	1
Occupational exposure to product	1	1
Occupational exposure to SARS-CoV-2	1	2
Ocular hyperaemia	2	3
Oesophageal pain	1	1
Off label use	71	97
Oral dysaesthesia	1	1
Oral herpes	3	5
Oral mucosal blistering	1	1
Oral pain		1
Orchitis		1
Oropharyngeal discomfort	2	3
Oropharyngeal pain	21	30
Overdose	25	35
Oxygen consumption	1	1
Oxygen saturation decreased	4	4
Pain	128	166
Pain in extremity	148	184
Pain in jaw	2	4
Pain of skin	1	1
Pallor	1	2
Palpitations	7	9
Pancytopenia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
3	4		
		1	1
2	2		
1	1		
		2	2
1	1		
4	4		
4	4		
1	1		
1	1		
	1	1	1
2	3		
1	1		
71	97		
		1	1
3	5		
1	1		
	1		
2	2		1
21	29		1
25	35		
1	1		
2	2	2	2
128	166		
148	183		1
2	4		
1	1		
1	2		
5	7	2	2
		1	1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Panic attack	1	1
Papule		1
Paraesthesia	29	37
Paraesthesia oral	12	16
Paranasal sinus hypersecretion	2	2
Parosmia	3	4
Pelvic pain	1	1
Pericarditis	1	2
Peripheral coldness	1	2
Peripheral swelling	38	40
Peripheral vascular disorder	1	1
Pharyngeal disorder	1	1
Pharyngeal hypoaesthesia	1	1
Pharyngeal inflammation	2	2
Pharyngeal paraesthesia	1	3
Pharyngeal swelling	1	5
Photophobia	1	2
Photopsia	1	1
Plantar erythema	1	1
Platelet count decreased		1
Platelet count increased	3	3
Pleurisy	1	1
Pneumonia		1
Pollakiuria	1	1
Polyneuropathy	1	1
Poor quality product administered	85	185
Poor quality sleep	3	4
Presyncope	2	3
Product administered at inappropriate site	9	13
Product administration error	9	9
Product complaint		1
Product dose omission issue	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
	1		
28	35	1	2
12	16		
2	2		
3	4		
1	1		
		1	2
1	2		
38	40		
1	1		
1	1		
2	2		
	2	1	1
	4	1	1
1	2		
		1	1
1	1		
	1		
3	3		
		1	1
			1
1	1		
		1	1
85	185		
3	4		
2	3		
9	13		
9	9		
	1		
2	2		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Productive cough	1	1
Product leakage	5	8
Product packaging quantity issue		4
Product preparation error	55	69
Product preparation issue	46	60
Product prescribing error	2	5
Product temperature excursion issue	14	104
Product use issue	70	97
Pruritus	23	33
Psoriatic arthropathy	1	1
Pulmonary congestion	1	1
Pulmonary embolism	1	2
Pulse abnormal	1	1
Pustule	2	2
Pyrexia	174	228
Rash	26	39
Rash erythematous	2	5
Rash macular	4	6
Rash papular	2	2
Rash pruritic	7	8
Rash vesicular	2	2
Reaction to excipient	1	1
Renal pain	1	1
Respiration abnormal	1	1
Respiratory disorder	1	1
Respiratory tract congestion	2	2
Respiratory tract infection	1	1
Restlessness	1	1
Retching	2	2
Rhinalgia	2	2
Rhinorrhoea	18	24
Rhinovirus infection	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
5	8		
	4		
55	69		
46	60		
2	5		
14	104		
70	97		
23	33		
		1	1
		1	1
		1	2
1	1		
2	2		
174	226		2
26	38		1
2	5		
3	5	1	1
2	2		
7	8		
2	2		
		1	1
1	1		
1	1		
1	1		
2	2		
		1	1
1	1		
2	2		
2	2		
18	24		
1	1		

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rubber sensitivity	1	1
SARS-CoV-2 ant body test negative	6	6
SARS-CoV-2 ant body test positive	1	4
SARS-CoV-2 test positive	88	117
Scratch	1	1
Seasonal allergy	1	1
Sedation		1
Seizure	1	1
Sensation of foreign body	2	4
Sensitive skin	1	1
Sensory disturbance	1	1
Shock symptom	1	1
Sinus disorder	2	2
Sinus headache	1	1
Sinusitis	4	5
Sitophobia	1	1
Skin discolouration	3	5
Skin disorder	3	3
Skin irritation	2	3
Skin laceration	1	1
Sleep disorder	2	3
Sneezing	3	5
Somnolence	5	8
Speech disorder	3	4
Spinal pain		1
Sputum discoloured	1	1
Staphylococcal infection	1	1
Stress	1	1
Suppressed lactation	1	1
Supraventricular tachycardia	2	2
Suspected COVID-19	9	11
Swelling	18	22

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
6	6		
1	4		
		88	117
		1	1
1	1		
	1		
		1	1
2	4		
1	1		
1	1		
		1	1
2	2		
1	1		
3	4	1	1
1	1		
2	2	1	3
3	3		
2	3		
1	1		
2	3		
3	5		
5	8		
3	4		
	1		
1	1		
		1	1
1	1		
1	1		
2	2		
2	3	7	8
17	20	1	2

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Swelling face	3	4
Swelling of eyelid	1	1
Swollen tongue	1	2
Syncope	3	5
Tachycardia	8	15
Tachypnoea		1
Tenderness	2	3
Tension	1	1
Therapeutic response unexpected	1	2
Thirst	1	1
Throat irritation	8	14
Throat tightness	3	7
Thrombocytopenia	1	1
Thrombosis	2	2
Tinnitus	3	5
Tongue pruritus		1
Tongue ulceration	1	1
Tonsillar erythema	1	1
Tonsillar hypertrophy	1	1
Toothache	1	2
Tooth infection	1	1
Tremor	16	18
Tuberculosis	2	2
Tunnel vision		1
Underdose	56	83
Upper airway obstruction	1	1
Upper respiratory tract congestion	2	2
Upper respiratory tract infection	1	1
Urinary tract infection	3	3
Urticaria	22	33
Vaccination complication	2	2
Vaccination site bruising	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	4		
1	1		
1	1		1
		3	5
6	12	2	3
	1		
2	3		
1	1		
1	2		
1	1		
6	11	2	3
3	6		1
		1	1
		2	2
3	4		1
			1
1	1		
1	1		
1	1		
1	2		
1	1		
12	14	4	4
		2	2
			1
56	83		
		1	1
2	2		
1	1		
3	3		
20	30	2	3
2	2		
	1	1	1

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Age Range

Unknown

Preferred Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
3	3		
2	2		
2	6		
22	26		
3	3		
2	6		
1	1		
6	6	1	1
2	2		
6	6	1	1
2	3		
1	1		
86	144		
	1	1	2
6	6		
6	6		
8	8		
13	15		
2	3		
1	1		
5	6		
		1	1
	1		
	1		
5	6		
	1		
	1		
1	1		
3	4		
2	2		
22	26		
	1		

Vaccination site discharge	3	3
Vaccination site discolouration	2	2
Vaccination site discomfort	2	6
Vaccination site erythema	22	26
Vaccination site extravasation	3	3
Vaccination site haemorrhage	2	6
Vaccination site hypoaesthesia	1	1
Vaccination site induration	6	6
Vaccination site inflammation	2	2
Vaccination site mass	6	7
Vaccination site movement impairment	2	3
Vaccination site nodule	1	1
Vaccination site pain	86	144
Vaccination site paraesthesia	1	3
Vaccination site pruritus	6	6
Vaccination site rash	6	6
Vaccination site reaction	8	8
Vaccination site swelling	13	15
Vaccination site urticaria	2	3
Vaccination site vesicles	1	1
Vaccination site warmth	5	6
Vaginal haemorrhage	1	1
Varicella		1
Vasodilatation		1
Vertigo	5	6
Vessel puncture site haemorrhage		1
Vessel puncture site injury		1
Viral infection	1	1
Vision blurred	3	4
Visual impairment	2	2
Vomiting	22	26
Vomiting projectile		1

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Age Range

Unknown

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Von Willebrand's disease		1				1
Weight decreased	1	1	1	1		
Wheezing	2	4	1	3	1	1
Wrong product administered	3	4	3	4		
Wrong technique in product usage process	16	38	16	38		
	4,036	5,479	3272	4496	764	983

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Country Where Event Occurred  
**UNITED STATES MINOR OUTLYING ISLA**

Age Range

**18 - 30 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Discomfort	1	1	1	1
Joint range of motion decreased	1	1	1	1
Lymphadenopathy	1	1	1	1
	3	3	3	3

Age Range

**51 - 64 years**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vaccination site pain		1		1
		1		1

Age Range

**Unknown**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inappropriate schedule of product administration	1	1	1	1
	1	1	1	1

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**APPENDIX 2.5.3: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Gender by Preferred Term per Country**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval) / 18,061 (Cumulative)

Total Number of Adverse Events (PT): 51,740 (Interval) / 63,975 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AFGHANISTAN**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills		1		1		
Erythema		1		1		
Facial paralysis		1				1
Feeling of body temperature change		1		1		
Muscle tightness		1		1		
Paraesthesia		1		1		
Pruritus		1		1		
Rash		1		1		
Swelling face		1		1		
		9		8		1

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Country Where Event Occurred  
**ANDORRA**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administered to patient of inappropriate age	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**AUSTRIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Asthenia	3	3	1	1	2	2
Burning sensation	1	1	1	1		
Cardiovascular disorder	1	1	1	1		
Death	2	2			2	2
Diarrhoea	2	2	2	2		
Fatigue	4	4	3	3	1	1
Feeling drunk	1	1	1	1		
Hangover	1	1	1	1		
Headache	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Malaise	1	1	1	1		
Migraine	1	1	1	1		
Myalgia	1	1	1	1		
Myocardial infarction	1	1			1	1
Nausea	4	4	4	4		
Pruritus	1	1	1	1		
Pulmonary embolism	1	1			1	1
Rales	1	1			1	1
Respiratory depression	1	1			1	1
Somnolence	1	1			1	1
Urinary retention	1	1			1	1
Vaccination site pain	4	4	4	4		
Vaccination site pruritus	1	1	1	1		
Vaginal discharge	1	1	1	1		
Vomiting	3	3	3	3		
Wrong technique in product usage process	1	1	1	1		
	42	42	30	30	12	12

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death	1	1			1	1
Drug ineffective	1	1			1	1
Headache	1	1	1	1		
Influenza	1	1	1	1		
Migraine	1	1	1	1		
Poor quality product administered	1	1	1	1		
Product preparation error	1	1	1	1		
Pruritus	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Urticaria	1	1	1	1		
Vaccination site pain	1	1	1	1		
	11	11	8	8	3	3

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Country Where Event Occurred  
**BAHRAIN**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**BELGIUM**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute kidney injury	1	1			1	1
Asthenia	1	1	1	1		
Blood lactic acid increased	1	1			1	1
Cardiovascular disorder	1	1			1	1
COVID-19	1	1			1	1
Death	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Fatigue	1	1	1	1		
Haemorrhage intracranial	1	1			1	1
Hypoglycaemia	1	1			1	1
Illness	1	1	1	1		
Intestinal dilatation	1	1			1	1
Intestinal ischaemia	1	1			1	1
Leukocytosis	1	1			1	1
Lung infiltration	1	1			1	1
Malaise	1	1	1	1		
Memory impairment	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Pain in extremity	1	1	1	1		
Palpitations	1	1	1	1		
Pneumonitis	1	1			1	1
Pulmonary embolism	1	1			1	1
Respiratory disorder	1	1			1	1
Sensory disturbance	1	1	1	1		
Sepsis	1	1			1	1
Sudden death	1	1			1	1
Swollen tongue	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site pruritus	1	1	1	1		
Vaccination site warmth	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	33	33	15	15	18	18

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory failure	1	1			1	1
Agitation	2	2			2	2
Amnesia	1	1			1	1
Bradycardia	1	1			1	1
Cardiovascular disorder	3	3			3	3
Confusional state	2	2			2	2
Depressed level of consciousness	1	1			1	1
Disorientation	1	1			1	1
Dyspnoea	1	1			1	1
Exposure via skin contact	1	1	1	1		
Eye movement disorder	1	1			1	1
Fatigue	2	2	2	2		
General physical health deterioration	1	1			1	1
Headache	1	1	1	1		
Hypotension	1	1			1	1
Hypovolaemic shock	1	1			1	1
Intestinal ischaemia	1	1			1	1
Liver function test abnormal	1	1			1	1
Malaise	3	3			3	3
Metabolic acidosis	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
Nervous system disorder	1	1			1	1
Neutropenia	1	1			1	1
Occupational exposure to product	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pain in extremity	1	1	1	1		
Patient elopement	1	1			1	1
Poor quality sleep	1	1	1	1		
Presyncope	2	2			2	2
Pyrexia	1	1			1	1
Renal disorder	1	1			1	1
Respiratory disorder	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Septic shock	1	1			1	1
Staring	1	1			1	1
Sudden death	1	1			1	1
Tachycardia	1	1			1	1
Tachypnoea	1	1			1	1
Vaccination site pain	2	2	2	2		
Vaccination site swelling	1	1	1	1		
	48	48	11	11	37	37

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	4	4			4	4
Drug ineffective	4	4			4	4
Fatigue	1	1	1	1		
Malaise	1	1	1	1		
Nausea	1	1	1	1		
	11	11	3	3	8	8

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Country Where Event Occurred  
**BERMUDA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**BULGARIA**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	2	2		
Asthenia	2	2	2	2		
Back pain	1	1	1	1		
Blood pressure diastolic decreased	1	1	1	1		
Body temperature increased	1	1	1	1		
Chills	2	2	1	1	1	1
COVID-19	1	1			1	1
Dizziness	2	2	1	1	1	1
Dizziness postural	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	1	1			1	1
Erythema	1	1	1	1		
Headache	2	2	1	1	1	1
Head discomfort	1	1			1	1
Hyperhidrosis	1	1			1	1
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Myalgia	4	4	4	4		
Nausea	2	2	1	1	1	1
Neck pain	1	1	1	1		
Pain	1	1	1	1		
Pallor	1	1	1	1		
Paraesthesia	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pyrexia	1	1	1	1		
Rash	1	1	1	1		
Rash erythematous	1	1	1	1		
Rash pruritic	1	1	1	1		
Swelling	2	2	2	2		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	8	8	8	8		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site swelling	2	2	2	2		
Vertigo	1	1			1	1
Vomiting	1	1	1	1		
	53	53	43	43	10	10

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia		1		1		
Anosmia		1		1		
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Body temperature increased	2	2	2	2		
Chills		1		1		
COVID-19	1	2			1	2
Diarrhoea	2	2	2	2		
Dizziness	1	1	1	1		
Drug ineffective	1	2			1	2
Fatigue	1	1	1	1		
Headache	3	3	3	3		
Hyperhidrosis		1		1		
Lymphadenopathy	2	2	2	2		
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Pain in extremity		1		1		
Palpitations	1	1	1	1		
Pyrexia	1	1	1	1		
Vaccination site erythema	1	1	1	1		
	20	27	18	23	2	4

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

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Country Where Event Occurred  
**CANADA**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain lower	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Administration site pain	1	1	1	1		
Affect lability	1	1	1	1		
Allergy to vaccine		1		1		
Anaphylactic reaction	2	2	1	1	1	1
Angioedema	1	1			1	1
Anxiety	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Arthralgia	10	10	9	9	1	1
Asthenia	3	4	3	4		
Back pain	1	1	1	1		
Blood pressure fluctuation	1	1	1	1		
Body temperature increased	1	1	1	1		
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	8	10	8	10		
Cold sweat	1	1	1	1		
COVID-19	1	1			1	1
Decreased appetite	2	2	2	2		
Depression	1	1	1	1		
Diarrhoea	6	8	6	8		
Disease recurrence	1	1	1	1		
Distractibility	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	6	6	6	6		
Drug ineffective	2	2			2	2
Dysgeusia		1		1		
Dysphagia	2	3	2	3		
Dyspnoea	1	1	1	1		
Ear discomfort	1	1	1	1		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eczema	1	1	1	1		
Erythema	2	2	1	1	1	1
Exposure during pregnancy	4	4	4	4		
Exposure via breast milk	3	3	3	3		
Eye pain	1	1	1	1		
Eye pruritus	1	1	1	1		
Eye swelling	1	1	1	1		
Face oedema	1	1			1	1
Facial paralysis		1				1
Fatigue	19	21	18	20	1	1
Fear	1	1	1	1		
Feeling abnormal	3	4	3	4		
Feeling cold	2	2	1	1	1	1
Feeling hot	1	1	1	1		
Fibromyalgia	1	1	1	1		
Fluid retention		1		1		
Flushing	1	1			1	1
Gastroenteritis	1	1	1	1		
Gastrooesophageal reflux disease	1	1	1	1		
Headache	25	28	25	28		
Heart rate increased	1	2	1	2		
Herpes zoster	1	1	1	1		
Hyperaesthesia	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	2	2	1	1	1	1
Hypersomnia		1		1		
Hypertension	2	3	1	2	1	1
Hypoaesthesia	4	4	3	3	1	1
Hypotension	1	1			1	1
Illness	1	1	1	1		
Impaired work ability	1	1	1	1		
Inappropriate schedule of product administration	2	2	2	2		

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	2	2	2	2		
Insomnia	1	1	1	1		
Joint swelling	2	2	1	1	1	1
Leukoplakia	1	1	1	1		
Lip swelling	2	2	2	2		
Lung disorder	1	1			1	1
Lymphadenopathy	5	6	5	6		
Malaise	2	2	2	2		
Maternal exposure during pregnancy	11	11	11	11		
Maternal exposure timing unspecified	2	2	2	2		
Metrorrhagia	1	1	1	1		
Migraine	1	1	1	1		
Muscle spasms	1	1	1	1		
Muscle twitching	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	2	2	2		
Myalgia	13	13	12	12	1	1
Nasal congestion	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	9	11	9	11		
Neck pain	2	2	2	2		
Odynophagia		1		1		
Off label use	17	17	17	17		
Oral mucosal blistering	1	1	1	1		
Oropharyngeal pain	2	3	2	3		
Overdose	2	2	2	2		
Pain	5	7	5	7		
Pain in extremity	11	14	11	14		
Pain of skin	1	1	1	1		
Palpitations	1	1	1	1		
Paraesthesia	5	7	4	5	1	2

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 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia oral	2	5	2	4		1
Peripheral swelling	1	1	1	1		
Petechiae	1	1	1	1		
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal swelling	2	2	1	1	1	1
Presyncope	1	2		1	1	1
Product administered at inappropriate site	1	1	1	1		
Product use issue	15	15	15	15		
Pruritus	6	6	5	5	1	1
Pulmonary pain	1	1			1	1
Pyrexia	12	14	12	14		
Rash	4	4	3	3	1	1
Rash macular	1	1	1	1		
Rheumatoid arthritis	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
Sinus pain	1	1	1	1		
Skin burning sensation	1	1	1	1		
Skin lesion	1	1	1	1		
Sneezing	1	1	1	1		
Stress	1	1	1	1		
Swelling	1	2		1	1	1
Swollen tongue	2	3	1	2	1	1
Syncope	1	1			1	1
Tachycardia	5	5	3	3	2	2
Tachypnoea	1	1	1	1		
Taste disorder	1	1	1	1		
Thirst		1		1		
Throat irritation	1	1	1	1		
Tongue disorder	1	1			1	1
Tongue pruritus		1		1		
Tremor	2	2	2	2		
Type IV hypersensitivity reaction	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	3	4	3	4		
Vaccination site induration	1	1	1	1		
Vaccination site pain	12	12	11	11	1	1
Vaccination site rash	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	4	4	4	4		
Vulval disorder	1	1			1	1
	354	396	318	357	36	39

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Adverse event	1	1	1	1		
Agitation	1	1	1	1		
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Buttock injury	1	1	1	1		
Cellulitis	1	1			1	1
COVID-19	2	2			2	2
Deafness	1	1			1	1
Decreased appetite	1	1	1	1		
Diarrhoea	2	2	2	2		
Drug ineffective	3	3			3	3
Genital blister	1	1	1	1		
Headache	2	2	2	2		
Herpes zoster	2	2	2	2		
Hot flush	1	1	1	1		
Lethargy	1	1	1	1		
Localised infection	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Myalgia	3	3	3	3		
Nausea	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Pyrexia	3	3	3	3		
Rash macular	1	1	1	1		
Rash pustular	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Skin lesion	1	1	1	1		
Somnolence	1	1	1	1		
Vaccination site pain	1	2	1	2		
Varicella	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Visual impairment	1	1	1	1		
Vital functions abnormal	1	1			1	1
Vomiting	1	1	1	1		
	45	46	36	37	9	9

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Drug ineffective	2	2			2	2
Exposure via breast milk	3	3	3	3		
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Hypersensitivity	2	2	2	2		
Incomplete course of vaccination	1	1	1	1		
Lethargy	1	1	1	1		
Malaise	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Overdose	4	4	4	4		
Pain	1	1	1	1		
Pain in extremity	2	2	2	2		
Product preparation issue	10	10	10	10		
Pyrexia	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Syncope		1				1
Underdose	4	4	4	4		
	37	38	33	33	4	5

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Country Where Event Occurred  
**CHILE**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1			1	1
Arthralgia	2	2	1	1	1	1
Arthritis	1	1			1	1
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Burning sensation	1	1	1	1		
Chills	2	2	1	1	1	1
Crying		1				1
Diarrhoea	3	3	3	3		
Disease recurrence	1	1	1	1		
Dry mouth		1				1
Feeling cold	1	1	1	1		
Headache	4	4	3	3	1	1
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1	1	1		
Joint swelling	2	2	1	1	1	1
Lymphadenopathy	2	3	1	2	1	1
Lymph node pain	2	2	2	2		
Malaise	1	2	1	2		
Maternal exposure timing unspecified	1	1	1	1		
Muscle spasms	1	1	1	1		
Myalgia	2	2	1	1	1	1
Nasal congestion	1	1	1	1		
Nausea	1	1			1	1
Off label use	1	1	1	1		
Pain		1		1		
Pain in extremity	1	1	1	1		
Pancreatitis	1	1			1	1
Paraesthesia		1				1
Photophobia	1	1			1	1
Product use issue	1	1	1	1		
Pyrexia	3	4	2	3	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sensory loss	1	1	1	1		
Urine analysis abnormal	1	1			1	1
Vaccination site pain	1	1			1	1
	44	51	30	34	14	17

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedema	1	1			1	1
Diarrhoea	1	1	1	1		
Dyspnoea	1	1			1	1
Eye pruritus	1	1			1	1
Eye swelling	1	1	1	1		
Fatigue	1	1	1	1		
Headache	1	2	1	2		
Myalgia		1		1		
Nausea		1		1		
Ocular hyperaemia	1	1			1	1
Off label use	1	1	1	1		
Pain in extremity	1	1	1	1		
Product use issue	1	1	1	1		
Swelling face	1	1	1	1		
Vaccination site pain		1		1		
	12	16	8	12	4	4

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Burning sensation	1	1	1	1
Dermatitis allergic		4		4
Dizziness		1		1
Erythema	1	1	1	1
Fatigue		1		1
Headache	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1
Lymphadenopathy	1	1	1	1
Peripheral swelling	1	1	1	1
Polydipsia	1	1	1	1
Vaccination site pain	1	1	1	1
	8	14	8	14

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Country Where Event Occurred  
**COLOMBIA**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Candida infection	1	1	1	1
Gingivitis	1	1	1	1
Hypersensitivity	1	1	1	1
Leukocytosis	1	1	1	1
Mouth swelling	1	1	1	1
Stomatitis	1	1	1	1
	6	6	6	6

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Country Where Event Occurred  
**COSTA RICA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal pain upper	1	1	1	1
Asthenia	1	1	1	1
Chills	1	1	1	1
Energy increased	1	1	1	1
Euphoric mood	1	1	1	1
Eye allergy	1	1	1	1
Eye inflammation	1	1	1	1
Fatigue	1	1	1	1
Feeling abnormal	1	1	1	1
Feeling hot	1	1	1	1
Headache	3	3	3	3
Insomnia	1	1	1	1
Limb discomfort	1	1	1	1
Lymph node pain	1	1	1	1
Pain in extremity	2	2	2	2
Tachycardia	1	1	1	1
Vaccination site pain	2	2	2	2
	21	21	21	21

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	1	1	1		
Headache	3	3	3	3		
Heart rate irregular	1	1	1	1		
Hepatic enzyme increased	1	1			1	1
Joint range of motion decreased	1	1			1	1
Malaise	2	2	1	1	1	1
Mobility decreased	1	1			1	1
Myalgia	2	2	1	1	1	1
Pain	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	3	3	2	2	1	1
Rash	1	1	1	1		
Red blood cell sedimentation rate increased	1	1	1	1		
Sleep disorder	1	1	1	1		
Splenomegaly	1	1			1	1
Vaccination site pain	1	1	1	1		
Vasculitis	1	1	1	1		
	23	23	16	16	7	7

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Country Where Event Occurred  
**CROATIA**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Body temperature increased	2	3	2	3		
Bronchospasm	1	1			1	1
Burning sensation	1	1			1	1
Chills	2	2	2	2		
Dizziness	1	1	1	1		
Dysgeusia	1	1			1	1
Dyspnoea	1	1			1	1
Erythema	2	2	1	1	1	1
Eyelid ptosis	1	1			1	1
Eye pain	1	1	1	1		
Facial paresis	1	1			1	1
Fatigue	2	4	2	4		
Feeling cold	1	1	1	1		
Headache	7	8	6	7	1	1
Hypoaesthesia oral	1	1			1	1
Lip disorder	1	1			1	1
Malaise	1	1	1	1		
Multi-organ disorder	1	1			1	1
Myalgia		2		2		
Neck pain	1	1	1	1		
Pain	1	1	1	1		
Paraesthesia	1	1			1	1
Peripheral swelling	1	1	1	1		
Pharyngeal paraesthesia	1	1			1	1
Pruritus	1	1			1	1
Pyrexia	6	6	6	6		
Rash	2	2	1	1	1	1
Rash erythematous	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract oedema	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Tachypnoea	1	1			1	1
Tongue oedema	1	1			1	1
Tremor	1	1			1	1
Type I hypersensitivity	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	7	9	6	8	1	1
Vaccination site swelling	1	1	1	1		
Wheezing	1	1			1	1
	65	73	36	44	29	29

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergy to chemicals	1	1	1	1
Feeling hot	1	1	1	1
Pain in extremity		1		1
Pyrexia		2		2
	2	5	2	5

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Country Where Event Occurred

**CYPRUS**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure increased	1	1			1	1
Cervix oedema	1	1	1	1		
Dizziness	1	1	1	1		
Dysgeusia	1	1	1	1		
Eyelid ptosis	1	1	1	1		
Facial paralysis	1	1			1	1
Facial paresis	1	1	1	1		
Headache	2	2	2	2		
Hypersensitivity	1	1	1	1		
Hypertension	1	1			1	1
Hypoaesthesia	1	1			1	1
Hypoaesthesia eye	1	1			1	1
Hypoaesthesia oral	1	1			1	1
Lymphadenopathy	1	1			1	1
Migraine	1	1	1	1		
Rash	1	1	1	1		
Swollen tongue	1	1	1	1		
Tachyarrhythmia	1	1			1	1
Tachycardia	1	1			1	1
Vaccination site pain	1	1	1	1		
	21	21	12	12	9	9

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	1	1	1		
Myocardial infarction		1				1
Pyrexia	1	1	1	1		
Vaccination site pain	1	1	1	1		
	3	4	3	3		1

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Country Where Event Occurred

**CZECH REPUBLIC**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2			2	2
Anaphylactic reaction	2	2			2	2
Angioedema	1	1			1	1
Anxiety	1	1	1	1		
Arthralgia	2	2	2	2		
Asthenia	2	2	2	2		
Asthma	1	1			1	1
Back pain	1	1	1	1		
Blood pressure increased	1	1			1	1
Body temperature increased	1	1	1	1		
Chills	2	2	1	1	1	1
Circulatory collapse	1	1			1	1
Cough	1	1	1	1		
COVID-19	2	2			2	2
Diarrhoea	1	1	1	1		
Dizziness	2	2	1	1	1	1
Drug ineffective	3	3			3	3
Dyspnoea	3	3	1	1	2	2
Erythema	2	2	2	2		
Facial paresis	1	1			1	1
Fatigue	8	8	8	8		
Headache	5	5	5	5		
Hypersensitivity	2	2	1	1	1	1
Hypertension	1	1	1	1		
Hyperventilation	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Joint stiffness	1	1	1	1		
Lip swelling	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Mobility decreased	1	1	1	1		
Musculoskeletal chest pain	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	1	1	1	1		
Nausea	4	4	3	3	1	1
Pain	1	1	1	1		
Pain in extremity	2	2	2	2		
Paraesthesia	2	2	1	1	1	1
Peripheral swelling	1	1			1	1
Pharyngeal swelling	1	1			1	1
Photophobia	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	3	3	3	3		
Rash	1	1	1	1		
Rhinitis	1	1	1	1		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Somnolence	2	2	2	2		
Swelling	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	2	2			2	2
Tachypnoea	1	1			1	1
Throat tightness	1	1			1	1
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vertigo	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	1	1			1	1
	93	93	61	61	32	32

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Myalgia	1	1	1	1
Pyrexia	1	1	1	1
	3	3	3	3

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Country Where Event Occurred  
**DENMARK**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Anaphylactic reaction	6	6			6	6
Anaphylactic shock	1	1			1	1
Angioedema	3	3			3	3
Anxiety	1	1			1	1
Arthralgia	9	9	9	9		
Asthenia	3	3	1	1	2	2
Axillary pain	1	1	1	1		
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	2	2			2	2
Body temperature increased	2	2	2	2		
Bronchospasm	1	1			1	1
Chest discomfort	4	4	1	1	3	3
Chills	11	11	8	8	3	3
Chronic obstructive pulmonary disease	1	1			1	1
Cold sweat	1	1	1	1		
Condition aggravated	1	1			1	1
Cough	2	2			2	2
COVID-19	1	1			1	1
Derealisation	1	1	1	1		
Dermatitis allergic	1	1			1	1
Diarrhoea	4	4	4	4		
Discomfort	3	3			3	3
Disturbance in attention	1	1			1	1
Dizziness	20	20	10	10	10	10
Dizziness postural	1	1			1	1
Drug ineffective	1	1			1	1
Dry eye	1	1	1	1		
Dysaesthesia	1	1	1	1		
Dysgeusia	1	1	1	1		
Dysphagia	1	1			1	1
Dysphonia	2	2			2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dyspnoea	8	8
Dyspnoea at rest	1	1
Erythema	2	2
Eye pain	3	3
Eye pruritus	1	1
Fatigue	11	11
Feeling hot	6	6
Fluid intake reduced	1	1
Flushing	3	3
Foaming at mouth	1	1
General physical health deterioration	2	2
Glossodynia	1	1
Headache	29	29
Heart rate increased	3	3
Hot flush	1	1
Hyperhidrosis	2	2
Hypersensitivity	5	5
Hypertension	2	2
Hyperventilation	1	1
Hypophagia	1	1
Hypotension	1	1
Incorrect route of product administration	1	1
Influenza like illness	2	2
Lymphadenopathy	3	3
Lymph node pain	1	1
Malaise	22	22
Migraine	1	1
Muscle fatigue	1	1
Myalgia	17	17
Nasopharyngitis	1	1
Nausea	15	15
Neck pain	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	7	7
		1	1
		2	2
3	3		
1	1		
9	9	2	2
2	2	4	4
1	1		
1	1	2	2
1	1		
		2	2
1	1		
24	24	5	5
2	2	1	1
1	1		
1	1	1	1
		5	5
1	1	1	1
		1	1
1	1		
		1	1
1	1		
2	2		
3	3		
1	1		
13	13	9	9
1	1		
1	1		
16	16	1	1
1	1		
8	8	7	7
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Obstructive airways disorder	1	1			1	1
Oropharyngeal discomfort	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pain	3	3	2	2	1	1
Pain in extremity	5	5	5	5		
Pallor	6	6	3	3	3	3
Palpitations	9	9	5	5	4	4
Paraesthesia	6	6	2	2	4	4
Paraesthesia oral	1	1			1	1
Pharyngeal swelling	4	4			4	4
Pneumonia	1	1			1	1
Presyncope	9	9	2	2	7	7
Prolonged expiration	1	1			1	1
Pruritus	4	4	3	3	1	1
Pulmonary oedema	1	1			1	1
Pyrexia	26	26	22	22	4	4
Rash	5	5	1	1	4	4
Rash erythematous	5	5	2	2	3	3
Rash pruritic	2	2	1	1	1	1
Respiratory failure	1	1			1	1
Restlessness	3	3	3	3		
Sensory disturbance	1	1	1	1		
Severe acute respiratory syndrome	1	1			1	1
Sinus tachycardia	1	1	1	1		
Skin lesion	1	1	1	1		
Stridor	1	1			1	1
Sudden death	1	1			1	1
Swelling face	5	5	1	1	4	4
Swollen tongue	3	3			3	3
Syncope	1	1			1	1
Tachycardia	3	3	1	1	2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	1	1			1	1
Throat tightness	2	2	1	1	1	1
Tremor	2	2			2	2
Underdose	1	1	1	1		
Urticaria	4	4	1	1	3	3
Vaccination site erythema	6	6	5	5	1	1
Vaccination site haematoma	1	1	1	1		
Vaccination site haemorrhage	1	1	1	1		
Vaccination site irritation	1	1			1	1
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site pain	31	31	29	29	2	2
Vaccination site pruritus	2	2	2	2		
Vaccination site rash	1	1			1	1
Vaccination site swelling	8	8	7	7	1	1
Vaccination site warmth	2	2	2	2		
Vertigo	1	1			1	1
Vision blurred	1	1			1	1
Visual impairment	1	1	1	1		
Vomiting	5	5	3	3	2	2
	427	427	254	254	173	173

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression	1	1			1	1
Aspiration	1	1			1	1
Asthenia	1	1	1	1		
Bacteraemia	1	1			1	1
Blood pressure systolic increased	1	1	1	1		
Cardiac arrest	1	1			1	1
Chills	1	1	1	1		
Coma	1	1			1	1
Confusional state	1	1			1	1
Death	1	1			1	1
Depressed level of consciousness	1	1			1	1
Diarrhoea	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	3	3	2	2	1	1
Drug interaction	1	1			1	1
Dyspnoea	1	1			1	1
Facial pain	1	1	1	1		
Fatigue	3	3	1	1	2	2
Feeling drunk	1	1	1	1		
Feeling hot	1	1	1	1		
Flushing	2	2	1	1	1	1
Gastrooesophageal reflux disease	1	1	1	1		
General physical health deterioration	1	1			1	1
Headache	8	8	7	7	1	1
Hemiparesis	1	1			1	1
Hypotension	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Influenza like illness	1	1	1	1		
Insomnia	1	1	1	1		
Loss of consciousness	1	1			1	1
Malaise	3	3	2	2	1	1
Mobility decreased	1	1			1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscle discomfort	1	1	1	1		
Myalgia	2	2	2	2		
Nasal obstruction	1	1	1	1		
Nausea	4	4	3	3	1	1
Odynophagia	1	1	1	1		
Oropharyngeal pain	2	2	2	2		
Pain	1	1	1	1		
Pain in extremity	2	2	2	2		
Pneumonia aspiration	1	1			1	1
Pyrexia	5	5	4	4	1	1
Rales	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory failure	1	1			1	1
Sepsis	1	1			1	1
Somnolence	1	1			1	1
Syncope	1	1			1	1
Thinking abnormal	1	1			1	1
Throat irritation	1	1	1	1		
Urinary incontinence	1	1			1	1
Vaccination site pain	8	8	8	8		
Vomiting	2	2			2	2
	85	85	51	51	34	34

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
Product administration error	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**ESTONIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Asymptomatic COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Facial nerve disorder	1	1	1	1		
Feeling hot	1	1	1	1		
Fracture	1	1			1	1
Headache	1	1	1	1		
Hypertension	1	1	1	1		
Hypoaesthesia	2	2	2	2		
Immunisation anxiety related reaction	2	2	2	2		
Malaise	1	1	1	1		
Maternal exposure during pregnancy	4	4	4	4		
Myalgia	1	1	1	1		
Off label use	1	1	1	1		
Palpitations	1	1	1	1		
Paraesthesia	3	3	3	3		
Product use issue	1	1	1	1		
Restlessness	1	1	1	1		
Syringe issue	1	1	1	1		
Tachycardia	1	1	1	1		
Underdose	1	1	1	1		
Vaccination site pain	1	1	1	1		
	29	29	26	26	3	3

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Country Where Event Occurred  
**FINLAND**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	2	2			2	2
Anaphylactic shock	1	1			1	1
Aneurysm	1	1			1	1
Axillary pain	1	1	1	1		
Chest discomfort	2	2			2	2
Cough	1	1			1	1
C-reactive protein increased	1	1	1	1		
Death	1	1			1	1
Derealisation	1	1	1	1		
Dizziness	1	1	1	1		
Dyspnoea	3	3	1	1	2	2
Erythema	3	3	1	1	2	2
Extrasystoles	1	1	1	1		
Fatigue	2	2	1	1	1	1
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	2	2			2	2
Heart rate increased	2	2			2	2
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypokalaemia	2	2			2	2
Hypotension	1	1			1	1
Lymphadenopathy	3	3	3	3		
Malaise	4	4	3	3	1	1
Migraine	1	1			1	1
Myalgia	2	2	2	2		
Nausea	2	2	1	1	1	1
Nodule	1	1	1	1		
Nuchal rigidity	1	1	1	1		
Pain in extremity	1	1	1	1		
Paraesthesia	1	1			1	1
Paraesthesia oral	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngeal oedema	1	1			1	1
Pharyngeal swelling	1	1			1	1
Presyncope	1	1	1	1		
Pyrexia	2	2	2	2		
Rash	1	1			1	1
Rash erythematous	1	1	1	1		
Seizure	1	1			1	1
Somnolence	1	1	1	1		
Subarachnoid haemorrhage	1	1			1	1
Syncope	1	1			1	1
Tachycardia	1	1	1	1		
Tenderness	1	1	1	1		
Throat irritation	1	1			1	1
Tremor	1	1			1	1
Type IV hypersensitivity reaction	1	1	1	1		
Urticaria	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site haematoma	1	1	1	1		
Vaccination site oedema	2	2	2	2		
Vaccination site pain	2	2	2	2		
Vaccination site plaque	1	1	1	1		
Vaccination site warmth	2	2	2	2		
Vomiting	1	1			1	1
	76	76	42	42	34	34

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Back pain	1	1	1	1
Gait disturbance	1	1	1	1
Irritability postvaccinal	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Vaccination site pain	1	1	1	1
	6	6	6	6

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Country Where Event Occurred  
**FRANCE**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Accidental overdose	1	1	1	1		
Acute respiratory failure	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Anxiety	2	2			2	2
Aortic dissection	1	1			1	1
Arrhythmia	1	1			1	1
Arrhythmia supraventricular	1	1			1	1
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Atrial fibrillation	2	2			2	2
Blood pressure systolic increased	1	1			1	1
Bronchial obstruction	1	1			1	1
Cardiac arrest	1	1			1	1
Cardiac failure	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Cerebrovascular accident	2	2			2	2
Chest pain	1	1			1	1
Chills	2	2	2	2		
Cognitive disorder	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	1	1			1	1
Constipation	1	1	1	1		
Cough	1	1	1	1		
COVID-19	5	5			5	5
Death	4	4			4	4
Depressed level of consciousness	1	1			1	1
Diarrhoea	2	2			2	2
Dizziness	2	2	1	1	1	1
Drug ineffective	6	6			6	6
Dysarthria	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysphagia	2	2
Dyspnoea	3	3
Erythema	2	2
Exposure via breast milk	1	1
Eyelid irritation	1	1
Fall	1	1
Fatigue	2	2
Fear	1	1
Formication	1	1
Haemorrhagic stroke	1	1
Headache	2	2
Hot flush	1	1
Hyperhidrosis	1	1
Hypersensitivity	1	1
Hypertension	2	2
Hypertonia	1	1
Hypotension	1	1
Inappropriate schedule of product administration	1	1
Increased bronchial secretion	1	1
Injection site erythema	1	1
Insomnia	1	1
Ischaemic stroke	1	1
Lip oedema	1	1
Loss of consciousness	2	2
Lymphopenia	1	1
Malaise	7	7
Musculoskeletal stiffness	1	1
Myalgia	2	2
Nausea	6	6
Neck pain	1	1
Occupational exposure to product	1	1
Ocular discomfort	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		2	2
		3	3
2	2		
1	1		
1	1		
		1	1
2	2		
		1	1
		1	1
		1	1
2	2		
1	1		
1	1		
		1	1
2	2		
		1	1
		1	1
1	1		
		1	1
		1	1
1	1		
		1	1
		2	2
1	1		
2	2	5	5
1	1		
2	2		
4	4	2	2
1	1		
1	1		
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oropharyngeal discomfort	1	1			1	1
Overdose	4	4	4	4		
Oxygen saturation decreased	1	1			1	1
Pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Palpitations	1	1	1	1		
Papule	1	1	1	1		
Paraesthesia	1	1	1	1		
Petit mal epilepsy	1	1			1	1
Productive cough	1	1			1	1
Product preparation error	1	1	1	1		
Product preparation issue	4	4	4	4		
Pruritus	2	2	2	2		
Pyrexia	5	5	4	4	1	1
Renal failure	1	1			1	1
Sudden death	4	4			4	4
Suspected COVID-19	1	1			1	1
Tachycardia	3	3	2	2	1	1
Thrombocytopenia	1	1			1	1
Underdose	1	1	1	1		
Urticaria	2	2			2	2
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vomiting	2	2			2	2
	146	146	63	63	83	83

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute respiratory distress syndrome	1	1			1	1
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Aortic dissection	1	1			1	1
Aphthous ulcer	1	1	1	1		
Arthralgia	1	1	1	1		
Blood uric acid increased	1	1	1	1		
Bronchitis	1	1			1	1
Cardiac failure	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
C-reactive protein increased	2	2	1	1	1	1
Death	1	1			1	1
Drug ineffective	1	1			1	1
Fatigue	2	2	2	2		
Glycosylated haemoglobin increased	1	1	1	1		
Haemoptysis	1	1			1	1
Headache	2	2	2	2		
Hyperleukocytosis	1	1			1	1
Hypertensive crisis	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	2	2	2	2		
Injection site pain	1	1	1	1		
Insomnia	1	1	1	1		
International normalised ratio abnormal	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	1	1	1	1		
Nasal congestion	1	1	1	1		
Needle issue	1	1	1	1		
Oedema peripheral	1	1			1	1
Off label use	1	1	1	1		
Otitis externa	1	1	1	1		
Overdose	2	2	2	2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Product preparation issue	2	2	2	2		
Product use issue	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	1	1	1	1		
Rales	1	1			1	1
Rash erythematous	1	1	1	1		
Rash maculo-papular	1	1	1	1		
Sudden death	2	2			2	2
Suspected COVID-19	1	1			1	1
Tongue haematoma	2	2	2	2		
Underdose	1	1	1	1		
Vaccination complication	1	1	1	1		
Vaccination site pain	5	5	5	5		
	59	59	42	42	17	17

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus test positive	1	1	1	1		
COVID-19	2	2			2	2
Death	5	5			5	5
Drug ineffective	3	3	1	1	2	2
Exposure via breast milk	1	1	1	1		
Herpes zoster	1	1	1	1		
Intercepted product preparation error	1	1	1	1		
Poor quality product administered	2	2	2	2		
Product administered at inappropriate site	1	1	1	1		
Product preparation issue	11	11	11	11		
Product temperature excursion issue	1	1	1	1		
Underdose	11	11	11	11		
Wrong technique in product usage process	2	2	2	2		
	42	42	33	33	9	9

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Country Where Event Occurred  
**GERMANY**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Abdominal pain lower	3	3	3	3		
Abdominal pain upper	1	1	1	1		
Abnormal faeces	2	2	2	2		
Abscess	1	1			1	1
Accidental overdose	4	11	4	10		1
Acute kidney injury	3	3			3	3
Acute myocardial infarction	4	4			4	4
Acute respiratory failure	1	1			1	1
Agitation		1		1		
Allergic oedema	1	1	1	1		
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	8	9			8	9
Anaphylactic shock	2	2			2	2
Anaphylactoid reaction	1	1			1	1
Angina pectoris	2	2			2	2
Angioedema	2	2			2	2
Anxiety		1		1		
Apathy	1	1			1	1
Arrhythmia	3	3	1	1	2	2
Arthralgia	14	14	14	14		
Asthenia	21	27	19	24	2	3
Asthenopia	1	1	1	1		
Asthma	2	2	1	1	1	1
Back pain	2	2	2	2		
Bedridden	1	1			1	1
Bladder discomfort	1	1	1	1		
Bladder pain	1	1	1	1		
Blood glucose fluctuation	1	1	1	1		
Blood pressure decreased	2	2	1	1	1	1
Blood pressure fluctuation	1	1	1	1		
Blood pressure increased	3	3	2	2	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood urine present	1	1			1	1
Body temperature increased	10	10	8	8	2	2
Bradycardia	1	1			1	1
Bronchial disorder	1	1	1	1		
Bronchitis	1	1			1	1
Bronchospasm	1	1	1	1		
Burning sensation	1	1			1	1
Cardiac arrest	1	1			1	1
Cardiac failure	3	3			3	3
Cardiac failure congestive	1	1			1	1
Cardiogenic shock	1	1			1	1
Cardiovascular disorder	5	5	5	5		
Cardiovascular insufficiency	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebral infarction	1	1			1	1
Chest discomfort	2	3	2	3		
Chills	25	25	24	24	1	1
Circulatory collapse	2	2			2	2
Condition aggravated	2	2			2	2
Confusional state	1	1	1	1		
Constipation	1	1	1	1		
Cough	5	6	5	6		
COVID-19	25	25			25	25
Crepitations	1	1			1	1
Deafness	1	1			1	1
Death	16	16			16	16
Dementia	1	1			1	1
Dermatitis allergic	2	2	2	2		
Diabetes mellitus		1				1
Diarrhoea	15	15	14	14	1	1
Diet refusal	1	1			1	1
Disease recurrence	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Disturbance in attention	5	5
Dizziness	40	44
Drug ineffective	35	35
Dry eye	1	1
Dry mouth	1	1
Dry skin	1	1
Dysaesthesia	1	1
Dyspepsia	1	1
Dysphagia	4	4
Dysphonia	2	2
Dyspnoea	13	15
Dyspnoea exertional	1	1
Dysstasia	1	1
Ear pain	1	1
Eczema	1	1
Epilepsy	2	3
Epistaxis	3	3
Erythema	5	5
Exposure during pregnancy	1	1
Eye haemorrhage	1	1
Eye irritation	1	1
Eye pruritus	2	2
Eye swelling	2	2
Facial pain	1	1
Fall	2	2
Fatigue	83	87
Febrile infection	1	1
Feeling cold	8	8
Feeling hot	2	2
Feeling of body temperature change	1	1
Flatulence	1	1
Flushing	4	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	4	1	1
35	38	5	6
		35	35
1	1		
1	1		
1	1		
		1	1
1	1		
		4	4
2	2		
7	8	6	7
		1	1
1	1		
1	1		
		2	3
3	3		
5	5		
1	1		
		1	1
1	1		
1	1	1	1
1	1	1	1
1	1		
		2	2
81	84	2	3
		1	1
7	7	1	1
2	2		
1	1		
1	1		
1	1	3	4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Food refusal	2	2			2	2
Gait disturbance	2	2	2	2		
General physical health deterioration	6	6			6	6
Haematoma	1	1	1	1		
Haematuria	1	1	1	1		
Haemoptysis	1	1	1	1		
Headache	85	92	82	88	3	4
Head discomfort	1	1	1	1		
Heart rate increased		1		1		
Herpes zoster	3	3	3	3		
Hordeolum	1	1	1	1		
Hot flush	1	1	1	1		
Huntington's disease	3	3			3	3
Hypercalcaemia	1	1			1	1
Hyperhidrosis	4	5	4	5		
Hypersensitivity	10	10	3	3	7	7
Hypertension	9	10	3	4	6	6
Hypoaesthesia	4	4	4	4		
Hypoaesthesia oral	1	1	1	1		
Hypotension	6	6	1	1	5	5
Hypotonia	2	2	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect route of product administration	6	6	6	6		
Increased upper airway secretion	1	1	1	1		
Infective exacerbation of chronic obstructive airways disease	1	1			1	1
Influenza like illness	12	12	12	12		
Insomnia	1	1	1	1		
Irregular breathing	1	1			1	1
Jaw clicking	1	1			1	1
Language disorder	1	1			1	1
Laryngeal oedema	2	2			2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenia		1				1
Limb discomfort	4	5	4	5		
Lip oedema	1	1	1	1		
Lip swelling	1	1	1	1		
Livedo reticularis	1	1	1	1		
Local reaction	4	4	4	4		
Loss of consciousness	2	2	1	1	1	1
Lymphadenopathy	9	9	9	9		
Lymph node pain	4	4	4	4		
Malaise	10	11	8	8	2	3
Maternal exposure during pregnancy	14	14	14	14		
Migraine		1		1		
Mobility decreased	2	2	2	2		
Movement disorder	1	2	1	2		
Multimorbidity	1	1			1	1
Muscle swelling	1	1	1	1		
Muscular weakness	4	4	4	4		
Musculoskeletal disorder	1	1			1	1
Musculoskeletal stiffness	1	1	1	1		
Myalgia	37	37	37	37		
Myocardial infarction	1	1			1	1
Nasal congestion	1	1	1	1		
Nasopharyngitis	4	4	4	4		
Nausea	24	25	22	23	2	2
Neck pain	4	4	4	4		
Neuralgia	1	1	1	1		
Neuralgic amyotrophy	1	1			1	1
Occupational exposure to product	1	1	1	1		
Oedema	1	1			1	1
Off label use	7	7	7	7		
Oral mucosa erosion	1	1	1	1		
Oropharyngeal pain	6	6	6	6		

Spontaneous			
Nonserious		Serious	
I	C	I	C
			1
4	5		
1	1		
1	1		
1	1		
4	4		
1	1	1	1
9	9		
4	4		
8	8	2	3
14	14		
	1		
2	2		
1	2		
		1	1
1	1		
4	4		
		1	1
1	1		
37	37		
		1	1
1	1		
4	4		
24	25	2	2
4	4		
1	1		
		1	1
1	1		
		1	1
7	7		
1	1		
6	6		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Orthostatic intolerance	1	1			1	1
Otitis media	1	1	1	1		
Oxygen saturation decreased	4	4			4	4
Pain	11	12	10	10	1	2
Pain in extremity	41	42	41	42		
Palpitations	13	15	12	14	1	1
Paraesthesia	8	8	8	8		
Paraesthesia oral	2	2	2	2		
Paresis		1		1		
Pathogen resistance	1	1			1	1
Performance status decreased		1		1		
Peripheral embolism	1	1	1	1		
Peripheral swelling	2	2	1	1	1	1
Peripheral vascular disorder	4	4	2	2	2	2
Personality change	1	1			1	1
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal inflammation	1	1	1	1		
Pharyngeal swelling	2	2			2	2
Photosensitivity reaction	1	1	1	1		
Pneumonia	2	2			2	2
Pneumonia aspiration	3	3			3	3
Poor quality sleep	2	2	1	1	1	1
Presyncope	1	1	1	1		
Product administered at inappropriate site	2	2	1	1	1	1
Product preparation issue	1	1	1	1		
Product use issue	7	7	7	7		
Protein urine present	1	1	1	1		
Pruritus	10	10	6	6	4	4
Pruritus allergic	1	1	1	1		
Psoriasis	1	1	1	1		
Psychological factor affecting medical condition	1	1			1	1
Pulmonary embolism	2	2			2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pyrexia	30	31	27	28	3	3
Rash	13	13	7	7	6	6
Rash macular	2	2	1	1	1	1
Rash maculo-papular	1	1	1	1		
Rash pruritic	2	2	2	2		
Reaction to excipient	1	1	1	1		
Renal failure	2	2			2	2
Renal pain	1	1	1	1		
Respiratory distress	7	7	1	1	6	6
Respiratory symptom	1	1	1	1		
Respiratory tract infection	2	2			2	2
Restlessness	2	2	2	2		
Retching	1	1	1	1		
Rhinalgia	2	2	2	2		
Rhinitis		1		1		
Rhinorrhoea	7	7	6	6	1	1
Rhonchi	2	2			2	2
Rosacea	1	1			1	1
SARS-CoV-2 test positive	9	9			9	9
Scratch	1	1	1	1		
Seizure	3	3	1	1	2	2
Sensation of foreign body	3	3			3	3
Sense of oppression	1	1	1	1		
Sensory disturbance	2	2	2	2		
Sensory loss	1	1			1	1
Sepsis	1	1			1	1
Septic shock	1	1			1	1
Sinus tachycardia	1	1			1	1
Skin discolouration	1	1	1	1		
Sleep disorder	1	1	1	1		
Sneezing	2	2	2	2		
Somnolence	4	4	3	3	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Speech disorder	1	1
Status epilepticus	1	1
Sudden cardiac death	1	1
Sudden death	6	6
Suspected COVID-19	3	3
Swelling	3	4
Swelling face	3	3
Swollen tongue	3	3
Syncope	3	3
Tachyarrhythmia	1	1
Tachycardia	14	15
Tachypnoea	1	1
Tension headache	1	1
Throat irritation	1	1
Throat tightness	4	4
Tongue disorder	1	1
Transient ischaemic attack	1	1
Tremor	7	7
Underdose	2	2
Unresponsive to stimuli	1	1
Urticaria	4	4
Vaccination site dermatitis	1	1
Vaccination site discomfort	1	1
Vaccination site erythema	9	10
Vaccination site haematoma	2	2
Vaccination site hyperaesthesia	1	2
Vaccination site induration	3	3
Vaccination site irritation	1	1
Vaccination site joint movement impairment	1	1
Vaccination site movement impairment	6	6
Vaccination site pain	115	119
Vaccination site paraesthesia	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	1
		6	6
		3	3
2	3	1	1
1	1	2	2
1	1	2	2
		3	3
		1	1
7	7	7	8
1	1		
		1	1
1	1		
2	2	2	2
1	1		
		1	1
5	5	2	2
2	2		
		1	1
2	2	2	2
1	1		
1	1		
1	1		
6	6		
114	118	1	1
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pruritus	4	4	4	4		
Vaccination site rash	1	1	1	1		
Vaccination site reaction	3	3	3	3		
Vaccination site swelling	17	20	17	20		
Vaccination site warmth	5	5	5	5		
Ventricular fibrillation	1	1			1	1
Vertigo	3	3	3	3		
Vision blurred	2	2	1	1	1	1
Visual impairment	2	2	1	1	1	1
Vomiting	8	8	4	4	4	4
Wrong technique in product usage process	1	1	1	1		
	1,259	1,325	926	978	333	347

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal pain	3	3
Abdominal pain upper	2	2
Abnormal faeces	3	3
Accidental overdose	1	2
Acne	1	1
Acute kidney injury	1	1
Acute myocardial infarction	2	2
Ageusia	1	1
Anaphylactic reaction	1	1
Anaphylactic shock	1	1
Anosmia	1	1
Apathy	1	1
Arrhythmia	1	1
Arthralgia	4	4
Asthenia	8	9
Atrial fibrillation	1	1
Atypical pneumonia	1	1
Back pain	1	1
Blister	1	1
Blood pressure decreased	1	1
Body temperature increased	1	1
Bone pain	1	1
Bradycardia	1	1
Burning sensation	1	1
Cardiac failure	3	3
Cardiac fibrillation	1	1
Cerebrovascular accident	2	2
Chest discomfort	1	1
Chills	11	12
Chronic kidney disease	1	1
Circulatory collapse	2	2
Cold sweat	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
		2	2		
		3	3		
			1	1	1
		1	1		
				1	1
				2	2
		1	1		
				1	1
				1	1
		1	1		
				1	1
				1	1
		4	4		
		6	7	2	2
				1	1
				1	1
		1	1		
		1	1		
				1	1
				1	1
		1	1		
		1	1		
				1	1
				3	3
				1	1
				2	2
		1	1		
		11	12		
				1	1
				2	2
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Coronavirus infection	2	2
Cough	2	3
COVID-19	16	16
COVID-19 pneumonia	4	4
Cranial nerve disorder	1	1
Cyanosis	1	1
Death	10	10
Decreased appetite	1	1
Dementia of the Alzheimer's type, with delirium	1	1
Depressed level of consciousness	1	1
Diarrhoea	7	7
Diplopia	1	1
Disorientation	1	1
Dizziness	7	7
Dizziness postural	1	1
Drug ineffective	34	34
Drug interaction	1	1
Dysgeusia	2	2
Dyspnoea	4	4
Ear pain	2	2
Episcleritis	1	1
Erythema	3	3
Eye irritation	1	1
Eye pain	1	1
Face oedema	1	1
Facial paralysis	1	2
Fall	2	2
Fatigue	29	29
Febrile infection	1	1
Feeling hot	2	2
Femoral neck fracture	1	1
Flatulence	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
		2	2		1
				16	16
				4	4
		1	1		
				1	1
				10	10
		1	1		
				1	1
				1	1
		7	7		
				1	1
		1	1		
		6	6	1	1
		1	1		
				34	34
		1	1		
		2	2		
		1	1	3	3
		2	2		
		1	1		
		3	3		
		1	1		
		1	1		
				1	1
				1	2
				2	2
1	1	29	29		
				1	1
		2	2		
				1	1
		1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Flushing	1	1
General physical condition abnormal	1	1
General physical health deterioration	4	4
Genital herpes	1	1
Headache	23	24
Head injury	1	1
Heart rate increased	1	1
Hemiparesis	1	1
Hunger	1	1
Hyperaesthesia	1	1
Hyperhidrosis	3	3
Hyperpyrexia	2	2
Hypersensitivity	3	3
Hypersomnia	1	1
Hypertension	3	4
Hypoaesthesia	4	4
Hypoaesthesia oral	1	1
Hypotension	1	1
Illness	2	2
Inappropriate schedule of product administration	1	1
Incorrect route of product administration	2	2
Induration	1	1
Influenza like illness	6	6
Injection site discomfort	1	1
Injection site pain	1	1
Ischaemic stroke	1	1
Lacrimation increased	1	1
Limb discomfort	3	3
Lip swelling	1	1
Lymphadenopathy	1	1
Malaise	4	5
Mesenteric vein thrombosis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		1	1	3	3
		1	1		
1	1	22	23	1	1
				1	1
				1	1
		1	1		
		1	1		
		3	3		
				2	2
		1	1	2	2
		1	1		
		1	1	2	3
		3	3	1	1
		1	1		
				1	1
		2	2		
		1	1		
		2	2		
		1	1		
		5	5	1	1
		1	1		
		1	1		
				1	1
		1	1		
1	1	3	3	1	2
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Middle insomnia	1	1
Mobility decreased	2	2
Motor dysfunction	1	1
Movement disorder	2	2
Multiple organ dysfunction syndrome	1	1
Muscle tightness	1	1
Muscle twitching	1	1
Muscular weakness	2	2
Myalgia	18	18
Nasopharyngitis	2	2
Nausea	8	9
Neck pain	5	5
Oropharyngeal pain	1	1
Pain	4	4
Pain in extremity	18	18
Palpitations	2	2
Paraesthesia	1	1
Peripheral vascular disorder	2	2
Pharyngeal swelling	1	1
Pneumonia	2	2
Pollakiuria	1	1
Pruritus	1	1
Pulmonary embolism	1	1
Pulmonary sepsis	1	1
Pyrexia	19	20
Rash	4	4
Rash pruritic	1	1
Respiratory distress	2	2
Respiratory failure	2	2
Rhinitis	1	1
Rhinorrhoea	2	2
SARS-CoV-2 ant body test positive	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1	1	1
				1	1
		1	1	1	1
				1	1
		1	1		
		1	1		
		2	2		
1	1	18	18		
		2	2		
		6	7	2	2
		5	5		
		1	1		
		3	3	1	1
		17	17	1	1
		1	1	1	1
		1	1		
				2	2
				1	1
		1	1	1	1
		1	1		
				1	1
				1	1
1	1	16	16	3	4
		2	2	2	2
		1	1		
				2	2
				2	2
		1	1		
		2	2		
		1	1	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
SARS-CoV-2 test positive	12	12
Seizure	1	2
Sensory disturbance	1	1
Sinusitis	1	1
Sleep disorder	1	1
Sneezing	1	1
Somnolence	1	1
Staphylococcal sepsis	1	1
Stridor	1	1
Sudden death	1	1
Sudden hearing loss	1	1
Suspected COVID-19	2	2
Swelling	2	2
Syncope	1	1
Tachyarrhythmia	2	2
Tachycardia	2	2
Taste disorder	1	1
Thirst	1	1
Throat irritation	3	3
Tongue discomfort	1	1
Unresponsive to stimuli	1	1
Vaccination site bruising	2	2
Vaccination site discomfort	1	1
Vaccination site pain	50	50
Vaccination site swelling	3	3
Vaccination site warmth	1	1
Ventricular fibrillation	1	1
Vertigo	1	1
Vomiting	6	6
Weight bearing difficulty	1	1
	<b>500</b>	<b>511</b>

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				12	12
				1	2
		1	1		
		1	1		
		1	1		
		1	1		
		1	1		
				1	1
				1	1
				1	1
				2	2
		2	2		
				1	1
				2	2
		1	1	1	1
		1	1		
		1	1		
		3	3		
		1	1		
				1	1
		2	2		
		1	1		
		50	50		
		3	3		
		1	1		
				1	1
		1	1		
		5	5	1	1
				1	1
		<b>5</b>	<b>5</b>	<b>176</b>	<b>182</b>

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower	1	1	1	1		
Ageusia	1	1	1	1		
Chills	1	1	1	1		
Circumstance or information capable of leading to medication error	1	1	1	1		
COVID-19	35	35			35	35
Death	6	6			6	6
Decreased appetite	1	1			1	1
Diet refusal	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	44	44			44	44
Erythema	2	2	2	2		
Exposure via breast milk	1	1	1	1		
Fatigue	3	3	3	3		
Headache	2	2	2	2		
Hypersensitivity	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Influenza like illness	1	1	1	1		
Local reaction	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	1	1	1	1		
Nausea	2	2	2	2		
Off label use	1	1	1	1		
Pain in extremity	4	4	4	4		
Paraesthesia	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Peripheral swelling	1	1	1	1		
Poor quality product administered	1	1	1	1		
Product leakage	1	1	1	1		
Product preparation error	2	2	2	2		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Product use issue	1	1	1	1		
Pyrexia	1	1	1	1		
SARS-CoV-2 ant body test positive	2	2	2	2		
SARS-CoV-2 test false positive	3	3	3	3		
SARS-CoV-2 test positive	15	15	6	6	9	9
Suspected COVID-19	1	1			1	1
Swelling	1	1	1	1		
Underdose	7	7	7	7		
Vaccination site hyperaesthesia	1	1	1	1		
Vaccination site pain	5	5	5	5		
Vomiting	1	1	1	1		
	161	161	64	64	97	97

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Country Where Event Occurred  
**GREECE**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Acute respiratory failure	1	1			1	1
Anaphylactic reaction	1	2			1	2
Anaphylactic shock	3	3			3	3
Anaphylactoid reaction	1	1			1	1
Angioedema	1	1			1	1
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	2	2	2	2		
Atrial fibrillation	1	1			1	1
Auscultation	1	1	1	1		
Blister	1	1	1	1		
Blood pressure decreased	1	1	1	1		
Blood pressure increased	1	1			1	1
Bronchospasm	2	2			2	2
Burning sensation	1	1	1	1		
Cardiac arrest	2	2			2	2
Chest pain	2	2	1	1	1	1
Chills	1	1	1	1		
Cough	3	3			3	3
Defaecation urgency		1				1
Diarrhoea	2	2	1	1	1	1
Diastolic hypertension	1	1			1	1
Dizziness	8	8	6	6	2	2
Drug interaction	1	1			1	1
Dry mouth	1	1	1	1		
Dysgeusia	4	4	2	2	2	2
Dysphagia	3	3	1	1	2	2
Dysphonia	3	3			3	3
Dysphoria	1	1			1	1
Dyspnoea	5	5	2	2	3	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythema	1	2	1	1		1
Eyelid ptosis	1	1			1	1
Eye oedema	1	1			1	1
Fatigue	3	3	2	2	1	1
Feeling cold	1	1	1	1		
Feeling hot	1	1			1	1
Flatulence		1				1
Flushing	1	2			1	2
Gait disturbance	2	2	2	2		
Gastrointestinal disorder	1	1	1	1		
Gastrointestinal hypermotility		1				1
Headache	9	9	8	8	1	1
Hyperhidrosis	2	2	2	2		
Hypersensitivity	7	7	4	4	3	3
Hypertension	2	2	1	1	1	1
Hypertensive emergency	1	1			1	1
Hypoaesthesia	5	5	4	4	1	1
Hypoaesthesia oral	4	4	1	1	3	3
Hypotension	1	1	1	1		
Incomplete course of vaccination	1	1	1	1		
Injury	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Laryngeal oedema	1	1			1	1
Limb discomfort	1	1	1	1		
Local reaction	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Maternal exposure during pregnancy	1	1	1	1		
Migraine	1	1	1	1		
Mucosal dryness		1				1
Muscle spasms	1	1	1	1		
Muscular weakness	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myalgia	2	2	1	1	1	1
Nasal congestion	1	1	1	1		
Nausea	4	4	3	3	1	1
Off label use	1	1	1	1		
Oral herpes	1	1	1	1		
Orthostatic hypotension	1	1	1	1		
Pain in extremity	3	3	3	3		
Palpitations	1	1	1	1		
Presyncope	3	3	1	1	2	2
Pruritus	3	3	2	2	1	1
Pulmonary thrombosis	1	1			1	1
Pyrexia	5	5	4	4	1	1
Rash	5	5	5	5		
Rash pruritic	1	1	1	1		
Rheumatoid arthritis	1	1			1	1
Rhinitis allergic	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Seizure	1	1			1	1
Skin burning sensation	1	1	1	1		
Sudden death	1	1			1	1
Tachycardia	4	5	2	2	2	3
Tachypnoea	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Throat irritation	2	2	2	2		
Tinnitus	1	1	1	1		
Tongue ulceration	1	1	1	1		
Tremor	1	2			1	2
Vaccination site induration	1	1	1	1		
Vaccination site pain	11	11	11	11		
Vaccination site warmth	1	1	1	1		
Vomiting	1	1	1	1		
	176	185	114	114	62	71

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Angioedema	1	1			1	1
Asthenia	2	2	2	2		
Blood pressure decreased	1	1	1	1		
Blood pressure diastolic increased	1	1	1	1		
Blood pressure inadequately controlled	1	1	1	1		
Burning sensation	1	1	1	1		
Cardiac arrest	1	1			1	1
Cardiac disorder	1	1			1	1
Cardiac valve disease	1	1			1	1
Chest pain	1	1			1	1
Chills	3	3	2	2	1	1
Condition aggravated	1	1			1	1
COVID-19	1	1			1	1
Cyanosis	1	1	1	1		
Deafness unilateral	1	1			1	1
Diarrhoea	1	1	1	1		
Discomfort	1	1	1	1		
Dizziness	2	2	1	1	1	1
Drug ineffective	1	1			1	1
Dry mouth	1	1	1	1		
Dry throat	1	1	1	1		
Dysphagia	1	1	1	1		
Dyspnoea	1	1			1	1
Fall	1	1			1	1
Fatigue	5	5	4	4	1	1
Flushing	1	1	1	1		
Gastrointestinal disorder	1	1	1	1		
Headache	3	3	3	3		
Hyperhidrosis	1	1			1	1
Hypertension	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypertensive crisis	1	1			1	1
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Injection site pain	1	1	1	1		
Leukocytosis	1	1			1	1
Liquid product physical issue	1	1	1	1		
Loss of consciousness	1	1			1	1
Malaise	1	1	1	1		
Myalgia	1	1	1	1		
Nausea	2	2	1	1	1	1
Pain	1	1	1	1		
Pain in extremity	2	2	2	2		
Pneumonia	1	1			1	1
Poor quality product administered	1	1	1	1		
Poor quality sleep	1	1	1	1		
Pyrexia	7	7	6	6	1	1
Rash	3	3	2	2	1	1
Respiratory tract infection	1	1			1	1
Somnolence	1	1	1	1		
Sudden death	1	1			1	1
Tachycardia	3	3	2	2	1	1
Tinnitus	1	1	1	1		
Vaccination site discomfort		1		1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vomiting	2	2	2	2		
	81	82	54	55	27	27

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Blood pressure increased	1	1	1	1
Dysgeusia	1	1	1	1
Hypersensitivity	2	2	2	2
Hypertension	1	1	1	1
Hypoaesthesia oral	2	2	2	2
Liquid product physical issue	2	2	2	2
No adverse event	1	1	1	1
Pain in extremity	1	1	1	1
Palpitations	1	1	1	1
Poor quality product administered	2	2	2	2
Product quality issue	1	1	1	1
Tachycardia	2	2	2	2
Vomiting	1	1	1	1
	18	18	18	18

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Country Where Event Occurred

**HUNGARY**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	2	2		
Anosmia	1	1	1	1		
Arthralgia	1	1			1	1
Asthenia	8	9	8	9		
Axillary pain	1	1	1	1		
Back pain	3	3	3	3		
Blister	1	1	1	1		
Blood glucose increased		1		1		
Blood pressure increased		1				1
Body temperature increased	2	2	2	2		
Burning sensation	2	2	2	2		
Chest pain	2	2	2	2		
Chills	6	7	5	6	1	1
Confusional state	1	1	1	1		
COVID-19	1	1			1	1
Depression	1	1	1	1		
Dizziness	6	6	6	6		
Drug ineffective	2	2			2	2
Dry mouth		1				1
Dysgeusia	1	1	1	1		
Ear discomfort	1	1	1	1		
Ear pain	1	1	1	1		
Ear pruritus	2	2	2	2		
Eczema	1	1	1	1		
Erythema	2	2	2	2		
Exposure via breast milk	1	1	1	1		
Fatigue	2	3	2	3		
Feeling abnormal	2	2	2	2		
Feeling hot	3	4	3	3		1
Gait disturbance	2	2	2	2		
Haemorrhage	1	1			1	1
Headache	13	13	11	11	2	2

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Gender

**FEMALE**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Heart rate increased	1	2
Herpes virus infection	1	1
Hyperaesthesia	1	1
Hyperhidrosis	1	1
Hypoaesthesia	3	3
Hypoaesthesia oral	2	2
Hypoglycaemia	1	1
Incorrect route of product administration	1	1
Infertility	1	1
Lacrimation increased	1	1
Lymphadenopathy	3	3
Lymph node pain	1	1
Malaise	8	8
Micturition urgency		1
Muscle fatigue	1	1
Myalgia	7	7
Nasopharyngitis	1	1
Nausea	6	6
No adverse event	1	1
Off label use	1	1
Oropharyngeal pain	2	2
Pain	2	2
Pain in extremity	11	11
Pallor	1	1
Palpitations	1	1
Panic attack	1	1
Paraesthesia	1	2
Peripheral swelling	1	1
Presyncope	1	1
Pruritus	3	3
Pyrexia	8	8
Rash	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
1	1		
1	1		
1	1		
3	3		
2	2		
1	1		
1	1		
		1	1
1	1		
2	2	1	1
1	1		
6	6	2	2
	1		
1	1		
6	6	1	1
1	1		
6	6		
1	1		
1	1		
2	2		
2	2		
11	11		
1	1		
1	1		
1	1		
1	1		
1	1		1
1	1		
3	3		
6	6	2	2
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
SARS-CoV-2 test positive	1	1			1	1
Somnolence	1	1	1	1		
Swelling face	1	1	1	1		
Thirst		1				1
Tremor	1	2	1	1		1
Vaccination site discomfort	1	1	1	1		
Vaccination site erythema	8	8	8	8		
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site nodule	2	2	2	2		
Vaccination site pain	8	8	8	8		
Vaccination site pruritus	2	2	2	2		
Vaccination site swelling	4	4	4	4		
Vaccination site warmth	1	1	1	1		
Vaginal discharge	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	4	4	4	4		
	185	197	169	175	16	22

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Asthenia	1	1	1	1		
Blood pressure increased	1	1	1	1		
Chest discomfort	1	1	1	1		
Cold sweat	1	1	1	1		
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	1	1			1	1
Fatigue	2	2	2	2		
Headache	4	4	4	4		
Hyperaesthesia		1		1		
Hypersensitivity		1		1		
Hypoaesthesia	1	1	1	1		
Laryngeal oedema	1	1			1	1
Lymphadenopathy	1	1	1	1		
Lymph node pain	1	1	1	1		
Malaise	1	1	1	1		
Mobility decreased	1	1	1	1		
Oedema peripheral	1	1			1	1
Pain in extremity	1	1	1	1		
Pain of skin	1	1	1	1		
Pyrexia	4	4	4	4		
Rash	1	1	1	1		
Rash maculo-papular	1	1			1	1
Rash pruritic	1	1	1	1		
Rash vesicular	1	1	1	1		
Sensation of foreign body	1	1			1	1
Skin lesion		1		1		
Swelling face	1	1	1	1		
Tinnitus	1	1	1	1		
Urticaria	1	2	1	2		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site coldness	1	1	1	1		
Vaccination site pain	1	1	1	1		
	38	42	30	34	8	8

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Vaccination site pain	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**ICELAND**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm	1	1			1	1
Arthralgia	1	1	1	1		
Asthenia	3	3	3	3		
Back pain	1	1	1	1		
Blood pressure increased	1	1	1	1		
Bone pain	1	1	1	1		
Bradycardia	1	1			1	1
Cardiac failure	1	1			1	1
Chest discomfort	1	1	1	1		
Chills	1	1	1	1		
Cold sweat	1	1	1	1		
Cough	3	3	2	2	1	1
Death	1	1			1	1
Disease progression	1	1			1	1
Dizziness	4	4	4	4		
Dry mouth	1	1	1	1		
Dry throat	1	1	1	1		
Dyspnoea	1	1	1	1		
Ear pain	1	1	1	1		
Erythema	1	1	1	1		
Fatigue	6	6	6	6		
Feeling cold	1	1	1	1		
Headache	12	12	12	12		
Head discomfort	1	1	1	1		
Heart rate increased	1	1	1	1		
Hot flush	1	1	1	1		
Hypoaesthesia	4	4	4	4		
Limb discomfort	1	1	1	1		
Malaise	5	5	4	4	1	1
Migraine	1	1	1	1		
Myalgia	2	2	2	2		
Nasopharyngitis	5	5	5	5		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	5	5	5	5		
Ocular discomfort	1	1	1	1		
Oropharyngeal pain	2	2	2	2		
Pallor	1	1	1	1		
Pharyngeal swelling	1	1	1	1		
Pneumonia	1	1			1	1
Pruritus	1	1	1	1		
Pyrexia	11	11	10	10	1	1
Rhinorrhoea	1	1	1	1		
Sensory loss	1	1	1	1		
Tachycardia	1	1	1	1		
Thirst	1	1	1	1		
Tremor	1	1	1	1		
Vaccination site erythema	3	3	3	3		
Vaccination site inflammation	1	1	1	1		
Vaccination site pain	3	3	3	3		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		
	104	104	95	95	9	9

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Bone pain	1	1	1	1		
Cardiac failure	1	1			1	1
Chills	1	1	1	1		
Death	1	1			1	1
Discomfort	1	1	1	1		
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Headache	1	1	1	1		
Malaise	2	2	1	1	1	1
Myalgia	1	1	1	1		
Myocardial infarction	1	1			1	1
Oropharyngeal pain	1	1	1	1		
Pain	1	1	1	1		
Pneumonia	1	1			1	1
Pyrexia	4	4	3	3	1	1
Respiration abnormal	1	1			1	1
Sepsis	1	1			1	1
Sudden death	1	1			1	1
Swelling	1	1	1	1		
Vaccination site pain	2	2	2	2		
	26	26	17	17	9	9

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rhinorrhoea	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**INDIA**

Gender

**UNKNOWN**

Preferred Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous	
Nonserious	
I	C
	1
	1

Suspected counterfeit product

1

1

1

1

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Country Where Event Occurred

**IRELAND**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Blindness	1	1			1	1
Cold sweat	1	1			1	1
Deafness	1	1			1	1
Death	1	1			1	1
Dizziness	1	1			1	1
Dyspnoea	1	1			1	1
Fatigue	2	2	2	2		
Headache	2	2	2	2		
Heart rate increased	1	1			1	1
Injected limb mobility decreased	1	1			1	1
IVth nerve paralysis	1	1			1	1
Lymphadenopathy	1	1	1	1		
Pain	1	1			1	1
Periarthritis	1	1			1	1
Pyrexia	1	1	1	1		
Syncope	2	2			2	2
Visual impairment	1	1			1	1
	21	21	7	7	14	14

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sudden death	1	1	1	1
	1	1	1	1

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
No adverse event	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**ISRAEL**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abdominal pain		1
Abdominal pain upper	1	1
Ageusia	1	1
Allergy to vaccine	3	3
Anaphylactic reaction	3	3
Anaphylactic shock	1	1
Anger	1	1
Anosmia	1	1
Aphonia	1	1
Arrhythmia	2	2
Arthralgia	5	6
Asthenia	30	33
Asthma	1	1
Back pain	5	5
Blood chloride increased	1	1
Blood glucose increased	2	2
Blood pressure decreased	1	1
Blood pressure increased	4	5
Bone pain		1
Cardiac arrest	2	2
Cardiac disorder	1	1
Cerebellar haemorrhage	1	1
Cerebral ischaemia	1	1
Cerebrovascular accident	1	1
Chest discomfort		1
Chest pain	2	2
Chills	18	18
Choking	1	1
Cold sweat	1	1
Contusion	1	1
Coronavirus infection		1
Cough	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
		1	1		
		1	1		
		1	1	2	2
				3	3
				1	1
		1	1		
		1	1		
				1	1
				2	2
		5	6		
		30	33		
		1	1		
		5	5		
				1	1
				2	2
		1	1		
		2	3	2	2
			1		
				2	2
				1	1
				1	1
				1	1
			1		
		1	1	1	1
		17	17	1	1
				1	1
		1	1		
				1	1
					1
		2	2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
COVID-19	2	2
Crying	1	1
Death	1	1
Decreased appetite	2	2
Depressed level of consciousness	1	1
Depressed mood	1	1
Depression	1	1
Diarrhoea	3	3
Disease recurrence	1	1
Dizziness	14	16
Drug ineffective	4	6
Dry mouth	1	1
Dyschromatopsia	1	1
Dysgeusia	6	6
Dyspepsia	4	4
Dysphagia	4	4
Dyspnoea	9	10
Ear discomfort	1	1
Ear pain	3	3
Eosinophilic oesophagitis	1	1
Erythema	6	7
Exposure during pregnancy		1
Exposure to SARS-CoV-2		
Exposure via breast milk		1
Facial asymmetry	1	1
Facial paralysis	5	5
Fall	3	3
Fatigue	10	15
Feeling abnormal	5	6
Feeling cold	4	5
Feeling hot	3	5
Feeling of body temperature change		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
1	1			2	2
		1	1		
				1	1
		2	2		
				1	1
		1	1		
		1	1		
		3	3		
		1	1		
		12	14	2	2
1	1			4	6
		1	1		
				1	1
		6	6		
		4	4		
		3	3	1	1
		4	5	5	5
		1	1		
		3	3		
		1	1		
		6	7		
			1		
1	1				
			1		
		1	1		
				5	5
		1	1	2	2
		10	15		
		4	5	1	1
		4	5		
		3	5		
			1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Food craving	1	1
Formication	2	2
Glomerular filtration rate decreased	1	1
Hangover	1	1
Headache	30	30
Heart rate increased	3	4
Hepatitis	1	1
Herpes zoster	1	1
Hip fracture	1	1
Hot flush	1	1
Hyperhidrosis	3	3
Hypersensitivity	2	3
Hypertension	1	2
Hypoaesthesia	11	13
Hypoaesthesia oral	4	6
Impaired quality of life	1	1
Inappropriate schedule of product administration	3	3
Influenza	1	2
Influenza like illness	4	4
Insomnia	1	2
International normalised ratio increased	1	1
Joint swelling	1	1
Leukocytosis	1	1
Limb discomfort	1	1
Lip pruritus	1	1
Lip swelling	2	2
Lymphadenopathy	4	4
Lymphopenia	1	1
Malaise	10	12
Mean cell haemoglobin decreased	2	2
Mean platelet volume increased	1	1
Migraine	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	2		
				1	1
		1	1		
		29	29	1	1
		3	4		
				1	1
		1	1		
				1	1
		1	1		
		3	3		
				2	3
			1	1	1
		11	13		
		3	5	1	1
		1	1		
		3	3		
		1	2		
		4	4		
		1	2		
				1	1
		1	1		
				1	1
		1	1		
		1	1	1	1
		4	4		
				1	1
		9	11	1	1
		1	1	1	1
		1	1		
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Miliaria	1	1
Mobility decreased		1
Multiple sclerosis	1	1
Multiple sclerosis relapse	2	2
Muscle contractions involuntary	2	2
Muscular weakness	1	1
Myalgia	11	13
Myocardial infarction	1	1
Nasopharyngitis	1	1
Nausea	16	17
Neck pain	1	2
Neuralgia	1	1
Neuralgic amyotrophy	1	1
Neuritis	1	1
Neutrophil count increased	1	1
Odynophagia	1	1
Off label use	1	2
Oral herpes	1	1
Oropharyngeal discomfort		1
Oropharyngeal pain	3	3
Overdose	1	1
Oxygen saturation decreased	2	2
Pain	6	6
Pain in extremity	20	22
Palpitations	5	5
Paraesthesia	12	16
Paraesthesia oral	6	8
Paralysis		1
Paraplegia	1	1
Parosmia	1	1
Pelvic fracture	1	1
Pelvic pain	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
					1
				1	1
				2	2
		2	2		
		1	1		
		11	13		
				1	1
		1	1		
		15	16	1	1
		1	2		
		1	1		
		1	1		
		1	1		
				1	1
		1	1		
		1	2		
		1	1		
			1		
		3	3		
		1	1		
		1	1	1	1
		6	6		
		20	22		
		5	5		
		11	15	1	1
		5	7	1	1
					1
				1	1
		1	1		
				1	1
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pericarditis	1	1
Peripheral swelling	1	1
Personality change	1	1
Pharyngeal swelling	1	2
Poor quality product administered		1
Presyncope	1	1
Product packaging quantity issue		1
Product preparation error	1	1
Product preparation issue	1	1
Product use issue	1	2
Pruritus	3	3
Pulse abnormal	1	1
Pyrexia	23	24
Rash	7	9
Rash macular	1	1
Rash pruritic	1	1
Respiratory rate increased	1	1
Rhinalgia		1
Rhinorrhoea	1	1
Rib fracture	1	1
SARS-CoV-2 ant body test negative	1	1
SARS-CoV-2 test positive	2	3
Sensory disturbance	1	1
Sensory loss		1
Skin burning sensation	2	2
Skin disorder		1
Somnolence	1	1
Stress	1	1
Swelling face	1	1
Swollen tongue	3	4
Syncope	3	3
Tachycardia	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
		1	1		
		1	2		
			1		
		1	1		
			1		
		1	1		
		1	1		
		1	2		
		2	2	1	1
				1	1
		22	23	1	1
		5	6	2	3
		1	1		
		1	1		
				1	1
			1		
		1	1		
				1	1
				2	3
		1	1		
			1		
		2	2		
			1		
		1	1		
		1	1		
		1	1		
				3	4
				3	3
		2	2	1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Tenderness		1
Throat tightness	1	1
Thrombosis	1	1
Tinnitus	1	1
Tremor	1	2
Underdose	1	2
Urticaria	3	3
Vaccination site bruising	1	1
Vaccination site erythema	3	3
Vaccination site joint movement impairment	1	1
Vaccination site movement impairment	1	2
Vaccination site pain	29	36
Vaccination site pruritus	1	1
Vaccination site reaction	1	1
Vaccination site swelling	3	4
Vision blurred	1	1
Vomiting	5	5
Wrong technique in product usage process	1	1
	514	592

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1		
				1	1
				1	1
		1	1		
		1	2		
		1	2		
		1	1	2	2
		1	1		
		3	3		
		1	1		
		1	2		
		29	36		
		1	1		
		1	1		
		3	4		
		1	1		
		5	5		
		1	1		
		3	3		
		419	488	95	104

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Acute myocardial infarction	1	1			1	1
Alopecia	1	1	1	1		
Anaesthesia oral		1		1		
Angina pectoris	1	1			1	1
Anxiety	1	1	1	1		
Arthralgia	4	4	3	3	1	1
Asthenia	12	14	12	14		
Atrial fibrillation	1	2			1	2
Back pain	1	1	1	1		
Blood chloride increased	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure increased	4	4	1	1	3	3
Blood pressure systolic increased	1	1	1	1		
Cardiac arrest	3	4			3	4
Cardiac disorder	1	1			1	1
Cardiac failure		1				1
Cerebrovascular accident	1	1			1	1
Chills	3	3	3	3		
Choking	1	1			1	1
Circulatory collapse	1	1			1	1
Condition aggravated	1	1	1	1		
Confusional state	1	1	1	1		
Coronavirus infection	1	1	1	1		
Coronavirus test positive	1	1			1	1
Cough	3	3	3	3		
COVID-19	2	2			2	2
C-reactive protein increased	1	1	1	1		
Death	2	4			2	4
Decreased appetite	2	2	1	1	1	1
Diarrhoea	3	3	2	2	1	1
Disease recurrence		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	6	8	5	7	1	1
Drug ineffective	8	8	1	1	7	7
Dysgeusia		1		1		
Dyspepsia	1	1	1	1		
Dysphagia	1	1	1	1		
Dyspnoea	3	4	2	3	1	1
Dyspnoea exertional	1	1	1	1		
Dysstasia	1	1			1	1
Eye irritation	2	2	1	1	1	1
Facial paralysis	3	4			3	4
Fatigue	4	6	3	5	1	1
Feeling abnormal	3	4	2	2	1	2
Feeling cold	1	2	1	2		
Gait disturbance	2	2			2	2
Gastroenteritis viral	1	1	1	1		
Gingival pain	1	1	1	1		
Haemolytic anaemia	1	1			1	1
Headache	6	8	5	7	1	1
Head injury	1	1			1	1
Heart rate increased	3	3	3	3		
Hypersensitivity		1		1		
Hypertension	2	2	1	1	1	1
Hypoaesthesia	7	9	7	9		
Hypoaesthesia oral	2	2	2	2		
Hypoaesthesia teeth	1	1	1	1		
Hypotension	1	1	1	1		
Hypoventilation	1	1			1	1
Illness	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Infection	1	1	1	1		
Inflammatory marker increased		1				1
Influenza like illness	4	4	4	4		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Jaundice	1	1
Lacrimation increased	2	2
Limb discomfort	1	1
Lip pruritus		1
Liquid product physical issue		1
Loss of consciousness	1	2
Lung disorder	1	1
Lymphadenopathy		1
Lymphocyte count increased	1	1
Lymphocytosis	1	1
Malaise	6	6
Mean cell haemoglobin concentration decreased	1	1
Mean cell haemoglobin decreased	1	1
Mean cell volume decreased	1	1
Movement disorder	2	2
Multiple sclerosis relapse	1	1
Muscle twitching	1	1
Myalgia	7	7
Myocardial infarction	1	1
Nasopharyngitis	1	1
Nausea	2	3
Neck pain	1	1
Odynophagia	1	1
Oral herpes	1	1
Oropharyngeal pain	4	4
Otitis media	1	1
Overdose	1	3
Pain	6	6
Pain in extremity	5	5
Pain in jaw	3	3
Palpitations	3	3
Pancreatitis	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	1	1	1
1	1		
	1		
	1		
		1	2
1	1		
	1		
1	1		
1	1		
4	4	2	2
1	1		
1	1		
1	1		
1	1	1	1
		1	1
1	1		
6	6	1	1
		1	1
1	1		
2	3		
1	1		
1	1		
1	1		
4	4		
1	1		
1	3		
6	6		
5	5		
3	3		
3	3		
		1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	4	4	4	4		
Paraesthesia oral	3	3	3	3		
Pericarditis		1				1
Pharyngeal paraesthesia		1		1		
Pleural effusion	1	1			1	1
Pleuritic pain		1				1
Poor quality product administered	1	3	1	3		
Poor quality sleep		1		1		
Product deposit		1		1		
Product preparation error	1	3	1	3		
Pyrexia	6	6	5	5	1	1
Red blood cell count increased	1	1	1	1		
Respiratory arrest	1	1			1	1
Respiratory distress	1	1			1	1
Rhinorrhoea	2	2	2	2		
SARS-CoV-2 test positive	3	3			3	3
Sepsis	1	1			1	1
Sinus tachycardia	1	1	1	1		
Sleep disorder due to general medical condition, insomnia type		1		1		
Sneezing	2	2	2	2		
Speech disorder	1	1	1	1		
Sudden cardiac death	1	1			1	1
Suffocation feeling	1	1	1	1		
Suspected COVID-19	1	1			1	1
Syncope	3	4			3	4
Systemic inflammatory response syndrome	1	1			1	1
Tachycardia	1	1	1	1		
Taste disorder	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Thrombosis	2	2			2	2
Tongue discomfort	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toothache	1	1	1	1		
Tremor	2	2	2	2		
Underdose	1	1	1	1		
Urticaria	1	2	1	2		
Vaccination site erythema		1		1		
Vaccination site hypersensitivity		1		1		
Vaccination site pain	7	13	7	13		
Vaccination site swelling	2	3	2	3		
Vision blurred	1	1	1	1		
Vomiting	3	4	3	4		
Weight decreased	2	2	1	1	1	1
Wrong technique in product usage process	1	1	1	1		
Yawning	1	1	1	1		
	250	303	180	220	70	83

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Adverse event	1	1	1	1		
Adverse reaction	1	1	1	1		
Anosmia		1		1		
Arthralgia	1	1			1	1
Arthropathy	1	1	1	1		
Asthenia	8	9	8	9		
Back pain	1	1	1	1		
Balance disorder		1		1		
Chills	3	4	3	4		
Cough	1	1	1	1		
COVID-19	2	2	1	1	1	1
Death	1	1			1	1
Diarrhoea	1	1	1	1		
Dizziness	2	4	2	4		
Drug ineffective	2	2	1	1	1	1
Dysgeusia	1	1	1	1		
Dyspnoea	1	1			1	1
Exposure via breast milk	2	3	2	3		
Eye haemorrhage	1	1			1	1
Eye infection		1		1		
Eye pain	2	2			2	2
Facial paralysis	2	2			2	2
Fatigue	8	8	8	8		
Headache	7	7	6	6	1	1
Head discomfort	2	2	2	2		
Hypertension	1	1			1	1
Hypoaesthesia	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		
Incomplete course of vaccination	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Initial insomnia		1		1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Liquid product physical issue		13		13		
Malaise	1	1			1	1
Myalgia	9	9	8	8	1	1
Nausea	2	3	2	3		
Neuralgic amyotrophy	1	1	1	1		
Oral herpes	1	1			1	1
Oropharyngeal pain	1	1	1	1		
Pain in extremity	3	4	3	4		
Peripheral swelling	1	1			1	1
Poor quality product administered	1	25	1	25		
Product complaint		1		1		
Product packaging quantity issue	1	11	1	11		
Pyrexia	8	9	7	8	1	1
Rash	1	1	1	1		
Seizure	1	1			1	1
Syncope	1	1			1	1
Therapeutic response unexpected	1	1	1	1		
Urticaria	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	7	9	7	9		
Vaccination site swelling	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	1	1	1	1		
Wheezing	1	1			1	1
Wrong technique in product usage process	1	1	1	1		
	103	166	82	145	21	21

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Country Where Event Occurred  
**ITALY**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	1	1			1	1		
Abdominal pain	7	8			7	8		
Abdominal pain upper	6	6			6	6		
Acute coronary syndrome	3	3					3	3
Administration site reaction	1	1					1	1
Ageusia	1	1			1	1		
Agitation	2	2			2	2		
Allergy to vaccine	1	1					1	1
Anaesthesia	2	2			1	1	1	1
Anaphylactic reaction	2	2					2	2
Anaphylactic shock	5	5					5	5
Angioedema	1	1					1	1
Anosmia	1	1			1	1		
Anxiety	2	2			2	2		
Arteriosclerosis	1	1					1	1
Arthralgia	28	28			27	27	1	1
Asphyxia	1	1					1	1
Asthenia	24	24			23	23	1	1
Atrioventricular block complete	1	1					1	1
Aura	1	1			1	1		
Axillary pain	5	5			4	4	1	1
Back pain	4	4			2	2	2	2
Balance disorder	1	1			1	1		
Band sensation	1	1			1	1		
Blood pressure diastolic increased	1	1			1	1		
Blood pressure increased	5	5			4	4	1	1
Body temperature decreased	1	1			1	1		
Body temperature increased	1	2			1	2		
Bone pain	3	3			3	3		
Bradycardia	2	2					2	2
Breast discomfort	1	1					1	1
Breast pain	1	1					1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast swelling	1	1
Bronchospasm	1	1
Burning sensation	1	1
Cardiac failure	1	1
Cerebellar haemorrhage	1	1
Cerebrovascular accident	1	1
Chest discomfort	3	3
Chest pain	1	1
Chills	25	26
Circulatory collapse	1	1
Coma scale abnormal	1	1
Condition aggravated	1	1
Confusional state	5	5
Constipation	1	1
Corneal bleeding	1	1
Cough	6	6
COVID-19	2	2
Crying	1	1
Death	1	1
Decreased appetite	2	2
Deep vein thrombosis	1	1
Dehydration	1	1
Depressed level of consciousness	3	3
Dermatitis	1	1
Dermatitis exfoliative generalised	1	1
Diarrhoea	17	17
Discomfort	1	1
Disorientation	1	1
Dizziness	14	14
Drug ineffective	2	2
Dry mouth	9	9
Dysaesthesia	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
		1	1		
				1	1
				1	1
				1	1
		3	3		
		1	1		
1	1	23	24	2	2
				1	1
				1	1
				1	1
		4	4	1	1
		1	1		
				1	1
		5	5	1	1
				2	2
		1	1		
				1	1
				1	1
		1	1	2	2
				1	1
				1	1
		17	17		
		1	1		
		1	1		
		14	14		
				2	2
		9	9		
		2	2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dysgeusia	10	10
Dyspepsia	1	1
Dysphagia	9	9
Dysphonia	1	1
Dyspnoea	13	13
Ear pain	1	1
Ear pruritus	1	1
Erythema	22	22
Eye irritation	2	2
Eyelid oedema	1	1
Eye pain	2	2
Eye pruritus	2	2
Face oedema	2	2
Facial pain	1	1
Facial paralysis	1	1
Facial spasm	1	1
Fatigue	15	15
Feeling abnormal	2	2
Feeling cold	3	3
Feeling hot	13	13
Feeling of body temperature change	1	1
Flatulence	1	1
Flushing	7	7
Gastritis	1	1
Gastrointestinal disorder	1	1
Gastrointestinal sounds abnormal	1	1
General physical health deterioration	1	1
Gingival swelling	1	1
Haematoma	1	1
Headache	82	82
Heart rate decreased	1	1
Hemiparesis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		10	10		
		1	1		
		5	5	4	4
		1	1		
1	1	7	7	6	6
		1	1		
		1	1		
		18	18	4	4
		2	2		
				1	1
		2	2		
		2	2		
		1	1	1	1
		1	1		
				1	1
				1	1
1	1	14	14	1	1
		2	2		
1	1	3	3		
		11	11	2	2
		1	1		
		1	1		
		7	7		
		1	1		
		1	1		
		1	1		
				1	1
		1	1		
		1	1		
1	1	80	80	2	2
		1	1		
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Herpes zoster	1	1
Hot flush	6	6
Hyperaesthesia	1	1
Hyperhidrosis	6	6
Hypersensitivity	2	2
Hypertension	5	5
Hypertensive crisis	4	4
Hyperthermia	2	2
Hyperventilation	1	1
Hypoaesthesia	4	4
Hypoaesthesia oral	7	7
Hypoglycaemia	1	1
Hypotension	8	8
Incorrect dose administered	2	2
Incorrect route of product administration	1	1
Inflammation	1	1
Influenza like illness	3	4
Injection site pain	2	2
Insomnia	2	2
Inspiratory capacity abnormal	1	1
Intranasal hypoaesthesia	1	1
Intranasal paraesthesia	1	1
Irritability	1	1
Joint range of motion decreased	1	1
Lacrimation increased	2	2
Laryngeal oedema	7	7
Laryngeal pain	1	1
Laryngospasm	1	1
Limb discomfort	3	3
Lip oedema	3	3
Lip pruritus	1	1
Lip swelling	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		6	6		
		1	1		
		6	6		
		1	1	1	1
		3	3	2	2
				4	4
		1	1	1	1
		1	1		
		4	4		
		7	7		
		1	1		
		6	6	2	2
		2	2		
		1	1		
				1	1
		3	4		
		1	1	1	1
		2	2		
		1	1		
		1	1		
		1	1		
		1	1		
		2	2		
				7	7
		1	1		
				1	1
		3	3		
		2	2	1	1
		1	1		
		2	2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Localised oedema	1	1
Lymphadenitis	1	1
Lymphadenopathy	20	20
Lymphangitis	1	1
Lymph node pain	4	4
Lymphoedema	1	1
Malaise	16	17
Mastitis	1	1
Mechanical urticaria	1	1
Migraine	3	3
Monoparesis	1	1
Muscle contractions involuntary	1	1
Muscle rigidity	1	1
Musculoskeletal pain	3	3
Myalgia	26	26
Myocardial ischaemia	1	1
Nasal congestion	2	2
Nasopharyngitis	2	2
Nausea	36	36
Neck pain	3	3
Neuralgia	2	2
Neuritis	1	1
Night sweats	1	1
Nuchal rigidity	1	1
Ocular hyperaemia	1	1
Oedema peripheral	1	1
Oral discomfort	1	1
Oral dysaesthesia	1	1
Oral herpes	2	2
Oropharyngeal pain	3	3
Oropharyngeal swelling	1	1
Overdose	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
		18	18	2	2
				1	1
		4	4		
		1	1		
		14	15	2	2
				1	1
		1	1		
		3	3		
		1	1		
				1	1
				1	1
		3	3		
		24	24	2	2
				1	1
		2	2		
		1	1	1	1
		34	34	2	2
		3	3		
		2	2		
		1	1		
		1	1		
		1	1		
				1	1
		1	1		
		1	1		
		1	1		
		2	2		
		3	3		
		1	1		
		3	3		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oxygen saturation decreased	1	1
Pain	10	10
Pain in extremity	21	21
Palatal oedema	1	1
Palatal swelling	1	1
Palpitations	3	3
Paraesthesia	25	25
Paraesthesia oral	16	16
Periorbital swelling	1	1
Peripheral coldness	3	3
Peripheral swelling	1	1
Pharyngeal erythema	1	1
Pharyngeal paraesthesia	2	2
Pharyngeal swelling	1	1
Pharyngitis	1	1
Photophobia	1	1
Presyncope	6	6
Product administered to patient of inappropriate age	1	1
Pruritus	22	22
Pulmonary embolism	1	1
Pyrexia	71	71
Q fever	1	1
Rash	21	21
Rash erythematous	2	2
Rash pruritic	1	1
Reduced facial expression	1	1
Renal failure	1	1
Renal pain	1	1
Respiratory arrest	1	1
Respiratory distress	1	1
Retching	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		8	8	2	2
		20	20	1	1
				1	1
		1	1		
		3	3		
		21	21	4	4
		13	13	3	3
		1	1		
		3	3		
		1	1		
		1	1		
		2	2		
				1	1
		1	1		
		1	1		
		6	6		
		1	1		
		19	19	3	3
				1	1
1	1	68	68	3	3
				1	1
		20	20	1	1
		2	2		
		1	1		
				1	1
				1	1
		1	1		
				1	1
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rhinorrhoea	4	4
SARS-CoV-2 ant body test positive	2	2
Sciatica	1	1
Sensation of foreign body	1	1
Sinus tachycardia	1	1
Skin reaction	1	1
Sneezing	1	1
Somnolence	7	7
Speech disorder	1	1
Spinal pain	4	4
Stupor	2	2
Swelling	3	3
Swelling face	3	3
Swollen tongue	2	2
Syncope	1	1
Systolic hypertension	1	1
Tachycardia	18	18
Tachycardia paroxysmal	1	1
Tachypnoea	1	1
Tenderness	1	1
Throat irritation	3	3
Throat tightness	11	11
Tongue discomfort	1	1
Tongue disorder	1	1
Tongue dry	1	1
Tongue oedema	2	2
Tongue pruritus	1	1
Tremor	7	7
Underdose	3	3
Urticaria	28	28
Vaccination site discolouration	1	1
Vaccination site discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	4		
		2	2		
		1	1		
		1	1		
				1	1
		1	1		
		1	1		
		7	7		
		1	1		
		4	4		
		2	2		
		2	2	1	1
		2	2	1	1
		2	2		
				1	1
				1	1
		14	14	4	4
				1	1
		1	1		
		1	1		
		3	3		
		7	7	4	4
		1	1		
		1	1		
				1	1
		1	1	1	1
		1	1		
		7	7		
		3	3		
		25	25	3	3
		1	1		
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vaccination site erythema	10	11			9	10	1	1
Vaccination site induration	1	1			1	1		
Vaccination site joint swelling	1	1			1	1		
Vaccination site joint warmth	1	1			1	1		
Vaccination site lymphadenopathy	2	2			1	1	1	1
Vaccination site movement impairment	2	2			2	2		
Vaccination site oedema	3	3			3	3		
Vaccination site pain	88	89			86	87	2	2
Vaccination site paraesthesia	3	3			3	3		
Vaccination site pruritus	3	3			2	2	1	1
Vaccination site rash	1	1			1	1		
Vaccination site swelling	9	9			8	8	1	1
Vaccination site urticaria	6	6			5	5	1	1
Vaccination site warmth	3	4			2	3	1	1
Vasoconstriction	1	1			1	1		
Vasomotor rhinitis	1	1			1	1		
Vertigo	16	16			16	16		
Vision blurred	3	3			3	3		
Visual impairment	1	1			1	1		
Vomiting	11	11			9	9	2	2
Weight decreased	1	1					1	1
Wrong technique in product usage process	1	1			1	1		
	1,161	1,169	6	6	992	1000	169	169

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	3	3	3		
Abdominal pain upper	2	2	2	2		
Acute myocardial infarction	2	2			2	2
Acute respiratory failure	1	1			1	1
Agitation	1	1	1	1		
Allergic respiratory symptom	1	1			1	1
Allodynia	1	1	1	1		
Anal incontinence	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Arthralgia	12	13	11	12	1	1
Asthenia	15	16	13	14	2	2
Back pain	1	1	1	1		
Balance disorder	1	1	1	1		
Blood glucose increased	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure increased	2	2	1	1	1	1
Body temperature decreased	1	1	1	1		
Body temperature increased	1	1			1	1
Bone pain	1	1	1	1		
Chest discomfort	1	1			1	1
Chills	13	13	13	13		
Circumstance or information capable of leading to medication error		1		1		
Confusional state	1	1	1	1		
Cough	3	3	3	3		
COVID-19	2	2			2	2
Cranial nerve disorder	1	1			1	1
Death	2	2			2	2
Dermatitis allergic	1	1			1	1
Diarrhoea	8	8	8	8		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dizziness	5	5	5	5		
Drug ineffective	4	4			4	4
Dry mouth	3	3	1	1	2	2
Dry throat	1	1	1	1		
Dysgeusia	5	5	3	3	2	2
Dysphagia	1	1	1	1		
Dysphonia	1	1	1	1		
Dyspnoea	3	3	1	1	2	2
Erythema	8	8	7	7	1	1
Exposure via breast milk	1	1	1	1		
Extremity contracture	1	1	1	1		
Fall	1	1			1	1
Fatigue	8	8	8	8		
Feeling cold	2	2	1	1	1	1
Feeling hot	2	2	2	2		
Flushing	2	2	2	2		
Headache	36	37	35	36	1	1
Head discomfort	1	1	1	1		
Herpes zoster	1	1	1	1		
Hot flush	2	2	2	2		
Hyperhidrosis	6	6	5	5	1	1
Hyperpyrexia	2	2			2	2
Hypertension	2	2			2	2
Hypertensive crisis	2	2			2	2
Hypoaesthesia	5	5	5	5		
Hypotension	2	2	2	2		
Incorrect route of product administration	1	1	1	1		
Influenza like illness	1	2	1	2		
Injection site pain	3	3	3	3		
Insomnia	2	2	2	2		
Laryngeal oedema	1	1			1	1
Limb discomfort	3	3	3	3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip oedema	3	3	2	2	1	1
Lip pruritus	1	1	1	1		
Localised oedema	1	1	1	1		
Loss of consciousness	1	1			1	1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	8	8	7	7	1	1
Lymph node pain	1	1	1	1		
Malaise	4	4	4	4		
Migraine	5	5	5	5		
Mucosal dryness	1	1	1	1		
Muscle spasms	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal pain	4	4	4	4		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	19	19	19	19		
Nausea	13	13	13	13		
Neck pain	1	1	1	1		
Obstructive airways disorder	1	1			1	1
Oedema mouth	2	2	1	1	1	1
Off label use	3	3	3	3		
Oropharyngeal pain	1	1	1	1		
Overdose	1	1	1	1		
Oxygen saturation decreased	1	1	1	1		
Pain	3	3	3	3		
Pain in extremity	13	13	12	12	1	1
Pallor	2	2	2	2		
Paraesthesia	2	2	2	2		
Paraesthesia oral	5	5	4	4	1	1
Paresis	1	1	1	1		
Paresis cranial nerve	1	1	1	1		
Parosmia	1	1	1	1		
Parotid gland enlargement	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Periorbital oedema	1	1			1	1
Periorbital swelling	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pharyngitis	1	1	1	1		
Pityriasis rosea	1	1	1	1		
Polyuria	1	1	1	1		
Presyncope	3	3	2	2	1	1
Product label confusion		1		1		
Product use issue	2	2	2	2		
Pruritus	5	5	5	5		
Pyrexia	32	32	31	31	1	1
Rash	4	4	4	4		
Rash erythematous	1	1	1	1		
Restlessness	1	1			1	1
SARS-CoV-2 test positive	2	2			2	2
Sinus tachycardia	1	1	1	1		
Skin reaction	1	1	1	1		
Somnolence	7	7	7	7		
Swelling	1	1	1	1		
Swelling of eyelid	1	1	1	1		
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachycardia	8	8	7	7	1	1
Tachycardia paroxysmal	1	1	1	1		
Throat irritation	1	1			1	1
Throat tightness	1	1	1	1		
Tongue dry	2	2	1	1	1	1
Tongue oedema	1	1			1	1
Tonic clonic movements	1	1			1	1
Tonsillar erythema	1	1	1	1		
Tonsillar hypertrophy	1	1	1	1		
Torticollis	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	3	3	2	2	1	1
Underdose	3	3	3	3		
Urticaria	2	2	2	2		
Vaccination site discomfort	2	2	2	2		
Vaccination site erythema	2	2	2	2		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	71	71	71	71		
Vaccination site paraesthesia	1	1	1	1		
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		
Vertigo	6	6	5	5	1	1
Vision blurred	2	2	2	2		
Vomiting	1	1	1	1		
	492	498	428	434	64	64

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anaphylactic reaction	3	3			3	3
Anaphylactic shock	1	1			1	1
Asthenia	1	1	1	1		
Asthenopia	1	1	1	1		
Confusional state	1	1	1	1		
COVID-19	1	1			1	1
Deafness bilateral	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	5	5			5	5
Dry mouth	1	1	1	1		
Dyspnoea	1	1			1	1
Dysuria	1	1			1	1
Erythema	1	1	1	1		
Feeling hot	1	1	1	1		
Flatulence	1	1	1	1		
Headache	1	1	1	1		
Hypersensitivity	1	1			1	1
Hypoaesthesia oral	1	1	1	1		
Hypotension	1	1			1	1
Incorrect dose administered	1	1	1	1		
Influenza like illness	1	1	1	1		
Laryngeal oedema	1	1			1	1
Lip oedema	2	2	2	2		
Lymphadenopathy	4	4	4	4		
Malaise	1	1	1	1		
Musculoskeletal pain	2	2	2	2		
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Pain	1	1	1	1		
Pallor	1	1	1	1		
Paraesthesia	2	2	2	2		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	1	1	1	1		
Poor quality product administered	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Product administration error	1	1	1	1		
Product preparation issue	1	1	1	1		
Pyrexia	3	3	2	2	1	1
SARS-CoV-2 test positive	4	4			4	4
Somnolence	1	1	1	1		
Sudden death	1	1			1	1
Tachycardia	1	1	1	1		
Underdose	1	1	1	1		
Urticaria	3	3	3	3		
Vaccination site oedema	2	2	2	2		
Vaccination site pain	3	3	3	3		
Vaccination site paraesthesia	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vertigo	1	1			1	1
Wrong technique in product usage process	1	1	1	1		
	72	72	49	49	23	23

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Country Where Event Occurred  
**KUWAIT**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Lymphadenopathy	1	1	1	1
Myalgia	1	1	1	1
Neck pain	1	1	1	1
Pyrexia	1	1	1	1
Swelling	1	1	1	1
Tenderness	1	1	1	1
Vaccination site pain	1	1	1	1
Vaccination site swelling	1	1	1	1
	9	9	9	9

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Country Where Event Occurred  
**LATVIA**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1			1	1
Arthralgia	4	4	3	3	1	1
Asthenia	3	3	2	2	1	1
Asthma	1	1	1	1		
Blood pressure increased	2	2	1	1	1	1
Body temperature increased	5	5	4	4	1	1
Burning sensation	1	1			1	1
Chest pain	1	1	1	1		
Chills	1	1	1	1		
Cold sweat	1	1			1	1
Cough	1	1	1	1		
COVID-19	2	2			2	2
Diarrhoea	1	1	1	1		
Drug ineffective	3	3			3	3
Dry mouth	1	1			1	1
Dysgeusia	1	1			1	1
Dyspnoea	1	1	1	1		
Erythema	1	1			1	1
Eye pain	1	1	1	1		
Fatigue	3	3	3	3		
Feeling hot	1	1	1	1		
Headache	4	4	2	2	2	2
Illness	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymph node pain	1	1			1	1
Malaise	1	1	1	1		
Musculoskeletal discomfort	1	1	1	1		
Myalgia	2	2	2	2		
Neuralgia	1	1			1	1
Night sweats	1	1	1	1		
Pain in extremity	2	2	1	1	1	1
Palatal swelling	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	1	1			1	1
Peripheral coldness	2	2	1	1	1	1
Pruritus	1	1			1	1
Pyrexia	3	3	2	2	1	1
SARS-CoV-2 test positive	1	1			1	1
Syncope	1	1			1	1
Throat irritation	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	6	6	6	6		
Vaccination site pruritus	2	2	2	2		
Vaccination site swelling	1	1	1	1		
Vomiting	1	1	1	1		
	74	74	47	47	27	27

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Blood pressure decreased	1	1	1	1		
Body temperature increased	1	1	1	1		
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Headache	1	1	1	1		
Myalgia	2	2	2	2		
Nausea	1	1	1	1		
Pain in extremity	1	1	1	1		
	12	12	10	10	2	2

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
COVID-19	1	1	1	1
Drug ineffective	1	1	1	1
	2	2	2	2

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Country Where Event Occurred  
**LITHUANIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Diarrhoea	1	1	1	1
Dizziness	1	1	1	1
Headache	2	2	2	2
Hypoaesthesia	1	1	1	1
Myalgia	2	2	2	2
Neck pain	1	1	1	1
Pain in extremity	2	2	2	2
Peripheral swelling	1	1	1	1
Pyrexia	3	3	3	3
Tachycardia	1	1	1	1
Vaccination site erythema	1	1	1	1
Vaccination site pain	1	1	1	1
	18	18	18	18

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	2	2	2	2
Back pain	1	1	1	1
Chills	1	1	1	1
Dizziness	1	1	1	1
Headache	2	2	2	2
Myalgia	3	3	3	3
Overdose	1	1	1	1
Pyrexia	3	3	3	3
Sensitive skin	1	1	1	1
Tremor	1	1	1	1
Vaccination complication	1	1	1	1
Vaccination site pain	1	1	1	1
	18	18	18	18

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Underdose	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**LUXEMBOURG**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Herpes zoster	1	1	1	1
Oral herpes	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**MALTA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea		1		1		
Dizziness		1		1		
Dyspnoea	1	1			1	1
Erythema		1		1		
Facial paralysis	1	1	1	1		
Fatigue	1	2	1	2		
Hot flush		1		1		
Hypersensitivity		1				1
Hypertension		1				1
Hypoaesthesia	1	1	1	1		
Lethargy	1	2	1	2		
Myalgia	1	1	1	1		
Nausea		1		1		
Pain	1	1	1	1		
Palpitations		1		1		
Paraesthesia	1	2	1	2		
Rash erythematous		1		1		
Rash pruritic	1	1			1	1
Somnolence	1	1	1	1		
Tachycardia		1				1
Vaccination site urticaria		1		1		
Vomiting		1		1		
Wheezing	1	1			1	1
	11	26	8	20	3	6

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	1	1			1	1
Drug ineffective	1	1			1	1
Malaise	1	1	1	1		
Myalgia	1	1	1	1		
Nausea	1	1	1	1		
Vaccination site pain	1	1	1	1		
	6	6	4	4	2	2

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Country Where Event Occurred  
**MEXICO**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Abdominal pain upper	2	2	2	2		
Akathisia	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock		1				1
Angina pectoris	1	1			1	1
Angioedema	1	2			1	2
Arthralgia	8	8	7	7	1	1
Asthenia	1	1			1	1
Asthma	1	1	1	1		
Axonal neuropathy	1	1			1	1
Burning sensation	2	2			2	2
Chest pain	1	1	1	1		
Chills	5	5	5	5		
COVID-19	2	2			2	2
COVID-19 pneumonia	1	1			1	1
Cyanosis		1		1		
Demyelination	2	2			2	2
Diarrhoea	1	1	1	1		
Discomfort	2	2	2	2		
Dizziness	4	4	4	4		
Drug ineffective	3	3			3	3
Dyspnoea	1	2	1	2		
Encephalitis post immunisation		1				1
Epigastric discomfort	1	1	1	1		
Eye inflammation	1	1	1	1		
Eye swelling	1	2		1	1	1
Face oedema	1	1	1	1		
Fatigue	2	2	2	2		
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Gastrointestinal motility disorder	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	12	12	10	10	2	2
Hypersensitivity		1		1		
Hypoaesthesia	2	2	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1		
Inflammation	1	1			1	1
Lip oedema	1	1	1	1		
Loss of consciousness		1				1
Loss of personal independence in daily activities	1	1			1	1
Maternal exposure during pregnancy	1	1	1	1		
Mechanical urticaria	1	1	1	1		
Mobility decreased	1	1	1	1		
Mononeuropathy	1	1			1	1
Muscle contractions involuntary	1	1	1	1		
Muscle contracture	1	1	1	1		
Muscle spasms	1	2	1	1		1
Muscle spasticity	1	1			1	1
Muscular weakness	1	1	1	1		
Myalgia	6	6	5	5	1	1
Myelitis transverse		1				1
Nasal congestion		1		1		
Nausea	3	3	1	1	2	2
Nerve degeneration	1	1			1	1
Neuritis	2	2			2	2
Off label use	2	2	2	2		
Oropharyngeal pain	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity		1		1		
Paraesthesia	2	3	1	1	1	2
Paralysis		1				1
Peripheral motor neuropathy	1	1			1	1
Peroneal nerve injury	1	1			1	1
Product use issue	2	2	2	2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	2	3	1	2	1	1
Pyrexia	5	5	5	5		
Radiculopathy	2	2			2	2
Rash	4	5	3	3	1	2
Respiratory distress	1	2			1	2
Sacroiliitis	1	1			1	1
Sciatica	1	1			1	1
Sciatic nerve neuropathy	1	1			1	1
Seizure		1				1
Sensory loss	1	1			1	1
Slow response to stimuli	1	1	1	1		
Sneezing		1		1		
Somnolence	1	1	1	1		
Throat irritation	1	2	1	2		
Vaccination site pain	6	6	6	6		
Vaccination site warmth	1	1	1	1		
	129	149	87	96	42	53

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anosmia	1	1	1	1		
Arthralgia	4	4	4	4		
Asthenia	2	2	2	2		
Chills	1	1	1	1		
Coagulation time prolonged	1	1			1	1
Cough	1	1	1	1		
COVID-19	1	1			1	1
COVID-19 pneumonia	1	1			1	1
Diarrhoea	2	2	1	1	1	1
Discomfort	1	1	1	1		
Drug ineffective	3	3			3	3
Fatigue	2	3	2	3		
Gastrointestinal disorder	1	1			1	1
Headache	3	4	3	4		
Hypoaesthesia	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Lymphopenia	1	1			1	1
Masticatory pain	1	1	1	1		
Muscle spasms	1	1	1	1		
Myalgia	6	6	6	6		
Nausea	3	3	3	3		
Pain	1	1	1	1		
Paraesthesia	2	2	2	2		
Parotid gland enlargement	1	1	1	1		
Parotitis	1	1	1	1		
Pyrexia	7	7	6	6	1	1
SARS-CoV-2 test positive	1	1			1	1
Tachycardia	1	1	1	1		
Vaccination site hypersensitivity	1	1	1	1		
Vaccination site pain	3	4	3	4		
Vaccination site reaction	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vertigo	1	1	1	1		
Vomiting	1	1			1	1
	60	63	48	51	12	12

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	3	3	3		
Allergy to vaccine	3	3	3	3		
Arthralgia	24	24	24	24		
Asthenia	20	20	19	19	1	1
Back pain	1	1	1	1		
Blood pressure increased	1	1			1	1
Body temperature increased	4	4	4	4		
Chest discomfort	1	1	1	1		
Chills	9	9	9	9		
Cough	8	8	8	8		
COVID-19	3	3			3	3
COVID-19 pneumonia	1	1			1	1
Decreased appetite	2	2	2	2		
Diarrhoea	3	3	3	3		
Discomfort	4	4	4	4		
Dizziness	14	14	13	13	1	1
Drug ineffective	5	5			5	5
Dysgeusia	2	2	2	2		
Dyspnoea	6	6	3	3	3	3
Ear pain	1	1	1	1		
Epilepsy	1	1			1	1
Erythema	2	2	2	2		
Eye pain	1	1	1	1		
Fatigue	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	39	39	38	38	1	1
Hot flush	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	2	2	2	2		
Hypertension	2	2	1	1	1	1
Hypertensive crisis	2	2			2	2
Inflammation	1	1	1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Laryngospasm		1
Local reaction	2	2
Lymphadenopathy	2	2
Mobility decreased	2	2
Myalgia	21	21
Nausea	10	10
Neck pain	1	1
Nodule	1	1
Oedema	7	7
Oropharyngeal pain	2	2
Oxygen saturation decreased	1	1
Pain	11	11
Pain in extremity	2	2
Palpitations	1	1
Paraesthesia	4	4
Paraesthesia oral	2	2
Pelvic pain	1	1
Pneumonia	3	3
Pruritus	2	2
Pyrexia	19	19
Rash	9	9
Rash maculo-papular	1	1
Rhinorrhoea	6	6
Seizure	5	5
Sensory loss	1	1
Suspected COVID-19	1	1
Swelling	1	1
Syncope	2	2
Tachycardia	10	10
Vaccination site erythema	2	2
Vaccination site hyperaesthesia	1	1
Vaccination site induration	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
2	2		
2	2		
2	2		
21	21		
10	10		
1	1		
1	1		
7	7		
2	2		
		1	1
10	10	1	1
2	2		
1	1		
3	3	1	1
1	1	1	1
1	1		
		3	3
2	2		
19	19		
8	8	1	1
1	1		
6	6		
		5	5
1	1		
		1	1
1	1		
		2	2
9	9	1	1
2	2		
1	1		
2	2		

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site inflammation	1	1	1	1		
Vaccination site nodule	3	3	3	3		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	31	31	30	30	1	1
Vaccination site rash	1	1	1	1		
Vomiting	3	3	3	3		
	344	345	306	307	38	38

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Country Where Event Occurred  
**NETHERLANDS**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	2	2			2	2
Angioedema	1	1			1	1
Anxiety	1	1			1	1
Axillary pain	1	1	1	1		
Chest discomfort	1	1			1	1
Chills	2	2	1	1	1	1
Cough	1	1	1	1		
Diarrhoea	1	1	1	1		
Dizziness	2	2	1	1	1	1
Dysphagia	1	1			1	1
Erythema	2	2	1	1	1	1
Headache	4	4	4	4		
Head discomfort	1	1			1	1
Hyperventilation	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Influenza like illness	1	1	1	1		
Malaise	1	1			1	1
Myalgia	2	2	2	2		
Nausea	2	2	2	2		
Oropharyngeal pain	1	1	1	1		
Palpitations	1	1			1	1
Paraesthesia	1	1			1	1
Paraesthesia oral	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Pruritus	1	1			1	1
Rash	1	1			1	1
Rash maculo-papular	1	1	1	1		
Sneezing	1	1	1	1		
Tongue oedema	1	1			1	1

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urticaria	2	2	1	1	1	1
Vaccination site pain	1	1	1	1		
Vomiting	1	1	1	1		
	45	45	25	25	20	20

Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error	1	1	1	1
Exposure via breast milk	1	1	1	1
Product label confusion	1	1	1	1
Product preparation error	1	1	1	1
	4	4	4	4

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Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Arthralgia	1	1	1	1
Chest discomfort	1	1	1	1
Chills	1	1	1	1
Disorientation	1	1	1	1
Dizziness	1	1	1	1
Fatigue	1	1	1	1
Headache	1	1	1	1
Pain in extremity	1	1	1	1
Poor quality sleep	1	1	1	1
	9	9	9	9

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Country Where Event Occurred  
**NORWAY**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute coronary syndrome	1	1			1	1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Anxiety	1	1	1	1		
Apathy	1	1			1	1
Blepharospasm	1	1	1	1		
Blood pressure decreased	1	1			1	1
Blood pressure diastolic decreased	1	1	1	1		
Body temperature decreased	1	1	1	1		
Body temperature increased	1	1	1	1		
Burning sensation	1	1			1	1
Cardiac failure	1	1			1	1
Cardiovascular disorder	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chest discomfort	1	1			1	1
Chills	1	1	1	1		
Cold sweat	3	3			3	3
Concomitant disease aggravated	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	2	2			2	2
Coordination abnormal	1	1			1	1
Cough	1	1			1	1
Death	5	5			5	5
Decreased appetite	1	1			1	1
Depressed level of consciousness	1	1			1	1
Diarrhoea	1	1			1	1
Disease recurrence	1	1			1	1
Dizziness	2	2	1	1	1	1
Dyspnoea	4	4			4	4
Fatigue	4	4	2	2	2	2
Feeling hot	2	2	1	1	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Flushing	1	1	1	1		
General physical health deterioration	5	5			5	5
Headache	2	2	2	2		
Heart rate increased	1	1			1	1
Heart rate irregular	1	1	1	1		
Hypersensitivity	1	1			1	1
Hyperventilation	1	1	1	1		
Hypotension	1	1			1	1
Infection	1	1			1	1
Influenza like illness	1	1			1	1
Intracardiac thrombus	1	1			1	1
Local reaction	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	3	3	1	1	2	2
Malignant hypertension	1	1			1	1
Nausea	2	2	1	1	1	1
Oxygen saturation decreased	2	2			2	2
Pain in extremity	1	1	1	1		
Pallor	2	2			2	2
Pneumonia	1	1			1	1
Product administered at inappropriate site	1	1	1	1		
Pupil fixed	2	2			2	2
Pyrexia	6	6	2	2	4	4
Rales	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory rate increased	3	3			3	3
Restlessness	1	1	1	1		
Retching	1	1	1	1		
Somnolence	2	2			2	2
Sudden death	3	3			3	3
Syncope	2	2			2	2
Tremor	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Urinary tract infection	1	1	1	1		
Vaccination site erythema	1	1			1	1
Vaccination site pain	1	1			1	1
Vaccination site swelling	2	2	1	1	1	1
Vomiting	4	4			4	4
	110	110	25	25	85	85

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Blood pressure decreased	1	1			1	1
Cerebrovascular accident	1	1			1	1
Confusional state	1	1			1	1
Death	3	3			3	3
Decreased appetite	1	1			1	1
Delirium	1	1			1	1
Depressed level of consciousness	1	1			1	1
Diarrhoea	1	1			1	1
Dysphagia	1	1			1	1
Fatigue	2	2	1	1	1	1
Gastrointestinal haemorrhage	1	1			1	1
General physical health deterioration	3	3			3	3
Hallucination	1	1			1	1
Heart rate increased	1	1			1	1
Hypophagia	1	1			1	1
Hypotension	1	1			1	1
Injection site muscle weakness	1	1	1	1		
Nausea	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pneumonia	2	2			2	2
Vaccination site pain	2	2	2	2		
Vomiting	1	1	1	1		
	30	30	6	6	24	24

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Incorrect dose administered	1	1	1	1
Poor quality product administered	6	6	6	6
Product preparation error	2	2	2	2
Product temperature excursion issue	6	6	6	6
Wrong technique in product usage process	1	1	1	1
	16	16	16	16

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Country Where Event Occurred

**OMAN**

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea		1		1
Fatigue		1		1
Gastritis		1		1
Headache		1		1
Pain		1		1
Pyrexia		1		1
		6		6

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Country Where Event Occurred  
**POLAND**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	3	3	3		
Abdominal pain upper	1	1			1	1
Ageusia	2	2	2	2		
Anosmia	3	3	3	3		
Anxiety	1	1	1	1		
Arrhythmia	1	1			1	1
Arthralgia	12	13	11	12	1	1
Arthritis		1		1		
Asthenia	17	18	16	17	1	1
Axillary pain	2	2	2	2		
Blood pressure decreased	1	1	1	1		
Blood pressure increased	2	2	1	1	1	1
Blood urine present	1	1	1	1		
Body temperature increased	2	2	2	2		
Bone pain	3	3	3	3		
Breast pain	1	1	1	1		
Chest discomfort	2	2	2	2		
Chills	9	9	8	8	1	1
Conjunctival hyperaemia	1	1	1	1		
Cough	1	1	1	1		
COVID-19	8	8			8	8
Cystitis	1	1	1	1		
Decreased activity	1	1	1	1		
Decreased appetite	2	2	2	2		
Diarrhoea	2	2	2	2		
Dizziness	4	4	4	4		
Drug ineffective	9	9			9	9
Dry mouth	1	1	1	1		
Dysgeusia	1	1	1	1		
Dyspnoea	2	2	2	2		
Dysstasia	1	1	1	1		
Dysuria	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Epistaxis	2	2	2	2		
Erythema	1	1			1	1
Exposure during pregnancy	1	1	1	1		
Eye pain	1	1	1	1		
Fatigue	5	5	5	5		
Feeling abnormal	4	4	4	4		
Feeling cold	2	2	1	1	1	1
Feeling hot	1	1	1	1		
Gait disturbance	1	1	1	1		
Haematoma	1	1	1	1		
Headache	19	19	18	18	1	1
Heart rate increased	2	2	1	1	1	1
Helplessness	1	1			1	1
Herpes virus infection	2	2	2	2		
Hot flush	2	2	1	1	1	1
Hyperaesthesia	1	1			1	1
Hyperaesthesia teeth	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1	1	1		
Hypoaesthesia	2	2	1	1	1	1
Hypoaesthesia oral	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Inflammation	2	2	2	2		
Influenza like illness	3	3	3	3		
Initial insomnia	1	1	1	1		
Insomnia	2	2	2	2		
Iritis	1	1	1	1		
Joint range of motion decreased	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	4	4	4	4		
Maternal exposure during pregnancy	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Myalgia	11	11	10	10	1	1
Nausea	7	7	7	7		
Neck pain	3	3	2	2	1	1
Oedema	1	1	1	1		
Off label use	7	7	6	6	1	1
Oropharyngeal pain	2	2	2	2		
Oxygen saturation decreased	1	1			1	1
Pain	2	2	1	1	1	1
Painful respiration	1	1	1	1		
Pain in extremity	13	14	11	12	2	2
Pain of skin	1	1	1	1		
Pallor	2	2	1	1	1	1
Pancreatitis	1	1			1	1
Paraesthesia	1	1	1	1		
Paralysis	1	1			1	1
Paresis	1	1			1	1
Peripheral swelling	1	1	1	1		
Pneumonia	1	1			1	1
Presyncope	1	1	1	1		
Product use issue	7	7	6	6	1	1
Pulpitis dental		1		1		
Pyrexia	22	22	18	18	4	4
Retching	1	1	1	1		
Rhinorrhoea	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Sinusitis	1	1	1	1		
Somnolence	2	2	2	2		
Spinal pain	2	2	1	1	1	1
Suppressed lactation	2	2	1	1	1	1
Swelling	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	2	2			2	2
Taste disorder	2	2	2	2		
Therapeutic response unexpected	1	1	1	1		
Toothache		1		1		
Tremor	2	2	2	2		
Urticaria	1	1	1	1		
Vaccination site erythema	4	4	4	4		
Vaccination site extravasation	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site macule	1	1	1	1		
Vaccination site movement impairment	2	2	2	2		
Vaccination site pain	20	20	19	19	1	1
Vaccination site pruritus	4	4	4	4		
Vaccination site reaction	6	6	6	6		
Vaccination site swelling	4	4	4	4		
Vaccination site warmth	1	1	1	1		
Vision blurred	1	1	1	1		
Visual field defect	1	1	1	1		
Vomiting	4	4	4	4		
	327	333	271	277	56	56

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	6	6	6	6		
Asymptomatic COVID-19	1	1			1	1
Back pain	1	1	1	1		
Chills	2	2	2	2		
Cough	1	1	1	1		
COVID-19	3	3			3	3
Diarrhoea	1	1	1	1		
Disease recurrence	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	4	4			4	4
Fatigue	1	1	1	1		
Headache	6	7	6	7		
Herpes virus infection	1	1	1	1		
Herpes zoster	1	1	1	1		
Hypersensitivity	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Influenza like illness	1	1	1	1		
Lymphadenopathy	3	3	3	3		
Myalgia	4	4	4	4		
Nausea	2	2	2	2		
Pain	1	1	1	1		
Pain in extremity	2	2	2	2		
Paraparesis	1	1			1	1
Product use issue	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	6	7	6	7		
Rash	1	1	1	1		
Rash macular	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site infection	1	1	1	1		
Vaccination site pain	14	15	14	15		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site reaction	1	1	1	1		
Vaccination site scab	1	1	1	1		
Vaccination site vesicles	1	1	1	1		
	76	79	66	69	10	10

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety	1	1	1	1
Arthralgia	7	7	7	7
Asthenia	3	3	3	3
Axillary pain	1	1	1	1
Back pain	1	1	1	1
Burning sensation	1	1	1	1
Chills	3	3	3	3
Circumstance or information capable of leading to medication error	1	1	1	1
Cough	1	1	1	1
Crying	1	1	1	1
Diarrhoea	2	2	2	2
Dysgeusia	1	1	1	1
Ear pain	1	1	1	1
Exposure via breast milk	7	7	7	7
Hot flush	1	1	1	1
Hypoaesthesia	1	1	1	1
Hypoaesthesia oral	1	1	1	1
Incorrect route of product administration	1	1	1	1
Lymphadenopathy	1	1	1	1
Lymph node pain	1	1	1	1
Malaise	4	4	4	4
Myalgia	5	5	5	5
Nausea	1	1	1	1
Needle issue	1	1	1	1
Off label use	1	1	1	1
Oropharyngeal pain	1	1	1	1
Pain in extremity	2	2	2	2
Paresis	1	1	1	1
Poor quality sleep	1	1	1	1
Product label confusion	2	2	2	2
Pyrexia	5	5	5	5

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rash	1	1	1	1
Somnolence	1	1	1	1
Swelling	2	2	2	2
Throat irritation	1	1	1	1
Tonsillar hypertrophy	1	1	1	1
Vaccination site induration	1	1	1	1
Vaccination site pain	3	3	3	3
Vaccination site swelling	2	2	2	2
Vaccination site warmth	1	1	1	1
	74	74	74	74

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Country Where Event Occurred  
**PORTUGAL**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1			1	1
Abdominal pain	1	1			1	1
Allergy to vaccine	2	2			2	2
Amnesia	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Blood pressure increased	1	1			1	1
Body temperature increased	1	1	1	1		
Cardio-respiratory arrest	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	4	4	1	1	3	3
Circumoral oedema	1	1			1	1
Cough	2	2			2	2
COVID-19	6	6			6	6
Decreased appetite	1	1	1	1		
Dermatitis allergic	1	1			1	1
Drug ineffective	8	8			8	8
Dry eye	1	1	1	1		
Dysarthria	1	1	1	1		
Dysgeusia	1	1			1	1
Dysphagia	1	1			1	1
Eructation	1	1	1	1		
Erythema	4	4	1	1	3	3
Exophthalmos	1	1	1	1		
Exposure via breast milk	1	1	1	1		
Eye irritation	1	1	1	1		
Eye movement disorder	1	1			1	1
Eye pain	1	1	1	1		
Eye paraesthesia	1	1			1	1
Face oedema	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial paralysis	1	1
Fatigue	7	7
Feeling abnormal	1	1
Feeling hot	1	1
Flushing	2	2
Generalised tonic-clonic seizure	1	1
Headache	10	10
Hypersensitivity	1	1
Hypoaesthesia	1	1
Hypoaesthesia oral	4	4
Hypothyroidism	1	1
Incorrect route of product administration	2	2
Laryngeal oedema	2	2
Lip oedema	2	2
Lip pruritus	1	1
Localised oedema	1	1
Lymphadenitis	1	1
Lymphadenopathy	6	6
Maternal exposure during pregnancy	1	1
Migraine	2	2
Muscular weakness	1	1
Myalgia	11	11
Nasal obstruction	1	1
Nausea	7	7
Nystagmus	1	1
Ocular discomfort	1	1
Odynophagia	1	1
Off label use	2	2
Oropharyngeal discomfort	1	1
Oropharyngeal oedema	1	1
Overdose	4	4
Pain	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
5	5	2	2
1	1		
		1	1
		2	2
		1	1
7	7	3	3
		1	1
1	1		
1	1	3	3
		1	1
2	2		
		2	2
		2	2
		1	1
1	1		
1	1		
4	4	2	2
1	1		
2	2	2	2
1	1	1	1
6	6	5	5
		1	1
3	3	4	4
		1	1
1	1		
		1	1
2	2		
		1	1
		1	1
4	4		
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	1	1			1	1
Palmar-plantar erythrodysesthesia syndrome	1	1			1	1
Palpitations	1	1	1	1		
Paraesthesia	5	5	3	3	2	2
Paraesthesia oral	2	2			2	2
Peripheral coldness	1	1			1	1
Pharyngeal paraesthesia	1	1			1	1
Presyncope	3	3	2	2	1	1
Product use issue	2	2	2	2		
Pruritus	5	5	2	2	3	3
Pyrexia	4	4	1	1	3	3
Rash	5	5	2	2	3	3
Rash maculo-papular	1	1	1	1		
Rhinorrhoea	1	1			1	1
SARS-CoV-2 test positive	3	3			3	3
Scar	1	1	1	1		
Somnolence	2	2	2	2		
Stomatitis	1	1	1	1		
Tachycardia	1	1			1	1
Tachypnoea	1	1			1	1
Tenosynovitis	1	1	1	1		
Throat irritation	1	1	1	1		
Throat tightness	1	1			1	1
Thyroid function test abnormal	1	1	1	1		
Tongue dry	1	1			1	1
Tongue eruption	1	1			1	1
Tongue oedema	2	2			2	2
Tongue pruritus	1	1			1	1
Tremor	1	1	1	1		
Urticaria	1	1			1	1
Vaccination site erythema	2	2	2	2		
Vaccination site oedema	1	1			1	1

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	15	15	9	9	6	6
Vaccination site swelling	1	1	1	1		
Vertigo positional	1	1			1	1
Vomiting	1	1			1	1
Weight decreased	1	1	1	1		
	207	207	91	91	116	116

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Arthritis reactive	1	1			1	1
Balance disorder		1				1
Chills	1	1	1	1		
COVID-19	3	3			3	3
Death	2	2			2	2
Dizziness		1				1
Drug ineffective	3	3			3	3
Embolism	1	1			1	1
Erythema		1				1
Exposure via breast milk		1		1		
Eyelid oedema	1	1			1	1
Functional gastrointestinal disorder	1	1			1	1
Headache	2	3	1	2	1	1
Hyperhidrosis	1	1			1	1
Hypersensitivity		1				1
Hypoaesthesia oral	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Intercostal neuralgia	1	1	1	1		
Lymphadenopathy	1	1			1	1
Malaise	2	3	1	1	1	2
Myalgia	5	5	4	4	1	1
Nausea		1				1
Odynophagia	1	2		1	1	1
Off label use	1	1	1	1		
Oropharyngeal pain	1	1			1	1
Pallor	2	2	1	1	1	1
Pharyngeal hypoaesthesia	1	1			1	1
Productive cough	1	1			1	1
Pruritus		1				1
Pyrexia	4	4	3	3	1	1
Rash		1				1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory tract congestion	1	1			1	1
Rhinorrhoea	1	1			1	1
Sinus tachycardia		1				1
Somnolence	2	2			2	2
Tachycardia	2	2	1	1	1	1
Throat irritation	1	1	1	1		
Upper-airway cough syndrome	1	1			1	1
Urticaria	1	1	1	1		
Vaccination site discomfort	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	6	6	6	6		
Vaccination site pruritus		1				1
	56	69	26	29	30	40

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**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain upper	1	1	1	1		
Asthenia	1	1	1	1		
Chest pain	2	2	1	1	1	1
Chills	1	1	1	1		
COVID-19	6	6			6	6
Decreased appetite	1	1	1	1		
Diarrhoea	2	2	2	2		
Dizziness	2	2	2	2		
Drug ineffective	7	7			7	7
Dysgeusia	1	1	1	1		
Eructation	1	1	1	1		
Erythema	3	3	2	2	1	1
Exposure via breast milk	2	2	2	2		
Face oedema	3	3	1	1	2	2
Headache	7	7	6	6	1	1
Hyperglycaemia	1	1			1	1
Hypersensitivity	5	5	4	4	1	1
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1			1	1
Laryngeal oedema	2	2			2	2
Lip oedema	2	2			2	2
Malaise	4	4	4	4		
Migraine	2	2	1	1	1	1
Myalgia	4	4	4	4		
Nausea	4	4	4	4		
Odynophagia	1	1			1	1
Oral disorder	1	1			1	1
Oropharyngeal oedema	1	1	1	1		
Pain in extremity	1	1	1	1		
Pain in jaw	1	1			1	1
Pallor	1	1	1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Paraesthesia	1	1			1	1
Paraesthesia oral	2	2	1	1	1	1
Presyncope	1	1	1	1		
Productive cough	1	1			1	1
Pruritus	1	1			1	1
Pyrexia	4	4	4	4		
Rash	6	6	5	5	1	1
Rash maculo-papular	1	1	1	1		
Rash pruritic	2	2	2	2		
Rhinorrhoea	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
Sensory loss	1	1			1	1
Somnolence	2	2	1	1	1	1
Stomatitis	1	1	1	1		
Tachycardia	2	2	2	2		
Taste disorder	2	2	2	2		
Throat irritation	1	1	1	1		
Tongue disorder	1	1	1	1		
Tongue oedema	1	1			1	1
Tremor	1	1	1	1		
Urticaria	1	1			1	1
Urticaria cholinergic	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1			1	1
Vaccination site pain	17	17	16	16	1	1
Vaccination site swelling	1	1	1	1		
Vomiting	2	2	1	1	1	1
	130	130	87	87	43	43

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Country Where Event Occurred  
**PUERTO RICO**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain		1		1		
Arthralgia	1	2	1	2		
Asthenia		1		1		
Axillary pain	1	1	1	1		
Bone disorder	1	1	1	1		
Bone pain	1	1	1	1		
Burning sensation	2	2	2	2		
Chills	2	2	2	2		
Decreased appetite		1		1		
Diarrhoea	1	2	1	2		
Dyskinesia	1	1			1	1
Dysphonia		1		1		
Erythema	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	2	3	2	3		
Gingival bleeding	1	1	1	1		
Haematoma	1	1	1	1		
Headache	4	8	4	8		
Heart rate decreased	1	1			1	1
Hypoaesthesia	1	4	1	4		
Inappropriate schedule of product administration	1	1	1	1		
Inflammation		1		1		
Joint range of motion decreased		1		1		
Lymphadenopathy	1	1	1	1		
Malaise		1		1		
Maternal exposure during pregnancy	1	1	1	1		
Migraine	1	1			1	1
Movement disorder	1	1	1	1		
Myalgia	1	1	1	1		
Nausea		3		3		
Neck pain	1	1	1	1		
Night sweats	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nodule		1		1		
Off label use	1	1	1	1		
Pain		2		2		
Pain in extremity	2	5	2	5		
Palpitations		1		1		
Paraesthesia		1		1		
Pruritus	1	1	1	1		
Pyrexia	2	4	2	4		
Sinus arrhythmia	1	1			1	1
Speech disorder		1		1		
Swelling face		1		1		
Taste disorder		1		1		
Vaccination site discomfort		1		1		
Vaccination site erythema	1	1	1	1		
Vaccination site induration		1		1		
Vaccination site inflammation	1	1	1	1		
Vaccination site pain	1	4	1	4		
Vaccination site swelling	1	2	1	2		
	41	80	35	74	6	6

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Abdominal discomfort	1	1	1	1
Arthralgia		1		1
Chills	1	1	1	1
Depression	1	1	1	1
Fatigue	3	3	3	3
Gait disturbance		1		1
Headache	1	1	1	1
Head discomfort	1	1	1	1
Hypertension		1		1
Limb discomfort		1		1
Muscle spasms	1	1	1	1
Musculoskeletal stiffness		1		1
Neuralgia		1		1
Pain	1	1	1	1
Paraesthesia	1	1	1	1
Pyrexia	2	2	2	2
Rash	1	1	1	1
Respiratory rate decreased	1	1	1	1
Tachycardia		1		1
	15	22	15	22

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Pyrexia	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**QATAR**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Dizziness		1		1
Erythema		1		1
Nausea		1		1
		3		3

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Myalgia		1		1
Overdose	1	1	1	1
Product preparation error	1	1	1	1
	2	3	2	3

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Country Where Event Occurred  
**ROMANIA**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Anaphylactoid reaction	1	1			1	1
Angle closure glaucoma	1	1			1	1
Anosmia	1	1	1	1		
Anxiety	3	3	1	1	2	2
Arthralgia	7	7	5	5	2	2
Asthenia	8	8	7	7	1	1
Axillary pain	1	1	1	1		
Balance disorder	1	1			1	1
Breast pain	1	1	1	1		
Chest discomfort	2	2	2	2		
Chest pain	1	1			1	1
Chills	13	14	11	12	2	2
Cough	2	2			2	2
COVID-19	6	6			6	6
Crying	1	1	1	1		
Decreased appetite	1	1	1	1		
Dizziness	3	3	3	3		
Drug ineffective	8	8			8	8
Dry mouth	1	1			1	1
Dysgeusia	1	1			1	1
Dysphagia	1	1			1	1
Dysphonia	1	1	1	1		
Dyspnoea	2	2			2	2
Emotional distress	1	1	1	1		
Epiglottic oedema	1	1			1	1
Erythema	3	4	2	3	1	1
Erythema nodosum	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Facial paralysis	3	3			3	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fatigue	11	11
Fear	1	1
Feeling cold	1	1
Feeling hot	1	1
Flushing	1	1
General physical health deterioration		1
Headache	17	18
Hyperhidrosis	2	2
Hypersensitivity	1	1
Hypertension	5	5
Hypertensive crisis	1	1
Hypoaesthesia	1	1
Hypocalcaemia	1	1
Inflammation	1	1
Injected limb mobility decreased	2	2
Joint ankylosis	1	1
Laryngeal oedema	1	1
Limb injury	1	1
Lip oedema	3	3
Lip swelling	1	1
Lymphadenopathy	5	5
Malaise	3	3
Maternal exposure during pregnancy	1	1
Migraine	2	2
Muscle contractions involuntary	1	1
Myalgia	17	18
Nasal discomfort	1	1
Nasal oedema	1	1
Nausea	10	10
Nystagmus	1	1
Odynophagia	1	1
Oedema peripheral	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
9	9	2	2
1	1		
		1	1
		1	1
1	1		
	1		
14	15	3	3
1	1	1	1
1	1		
		5	5
		1	1
		1	1
		1	1
1	1		
2	2		
		1	1
		1	1
		1	1
5	5		
3	3		
1	1		
1	1	1	1
1	1		
2	2	1	1
		1	1
5	5		
3	3		
1	1		
1	1	1	1
1	1		
15	16	2	2
1	1		
		1	1
8	8	2	2
1	1		
1	1		
		1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Off label use	1	1	1	1		
Oropharyngeal discomfort	1	1			1	1
Pain	5	5	5	5		
Pain in extremity	12	16	11	15	1	1
Palpitations	2	2			2	2
Paraesthesia	2	2	1	1	1	1
Paraesthesia oral	1	1	1	1		
Peripheral coldness	1	1	1	1		
Presyncope	2	2	2	2		
Product use issue	1	1	1	1		
Pruritus	4	4	3	3	1	1
Pyrexia	15	15	15	15		
Rash	5	5	5	5		
Rash erythematous	2	2			2	2
Rash pruritic	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Scar pain	1	1	1	1		
Seizure	1	1			1	1
Somnolence	3	3	3	3		
Spinal pain	1	1	1	1		
Suppressed lactation	1	1	1	1		
Suspected COVID-19	1	1			1	1
Systolic hypertension	1	1			1	1
Tachycardia	5	5	2	2	3	3
Thirst	1	1			1	1
Tongue oedema	1	1			1	1
Tremor	1	1			1	1
Urticaria	1	1	1	1		
Urticaria papular	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site induration	2	2	2	2		
Vaccination site lymphadenopathy	2	2	2	2		

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
		1	1
5	5		
11	15	1	1
		2	2
1	1	1	1
1	1		
1	1		
2	2		
1	1		
3	3	1	1
15	15		
5	5		
		2	2
1	1		
		1	1
1	1		
3	3		
1	1		
1	1		
		1	1
		1	1
2	2	3	3
		1	1
		1	1
		1	1
1	1		
1	1		
2	2		
2	2		
2	2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site movement impairment	3	3	3	3		
Vaccination site pain	20	21	20	21		
Vaccination site pruritus	1	1	1	1		
Vaccination site reaction	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Ventricular extrasystoles	1	1	1	1		
Vertigo	2	2	1	1	1	1
Vestibular disorder	1	1	1	1		
Vomiting	3	3	2	2	1	1
Wrong technique in product usage process	1	1	1	1		
	292	302	205	215	87	87

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1			1	1
Allergy to vaccine	1	1	1	1		
Angina pectoris	1	1			1	1
Anosmia	1	1			1	1
Anxiety	3	3	3	3		
Arthralgia	2	2	2	2		
Asthenia	2	2	2	2		
Back pain	2	2	2	2		
Blood pressure increased		1		1		
Body temperature abnormal	1	1	1	1		
Body temperature increased	1	1	1	1		
Chills	6	6	6	6		
COVID-19	4	4			4	4
Diarrhoea	1	1	1	1		
Disturbance in attention	1	1	1	1		
Dizziness	4	4	4	4		
Drug administered in wrong device	1	1	1	1		
Drug ineffective	6	6			6	6
Ear pain	1	1	1	1		
Erythema	3	3	3	3		
Eyelid oedema	1	1	1	1		
Facial pain	1	1	1	1		
Fatigue	6	6	6	6		
Feeling abnormal	1	1	1	1		
Headache	11	11	11	11		
Horner's syndrome	1	1			1	1
Hyperhidrosis	2	2	2	2		
Hypersensitivity	1	1	1	1		
Hyperthermia	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Insomnia	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphadenopathy	2	2	2	2		
Malaise	1	1	1	1		
Medication error	1	1	1	1		
Muscle swelling	1	1	1	1		
Muscular weakness	2	2	2	2		
Myalgia	6	6	6	6		
Nausea	2	2	2	2		
Oedema	1	1	1	1		
Off label use	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	3	5	3	5		
Panic attack	1	2	1	2		
Paraesthesia	5	5	5	5		
Paraesthesia ear	1	1	1	1		
Presyncope	1	1	1	1		
Product preparation issue	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus	1	1	1	1		
Pyrexia	8	8	8	8		
Rash	2	2	2	2		
SARS-CoV-2 test positive	2	2			2	2
Skin discolouration	1	1	1	1		
Somnolence	1	1	1	1		
Syncope	1	1			1	1
Transaminases increased	1	1	1	1		
Tremor	1	1	1	1		
Urticaria	1	2	1	2		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	14	14	14	14		
Vertigo	1	1	1	1		
Wrong technique in product usage process	2	2	2	2		
	138	143	121	126	17	17

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	5	5	5	5		
Blood pressure abnormal	1	1	1	1		
Chills	1	1	1	1		
Circumstance or information capable of leading to medication error	3	3	3	3		
Cough	1	1	1	1		
COVID-19	1	1			1	1
Drug ineffective	5	5			5	5
Erythema	3	3	3	3		
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Headache	3	3	3	3		
Heart rate increased	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Injected limb mobility decreased	1	1	1	1		
Intercepted medication error	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	1	1	1	1		
Medication error	2	2	2	2		
Myalgia	2	2	2	2		
Nausea	1	1	1	1		
Off label use	1	1	1	1		
Pain	1	1	1	1		
Pain in extremity	6	6	6	6		
Paraesthesia	1	1	1	1		
Product preparation error	7	11	7	11		
Product preparation issue	4	5	4	5		
Product quality issue		1		1		
Pyrexia	9	9	9	9		
SARS-CoV-2 test negative	1	1	1	1		
SARS-CoV-2 test positive	4	4			4	4

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Underdose	1	1	1	1		
Vaccination site discomfort	3	3	3	3		
Vaccination site erythema	12	12	12	12		
Vaccination site inflammation	1	1	1	1		
Vaccination site nodule	1	1	1	1		
Vaccination site pain	15	16	15	16		
Vaccination site warmth	1	1	1	1		
Wrong technique in product usage process	9	10	9	10		
	115	123	105	113	10	10

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Country Where Event Occurred  
**SAUDI ARABIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Chills	1	1	1	1
Headache	1	1	1	1
Hyperhidrosis	1	1	1	1
Lymphadenopathy	1	1	1	1
Mouth ulceration	1	1	1	1
Movement disorder	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Myalgia	1	1	1	1
Pain of skin	1	1	1	1
Pyrexia	1	1	1	1
Vaginal infection	1	1	1	1
	11	11	11	11

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Arthralgia	1	1	1	1		
Dizziness	1	1	1	1		
Fatigue	3	3	3	3		
Headache	1	1	1	1		
Herpes zoster	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypotension	1	1			1	1
Malaise	1	1	1	1		
Myalgia	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Pain	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pollakiuria	1	1	1	1		
Pyrexia	1	1	1	1		
Rhinorrhoea	1	1	1	1		
Syncope	1	1			1	1
Vaccination site pain	2	2	2	2		
	21	21	19	19	2	2

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Pain in extremity	1	1	1	1
	2	2	2	2

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Country Where Event Occurred  
**SERBIA**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	1	1	1	1		
Anaphylactoid reaction	1	1			1	1
Anosmia	1	1	1	1		
Anxiety	1	1	1	1		
Arthralgia	3	3	3	3		
Asphyxia	1	1			1	1
Asthenia	3	3	3	3		
Axillary pain	1	1	1	1		
Blood pressure increased	1	1	1	1		
Body temperature increased	1	1	1	1		
Bone pain	1	1	1	1		
Chest pain	1	1	1	1		
Chills	2	2	2	2		
Cough	1	1			1	1
Dizziness	1	1	1	1		
Dry mouth	1	1	1	1		
Erythema	3	3	3	3		
Fall	1	1	1	1		
Fatigue	2	2	2	2		
Fear of death	1	1	1	1		
Headache	2	2	2	2		
Huntington's disease	1	1			1	1
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1			1	1
Hypertension	2	2	1	1	1	1
Inflammatory marker increased	1	1	1	1		
Influenza like illness	1	1	1	1		
Malaise	2	2	2	2		
Muscular weakness	1	1	1	1		
Myalgia	4	4	4	4		
Nausea	1	1	1	1		
Oropharyngeal pain	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in extremity	2	2	2	2		
Palpitations	1	1	1	1		
Paraesthesia	1	1	1	1		
Pyrexia	11	11	11	11		
Rash	1	1			1	1
Rash macular	1	1			1	1
Sleep disorder	1	1	1	1		
Swelling of eyelid	1	1	1	1		
Tachycardia	1	1			1	1
Tinnitus	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site induration	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	6	6	6	6		
Vaccination site swelling	1	1	1	1		
	77	77	68	68	9	9

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abscess	1	1			1	1
Asthenia	1	1	1	1		
Body temperature increased	2	2	1	1	1	1
Bone pain	1	1	1	1		
Chest discomfort	1	1	1	1		
Chills	1	1			1	1
Confusional state	1	1	1	1		
Diarrhoea	1	1	1	1		
Fatigue	2	2	2	2		
Headache	2	2	2	2		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1	1	1		
Intraocular pressure increased	1	1			1	1
Loss of consciousness	1	1			1	1
Lymphadenopathy	2	2	1	1	1	1
Malaise	1	1	1	1		
Monocyte count increased	1	1	1	1		
Muscular weakness	1	1	1	1		
Myalgia	1	1	1	1		
Nausea	5	5	5	5		
Pain in extremity	2	2	2	2		
Pain in jaw	1	1	1	1		
Peripheral swelling	1	1			1	1
Phlebitis	1	1			1	1
Pyrexia	6	6	5	5	1	1
Rash	1	1	1	1		
Skin reaction	1	1			1	1
Urticaria	1	1	1	1		
Vaccination site haematoma	1	1			1	1
Vaccination site pain	5	5	5	5		
Vomiting	2	2	2	2		
	50	50	39	39	11	11

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Country Where Event Occurred  
**SINGAPORE**

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	5	5			5	5
Chills	1	1	1	1		
Eye swelling	1	1	1	1		
Pyrexia	1	1	1	1		
Urticaria	1	1	1	1		
	9	9	4	4	5	5

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Country Where Event Occurred  
**SLOVAKIA**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenia	1	1	1	1		
Blood pressure increased	1	1	1	1		
Body temperature increased	1	1	1	1		
Burning sensation	1	1	1	1		
Chills	5	5	5	5		
Cough	2	2	2	2		
COVID-19	3	3			3	3
Diplopia	1	1	1	1		
Dizziness	2	2	2	2		
Drug ineffective	5	5			5	5
Dyspnoea	1	1	1	1		
Fatigue	1	1	1	1		
Headache	4	4	4	4		
Hyperhidrosis	1	1	1	1		
Hypertension	2	2	2	2		
Hypoaesthesia	1	1	1	1		
Lymphadenopathy	1	1	1	1		
Maternal exposure during pregnancy	1	1	1	1		
Myalgia	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	4	4	4	4		
Palpitations	1	1	1	1		
Pyrexia	4	4	4	4		
Rhinitis	1	1	1	1		
SARS-CoV-2 ant body test positive	1	1			1	1
SARS-CoV-2 test positive	2	2			2	2
Syncope	1	1			1	1
Tachycardia	1	1	1	1		
Throat irritation	1	1	1	1		
Throat tightness	1	1	1	1		
Vaccination site joint movement impairment	1	1	1	1		
Vaccination site pain	4	4	4	4		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vomiting	1	1	1	1		
	59	59	47	47	12	12

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chills	1	1	1	1		
Drug ineffective	1	1			1	1
Pain in extremity	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Rash	1	1	1	1		
Rash pruritic	1	1	1	1		
SARS-CoV-2 test positive	1	1			1	1
Vaccination site pain	1	1	1	1		
Vaccination site urticaria	1	1	1	1		
	9	9	7	7	2	2

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Body temperature	1	1	1	1
Chills	1	1	1	1
Erythema	1	1	1	1
Headache	1	1	1	1
Paraesthesia	1	1	1	1
Pruritus	1	1	1	1
Vaccination site pain	1	1	1	1
Vaccination site swelling	1	1	1	1
	8	8	8	8

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Country Where Event Occurred  
**SLOVENIA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Administration site pain	1	1	1	1		
Asthenia	2	2	2	2		
Disease recurrence	1	1			1	1
Fatigue	1	1	1	1		
Hypertension	1	1			1	1
Nausea	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vertigo	1	1			1	1
Vomiting	1	1			1	1
White blood cell count increased	1	1	1	1		
	13	13	7	7	6	6

Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Sudden death	1	1	1	1
	1	1	1	1

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Wrong technique in product usage process	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**SPAIN**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	3	3	2	2	1	1
Abdominal pain upper	1	1	1	1		
Acute respiratory failure	3	3			3	3
Anaphylactic reaction	1	2			1	2
Anaphylactic shock	2	2			2	2
Angioedema	1	1			1	1
Angular cheilitis	1	1	1	1		
Anxiety	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Arthralgia	6	6	5	5	1	1
Asthenia	3	3	3	3		
Balance disorder	1	1	1	1		
Body temperature increased	1	1	1	1		
Burning sensation mucosal	1	1	1	1		
Cardio-respiratory distress	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	2	2	1	1	1	1
Chills	7	7	7	7		
Circumoral swelling	1	1	1	1		
Cough	2	2	2	2		
COVID-19	3	3			3	3
Death	1	1			1	1
Depressed mood	1	1	1	1		
Diarrhoea	10	10	9	9	1	1
Discomfort	3	3	3	3		
Dizziness	9	9	8	8	1	1
Drug ineffective	3	3			3	3
Drug interaction	1	1	1	1		
Dry mouth	1	1	1	1		
Dry throat	1	1	1	1		
Dysgeusia	3	3	2	2	1	1
Dysphagia	1	1			1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	5	5			5	5
Erythema	3	3	3	3		
Euphoric mood	1	1	1	1		
Exposure during pregnancy	1	1	1	1		
Eye pruritus	1	1	1	1		
Facial paralysis	1	1			1	1
Fatigue	5	5	4	4	1	1
Feeling cold	1	1			1	1
Feeling drunk	1	1	1	1		
Feeling hot	1	1	1	1		
Flatulence	1	1			1	1
Formication	1	1	1	1		
Glossitis	1	1			1	1
Haematoma muscle	1	1			1	1
Headache	25	25	21	21	4	4
Hyperglycaemia	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1			1	1
Hypoaesthesia	1	1	1	1		
Hypoaesthesia oral	1	1	1	1		
Hypotension	3	3	1	1	2	2
Immunisation reaction	1	1	1	1		
Incorrect route of product administration	1	1	1	1		
Insulin resistance	1	1	1	1		
Jaw disorder	1	1	1	1		
Joint contracture	1	1	1	1		
Joint range of motion decreased	1	1			1	1
Laryngeal oedema	2	2			2	2
Lip oedema	1	1	1	1		
Lip pruritus	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	10	10	8	8	2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	2	2	1	1	1	1
Mobility decreased	1	1			1	1
Movement disorder	1	1	1	1		
Multiple organ dysfunction syndrome	1	1			1	1
Muscle tightness	1	1	1	1		
Muscular weakness	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	2	2	1	1	1	1
Myalgia	14	14	14	14		
Nasal congestion	2	2	2	2		
Nausea	11	11	9	9	2	2
Neck pain	1	1			1	1
Nervousness	1	1	1	1		
Off label use	2	2	2	2		
Oral discomfort	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Overdose	1	1	1	1		
Pain	2	2	2	2		
Pain in extremity	7	7	5	5	2	2
Palatal oedema	1	1			1	1
Palpitations	3	3	2	2	1	1
Paraesthesia	4	4	4	4		
Paraesthesia oral	1	1	1	1		
Pelvic pain	1	1	1	1		
Periorbital oedema	1	1	1	1		
Peripheral ischaemia	1	1			1	1
Peripheral swelling	2	2	1	1	1	1
Product use issue	2	2	2	2		
Pruritus	5	5	4	4	1	1
Psychomotor hyperactivity	1	1	1	1		
Pyrexia	36	36	34	34	2	2
Rash	6	6	6	6		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash pruritic	1	1			1	1
Rectal haemorrhage	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory distress	1	1			1	1
Rhinitis	1	1	1	1		
Rhinorrhoea	2	2	2	2		
Sensory loss	1	1	1	1		
Skin lesion	1	1	1	1		
Somnolence	4	4	4	4		
Stomatitis	3	3	2	2	1	1
Sudden death	3	3			3	3
Tachycardia	1	1	1	1		
Temperature regulation disorder	2	2	2	2		
Tension headache	1	1	1	1		
Throat irritation	3	3	3	3		
Tongue discomfort	1	1	1	1		
Tongue eruption	1	1	1	1		
Tongue oedema	1	1	1	1		
Tongue pruritus	2	2	1	1	1	1
Tongue ulceration	1	1	1	1		
Troponin T increased	1	1			1	1
Urinary tract infection	1	1	1	1		
Urticaria	2	2	1	1	1	1
Vaccination complication	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site inflammation	7	7	6	6	1	1
Vaccination site joint erythema	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	24	24	23	23	1	1
Vaccination site swelling	2	2	2	2		
Vaccination site warmth	1	1	1	1		

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		1	1
		1	1
		1	1
1	1		
2	2		
1	1		
1	1		
4	4		
2	2	1	1
		3	3
1	1		
2	2		
1	1		
3	3		
1	1		
1	1		
1	1		
1	1		
2	2	1	1
1	1		
		1	1
1	1		
2	2	1	1
1	1		
1	1		
7	7	1	1
1	1		
1	1		
24	24	1	1
2	2		
1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaginal haemorrhage	1	1	1	1		
Vomiting	7	7	6	6	1	1
Wrong technique in product usage process	1	1	1	1		
	357	358	281	281	76	77

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Anaphylactic shock	1	1			1	1
Aspiration	1	1			1	1
Back pain	1	1	1	1		
Blood pressure increased	1	1			1	1
Bruxism	1	1	1	1		
Chest pain	1	1			1	1
Chills	1	1	1	1		
Confusional state	1	1			1	1
COVID-19	1	1			1	1
Depressed mood	1	1	1	1		
Diarrhoea	4	4	4	4		
Dizziness	2	2	1	1	1	1
Drug ineffective	2	2			2	2
Dry mouth	1	1			1	1
Dysarthria	1	1	1	1		
Dyspnoea	2	2			2	2
Face oedema	1	1			1	1
Fatigue	2	2	1	1	1	1
Feeling abnormal	1	1	1	1		
Formication	1	1	1	1		
Headache	8	8	7	7	1	1
Hypotension	1	1	1	1		
Hypoxia	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Influenza like illness	1	1	1	1		
Intestinal ischaemia	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	5	5	4	4	1	1
Muscle contractions involuntary	1	1	1	1		
Muscle contracture	1	1	1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Myoclonus	1	1			1	1
Nasopharyngitis	1	1	1	1		
Pain	2	2	2	2		
Palpitations	1	1			1	1
Paraesthesia	3	3	3	3		
Pneumonia	1	1			1	1
Presyncope	1	1			1	1
Pruritus	1	1			1	1
Pyrexia	9	9	8	8	1	1
Rash	1	1	1	1		
Respiratory failure	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
Sepsis	1	1			1	1
Speech disorder	1	1			1	1
Tachycardia	1	1			1	1
Tension headache	1	1	1	1		
Vaccination complication	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vomiting	1	1	1	1		
	82	82	51	51	31	31

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
COVID-19	2	2			2	2
Diarrhoea	1	2	1	2		
Drug ineffective	2	2			2	2
Exposure via breast milk	1	1	1	1		
Petechiae	1	1	1	1		
SARS-CoV-2 test positive	1	1	1	1		
Underdose	1	1	1	1		
Vomiting		1		1		
	9	11	5	7	4	4

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Country Where Event Occurred  
**SWEDEN**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Abdominal pain	2	2	2	2		
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Arthralgia	4	4	3	3	1	1
Asthenia	1	1	1	1		
Axillary pain	1	1	1	1		
Blood pressure abnormal	1	1			1	1
Blood pressure fluctuation	1	1			1	1
Cardiac arrest	1	1			1	1
Cardiac disorder	1	1			1	1
Chills	9	9	8	8	1	1
Cough	1	1	1	1		
COVID-19	1	1			1	1
Crepitations	1	1	1	1		
Death	6	6			6	6
Dehydration	1	1			1	1
Diarrhoea	3	3	3	3		
Dizziness	2	2	1	1	1	1
Drug ineffective	1	1			1	1
Dyspnoea	4	4			4	4
Epistaxis	1	1	1	1		
Erysipelas	1	1			1	1
Erythema	1	1	1	1		
Facial paresis	1	1			1	1
Fatigue	7	7	6	6	1	1
Feeling abnormal	2	2	2	2		
Feeling hot	1	1	1	1		
Fibromyalgia	1	1			1	1
Formication	1	1	1	1		
General physical health deterioration	4	4	1	1	3	3

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hallucination, visual	1	1			1	1
Headache	14	14	13	13	1	1
Heart rate increased	1	1			1	1
Hypertension	1	1			1	1
Hypoaesthesia	2	2	1	1	1	1
Hypoaesthesia oral	1	1	1	1		
Hypotension	1	1			1	1
Infection	1	1			1	1
Injected limb mobility decreased	1	1	1	1		
Ischaemic stroke	2	2			2	2
Joint range of motion decreased	1	1	1	1		
Lip swelling	1	1			1	1
Lymphadenopathy	1	1			1	1
Malaise	1	1	1	1		
Memory impairment	1	1			1	1
Migraine	2	2	2	2		
Muscular weakness	1	1	1	1		
Myalgia	7	7	6	6	1	1
Myocardial infarction	1	1			1	1
Nausea	7	7	6	6	1	1
Neck pain	1	1	1	1		
Oral pruritus	1	1			1	1
Oropharyngeal pain	1	1	1	1		
Oropharyngeal spasm	1	1			1	1
Oxygen saturation decreased	1	1	1	1		
Pain	3	3	2	2	1	1
Pain in extremity	8	8	8	8		
Palpitations	3	3	3	3		
Paraesthesia	3	3	2	2	1	1
Paraesthesia oral	1	1	1	1		
Peripheral coldness	1	1	1	1		
Pharyngeal swelling	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pharyngitis	1	1	1	1		
Poor quality product administered	5	5	5	5		
Post viral fatigue syndrome	1	1	1	1		
Product administered at inappropriate site	1	1	1	1		
Product colour issue	5	5	5	5		
Pulmonary oedema	1	1			1	1
Pulse abnormal	1	1			1	1
Pyrexia	11	11	8	8	3	3
Respiratory rate increased	1	1			1	1
Sensation of foreign body	1	1			1	1
Sepsis	1	1			1	1
Skin ulcer	1	1			1	1
Sleep talking	1	1			1	1
Sudden death	2	2			2	2
Swelling	1	1	1	1		
Swelling face	2	2	2	2		
Throat irritation	1	1			1	1
Throat tightness	1	1			1	1
Tongue pruritus	1	1			1	1
Underdose	1	1	1	1		
Upper respiratory tract congestion	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site erythema	3	3	2	2	1	1
Vaccination site hypoaesthesia	1	1	1	1		
Vaccination site pain	7	7	6	6	1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	4	4	3	3	1	1
Vaccination site warmth	3	3	2	2	1	1
Vertigo positional	1	1	1	1		
Vomiting	1	1	1	1		
	201	201	134	134	67	67

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1	1	1		
Acute kidney injury	1	1			1	1
Anxiety	1	1			1	1
Blood pressure decreased	1	1	1	1		
Blood pressure diastolic decreased	1	1	1	1		
Cardiac arrest	2	3			2	3
Cardiac failure	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chronic obstructive pulmonary disease	2	2			2	2
Circulatory collapse	1	1			1	1
Confusional state	1	1			1	1
Cough	2	2			2	2
C-reactive protein increased	1	1			1	1
Death	4	4			4	4
Depressed level of consciousness	1	1			1	1
Dermatitis	1	1	1	1		
Diarrhoea	3	3	1	1	2	2
Dizziness	1	1	1	1		
Dyspnoea	3	3			3	3
Dysstasia	1	1	1	1		
Escherichia sepsis	1	1			1	1
Fatigue	4	4	2	2	2	2
General physical health deterioration	1	1			1	1
Hypotension	1	1			1	1
Infection	2	2			2	2
Insomnia	2	2	2	2		
Loss of consciousness	1	1			1	1
Myalgia	1	1			1	1
Nausea	1	1	1	1		
Oropharyngeal pain	1	1			1	1
Oxygen saturation decreased	1	1	1	1		
Pain in extremity	3	3	3	3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	1	1			1	1
Pneumonia bacterial	1	1			1	1
Poor quality product administered	2	2	2	2		
Product colour issue	2	2	2	2		
Productive cough	2	2			2	2
Pruritus	1	1			1	1
Pulmonary oedema	1	1			1	1
Pyrexia	4	4	1	1	3	3
Respiratory distress	2	2			2	2
Rhinorrhoea	1	1	1	1		
Sudden death	1	1			1	1
Systemic inflammatory response syndrome	1	1			1	1
Tachycardia	1	1			1	1
Tachypnoea	1	1	1	1		
Underdose	1	1	1	1		
Upper respiratory tract infection	1	1			1	1
Urinary tract infection	1	1			1	1
Urosepsis	2	2			2	2
Vomiting	1	1	1	1		
Wheezing	1	1	1	1		
	77	78	26	26	51	52

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Circumstance or information capable of leading to medication error	29	29	29	29
Myalgia	2	2	2	2
Poor quality product administered	28	28	28	28
Product colour issue	29	29	29	29
Pyrexia	2	2	2	2
	90	90	90	90

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Country Where Event Occurred  
**SWITZERLAND**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Dizziness	1	1	1	1		
Fatigue	1	1	1	1		
Pneumonia	1	1			1	1
Respiratory failure	1	1			1	1
Vaccination site pain	2	2	2	2		
	7	7	4	4	3	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Anal haemorrhage	1	1	1	1		
Asthenia	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure decreased	2	2	1	1	1	1
Chills	1	1	1	1		
Coma	1	1			1	1
C-reactive protein increased	1	1			1	1
Death	1	1			1	1
Fatigue	1	1	1	1		
Feeling cold	1	1	1	1		
Gastric disorder	1	1	1	1		
General physical health deterioration	2	2			2	2
Heart rate decreased	1	1			1	1
Heart rate increased	1	1	1	1		
Malaise	1	1	1	1		
Myalgia	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pain in extremity	1	1	1	1		
Pyrexia	1	1	1	1		
Restlessness	1	1	1	1		
Skin lesion	1	1	1	1		
Somnolence	1	1			1	1
Tachypnoea	1	1			1	1
Urethral pain	1	1	1	1		
Vaccination site pain	1	1	1	1		
	29	29	19	19	10	10

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Death	2	2			2	2
Dysgeusia	1	1	1	1		
Nausea	1	1	1	1		
	4	4	2	2	2	2

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Country Where Event Occurred  
**UNITED ARAB EMIRATES**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chest pain	1	1			1	1
Depressed level of consciousness	1	1			1	1
Depressed mood	1	1			1	1
Dizziness	1	1			1	1
Facial paralysis	1	1			1	1
Headache	1	1			1	1
Hypertension	1	1			1	1
Hypoacusis	1	1			1	1
Hypoaesthesia	1	1			1	1
Nausea	1	1			1	1
Off label use		1		1		
Product use issue		1		1		
Vaccination site pain	1	1	1	1		
	11	13	1	3	10	10

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
COVID-19	1	1			1	1
Diarrhoea	1	1	1	1		
Drug ineffective	1	1			1	1
Erectile dysfunction	1	1			1	1
Fatigue	1	1	1	1		
Headache	1	1	1	1		
Hypertension	1	1	1	1		
Pyrexia	2	2	2	2		
Vaccination site pain	1	1	1	1		
	11	11	8	8	3	3

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Country Where Event Occurred  
**UNITED KINGDOM**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	14	16			4	6	10	10
Abdominal distension	6	8			2	3	4	5
Abdominal pain	41	52			17	26	24	26
Abdominal pain lower	3	3			2	2	1	1
Abdominal pain upper	51	64			16	24	35	40
Abdominal tenderness	3	4			1	2	2	2
Abnormal dreams	6	8			4	6	2	2
Abnormal faeces		1				1		
Abnormal sensation in eye	2	2			1	1	1	1
Abortion spontaneous	2	2					2	2
Accidental overdose	1	1			1	1		
Acidosis	1	1			1	1		
Acute kidney injury	2	2					2	2
Acute myocardial infarction	1	3					1	3
Acute respiratory failure	1	1					1	1
Adverse drug reaction	2	2					2	2
Aerophagia	1	1					1	1
African trypanosomiasis	1	1					1	1
Age-related macular degeneration	1	1					1	1
Ageusia	17	22			5	9	12	13
Agitation	6	6			2	2	4	4
Alanine aminotransferase increased	3	3			1	1	2	2
Alcohol interaction		1						1
Allergic cough	1	1					1	1
Allergy to vaccine	10	17			3	9	7	8
Allodynia	1	1					1	1
Amblyopia	1	1			1	1		
Amnesia	1	1			1	1		
Anal haemorrhage		1						1
Anaphylactic reaction	56	61					56	61
Anaphylactic shock	1	1					1	1
Anaphylactoid reaction	2	5					2	5

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Anger	1	1
Angina pectoris	1	1
Angioedema	12	15
Anosmia	12	14
Antibody test positive	1	1
Anticholinergic syndrome	1	1
Anticoagulation drug level increased	1	1
Anxiety	22	31
Apathy	1	1
Aphasia	2	2
Aphonia	2	4
Aphthous ulcer	1	1
Appendicitis	1	1
Appetite disorder	1	1
Arrhythmia	3	3
Arrhythmia supraventricular	2	2
Arthralgia	385	434
Arthritis	4	5
Arthritis reactive		1
Asthenia	91	102
Asthenopia	2	3
Asthma	15	18
Asthma prophylaxis	1	1
Asymptomatic COVID-19	1	1
Atrial fibrillation	8	9
Aura	4	5
Auricular swelling	1	1
Axillary mass	6	7
Axillary pain	47	59
Back pain	80	89
Balance disorder	10	12
Bladder discomfort	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				12	15
		7	9	5	5
		1	1		
				1	1
				1	1
		7	13	15	18
				1	1
				2	2
				2	4
				1	1
				1	1
				3	3
		1	1	1	1
1	1	106	137	279	297
			1	4	4
					1
		34	39	57	63
		1	2	1	1
		3	4	12	14
				1	1
				1	1
				8	9
		2	3	2	2
				1	1
		4	5	2	2
		16	24	31	35
		24	32	56	57
		2	2	8	10
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blepharitis	1	1
Blepharospasm	2	2
Blister	8	8
Blood alkaline phosphatase increased	2	2
Blood glucose decreased	2	2
Blood glucose increased	7	7
Blood ketone body present	1	1
Blood lactic acid increased	2	2
Blood pH increased	1	1
Blood potassium abnormal	1	1
Blood pressure decreased	4	7
Blood pressure fluctuation	1	1
Blood pressure increased	30	40
Blood pressure orthostatic abnormal	1	1
Blood pressure orthostatic decreased		1
Blood pressure systolic decreased	1	1
Blood pressure systolic increased	2	2
Blood test abnormal		1
Blood urine present	2	2
Body temperature	2	2
Body temperature abnormal	12	12
Body temperature decreased	2	2
Body temperature fluctuation	2	4
Body temperature increased	37	42
Bone pain	14	18
Bone swelling	1	2
Bradycardia	6	7
Bradyphrenia	1	1
Breast abscess	1	1
Breast discomfort	1	1
Breast mass	1	1
Breast pain	11	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				2	2
		5	5	3	3
		1	1	1	1
				2	2
		1	1	6	6
				1	1
		1	1	1	1
		1	1		
				1	1
		1	2	3	5
				1	1
		17	23	13	17
				1	1
					1
				1	1
				2	2
					1
		2	2		
				2	2
		2	2	10	10
		1	1	1	1
			2	2	2
1	1	10	13	27	29
		7	10	7	8
			1	1	1
				6	7
				1	1
				1	1
		1	1		
				1	1
		4	5	7	7

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Breast swelling	3	3
Breath odour	1	1
Bronchospasm	2	2
Burning sensation	20	22
Cardiac arrest	7	8
Cardiac disorder	1	1
Cardiac failure	2	2
Cardiac failure congestive	1	1
Cardiac flutter	3	3
Cardiopulmonary failure	1	1
Cataplexy		1
Catarrh		1
Cellulitis	15	16
Cerebellar stroke	1	1
Cerebral haemorrhage	2	2
Cerebral infarction		1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	10	11
Chapped lips	1	1
Cheilitis	1	1
Chest discomfort	68	82
Chest pain	73	81
Chillblains	1	1
Chills	527	588
Cholecystitis infective	1	1
Chromaturia	1	1
Chronic fatigue syndrome		1
Circulatory collapse	8	9
Circumstance or information capable of leading to medication error	1	2
Clostridium difficile colitis	1	1
Clumsiness	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
		1	1		
				2	2
		3	4	17	18
				7	8
				1	1
				2	2
				1	1
				3	3
				1	1
					1
			1		
				15	16
				1	1
				2	2
					1
				1	1
				10	11
		1	1		
				1	1
		18	25	50	57
		19	24	54	57
				1	1
1	1	167	210	360	378
				1	1
				1	1
			1		
				8	9
		1	2		
				1	1
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cluster headache	7	7
Cognitive disorder	3	3
Cold sweat	34	43
Communication disorder	1	1
Condition aggravated	16	20
Confusional state	23	25
Conjunctival haemorrhage	2	3
Conjunctivitis	4	4
Consciousness fluctuating	1	1
Constipation	2	2
Contraindicated product administered	2	2
Contusion	11	12
Coordination abnormal	1	1
Coronary artery disease	2	2
Coronavirus infection		1
Cortisol decreased	1	1
Costochondritis	2	2
Costovertebral angle tenderness	1	1
Cough	92	104
COVID-19	40	45
COVID-19 pneumonia	1	1
C-reactive protein increased	1	1
Crying	3	3
Culture negative	1	1
Cyanosis	4	4
Deafness	2	2
Death	27	27
Decreased appetite	75	82
Decreased interest	2	2
Deep vein thrombosis	4	4
Defaecation urgency	2	2
Dehydration	11	12

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	6	6
				3	3
		13	15	21	28
				1	1
		4	7	12	13
		4	4	19	21
				2	3
		1	1	3	3
				1	1
		1	1	1	1
		1	1	1	1
		3	4	8	8
		1	1		
				2	2
					1
				1	1
				2	2
		1	1		
		25	33	67	71
				40	45
				1	1
				1	1
		1	1	2	2
				1	1
				4	4
				2	2
				27	27
		20	21	55	61
		1	1	1	1
				4	4
				2	2
		5	6	6	6

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Delirium	7	7
Delusion	1	1
Dementia	1	1
Depersonalisation/derealisation disorder	2	2
Depressed level of consciousness	3	3
Depressed mood	2	3
Depression	2	2
Derealisation	1	1
Dermatitis	6	6
Dermatitis allergic	7	12
Diabetes mellitus inadequate control		1
Diabetic complication	1	1
Diabetic ketoacidosis	2	3
Diarrhoea	155	192
Diarrhoea haemorrhagic		1
Diplopia	5	7
Discoloured vomit	2	2
Discomfort	14	15
Disease recurrence	8	8
Disorganised speech	1	1
Disorientation	8	10
Dissociation	1	2
Disturbance in attention	14	16
Dizziness	334	405
Dizziness exertional	1	1
Dizziness postural	24	31
Drooling	1	1
Drug eruption	2	2
Drug hypersensitivity	3	3
Drug ineffective	105	119
Dry eye	2	3
Dry mouth	19	29

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				7	7
				1	1
				1	1
		1	1	1	1
			1	3	3
				2	2
				2	2
				1	1
		4	4	2	2
		3	5	4	7
					1
				1	1
				2	3
		48	73	107	119
					1
		2	4	3	3
		2	2		
		7	7	7	8
		2	2	6	6
		1	1		
			2	8	8
		1	2		
		5	6	9	10
1	1	121	165	213	240
		1	1		
		4	8	20	23
				1	1
				2	2
		1	1	2	2
				105	119
		1	2	1	1
		7	13	12	16

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry skin	5	5
Dry throat	8	10
Dysarthria	6	6
Dysgeusia	42	59
Dyskinesia	2	2
Dysmenorrhoea	2	3
Dyspepsia	8	8
Dysphagia	18	19
Dysphonia	9	12
Dyspnoea	129	158
Dyspnoea exertional	4	7
Dysstasia	4	4
Dysuria	1	1
Ear discomfort	7	7
Ear infection	1	1
Ear pain	22	26
Ear pruritus	2	2
Ear swelling		1
Eating disorder	1	1
Eczema	5	5
Electrocardiogram ST segment elevation	1	1
Enlarged uvula	1	1
Enuresis	2	2
Eosinophilia	1	1
Epilepsy	3	4
Episcleritis	1	1
Epistaxis	14	16
Eructation	3	3
Erythema	90	112
Erythema multiforme	2	2
Euphoric mood	1	1
Exercise tolerance decreased	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		5	5		
		1	3	7	7
				6	6
		26	38	16	21
				2	2
		1	2	1	1
		5	5	3	3
		5	5	13	14
		3	3	6	9
		25	38	104	120
		1	4	3	3
		1	1	3	3
		1	1		
		5	5	2	2
				1	1
		8	9	14	17
		1	1	1	1
					1
				1	1
		2	2	3	3
				1	1
		1	1		
		1	1	1	1
				3	4
		1	1		
		5	7	9	9
				3	3
		41	58	49	54
				2	2
				1	1
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Exertional headache	1	1
Expired product administered		1
Exposure during pregnancy	3	3
Exposure to SARS-CoV-2	1	1
Exposure via breast milk	1	1
Extrasystoles	2	3
Eye allergy	1	1
Eye contusion	2	2
Eye disorder	9	10
Eye injury	1	1
Eye irritation	6	7
Eyelid exfoliation	1	1
Eyelid irritation	1	1
Eyelid pain	1	1
Eyelid ptosis		1
Eyelid rash	2	2
Eyelids pruritus	2	2
Eye movement disorder	3	3
Eye pain	37	39
Eye pruritus	12	14
Eye swelling	18	22
Face crushing	1	1
Facial discomfort	2	2
Facial neuralgia	1	1
Facial pain	14	14
Facial paralysis	24	25
Facial paresis	4	6
Facial spasm	1	2
Faeces discoloured	2	2
Faeces pale	1	1
Fall	12	12
Fatigue	773	901

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
			1		
		3	3		
				1	1
		1	1		
		1	1	1	2
				1	1
		1	1	1	1
		3	4	6	6
				1	1
		2	2	4	5
				1	1
		1	1		
				1	1
			1		
				2	2
		1	1	1	1
				3	3
		12	12	25	27
		3	4	9	10
		3	5	15	17
				1	1
				2	2
		1	1		
		4	4	10	10
				24	25
			2	4	4
		1	2		
		1	1	1	1
				1	1
		3	3	9	9
4	4	253	336	520	565

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Fear	2	3
Fear of injection	1	1
Feeding disorder	4	4
Feeling abnormal	65	75
Feeling cold	78	86
Feeling drunk	5	8
Feeling hot	77	108
Feeling jittery		2
Feeling of body temperature change	27	33
Fibrin D dimer increased	1	1
Fibromyalgia	2	2
Flank pain	1	2
Fluid intake reduced	2	2
Fluid retention		1
Flushing	30	48
Folliculitis	1	2
Foreign body sensation in eyes	1	1
Formication	1	1
Frequent bowel movements	1	4
Frustration tolerance decreased	1	1
Gait disturbance	15	17
Gait inability	3	3
Gamma-glutamyltransferase increased	1	1
Gastric disorder	2	2
Gastritis	2	3
Gastroenteritis viral	1	1
Gastrointestinal disorder	1	1
Gastrointestinal pain	2	3
Gastrointestinal stoma complication	1	1
Gastroesophageal reflux disease	4	4
Generalised tonic-clonic seizure	4	6
General physical health deterioration	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	2
		1	1		
		4	4		
		28	34	37	41
		30	34	48	52
		2	2	3	6
		36	58	41	50
			1		1
		12	18	15	15
				1	1
				2	2
		1	2		
			1		
		10	22	20	26
			1	1	1
				1	1
			2	1	2
		1	1		
		5	6	10	11
		2	2	1	1
				1	1
		1	1	1	1
			1	2	2
		1	1		
		1	1		
				2	3
				1	1
		1	1	3	3
				4	6
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Gingival bleeding	3	3
Gingival blister	1	1
Gingival pain	6	7
Gingivitis ulcerative	1	1
Glossitis	1	1
Glossodynia	6	8
Grip strength decreased	3	3
Groin pain	8	8
Haematemesis	4	5
Haematochezia	1	1
Haematoma	2	2
Haematuria		1
Haemoglobin decreased	1	1
Haemoptysis		1
Haemorrhage intracranial	1	1
Haemorrhage subcutaneous	1	1
Haemorrhage urinary tract	1	1
Haemorrhagic stroke	2	2
Hair colour changes	1	1
Hallucination	13	13
Hallucination, olfactory		1
Hallucination, tactile	1	1
Hallucination, visual	2	2
Hangover	4	4
Headache	1,078	1,253
Head discomfort	8	9
Head injury	6	6
Heart rate abnormal	3	3
Heart rate decreased	1	1
Heart rate increased	49	58
Heart rate irregular	2	2
Heat illness	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	2
		1	1		
		2	3	4	4
				1	1
		1	1		
		4	5	2	3
		3	3		
		5	5	3	3
				4	5
				1	1
		1	1	1	1
			1		
				1	1
					1
				1	1
				1	1
				1	1
				2	2
		1	1		
				13	13
					1
				1	1
				2	2
		1	1	3	3
5	5	350	461	728	792
		3	4	5	5
		3	3	3	3
		1	1	2	2
				1	1
		17	22	32	36
				2	2
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Heat oedema	1	1
Heat stroke	1	1
Hemiparaesthesia	1	1
Hemiparesis	6	7
Hepatitis	1	1
Herpes virus infection		1
Herpes zoster	15	19
Herpes zoster reactivation	1	1
Hot flush	30	38
Hunger	1	1
Hyperacusis	2	3
Hyperaesthesia	7	7
Hyperchlorhydria	1	1
Hyperglycaemia	1	3
Hyperhidrosis	82	95
Hyperpyrexia	2	2
Hypersensitivity	31	45
Hypersomnia	10	12
Hypertension	39	48
Hypertensive crisis	1	1
Hypertonia	1	1
Hypoacusis	2	3
Hypoaesthesia	66	82
Hypoaesthesia eye	1	1
Hypoaesthesia oral	29	38
Hypoglycaemia	5	7
Hypokinesia	2	2
Hyponatraemia	1	1
Hypophagia	1	1
Hypopnoea	2	2
Hyporeflexia	2	2
Hyporesponsive to stimuli	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
				1	1
				6	7
				1	1
					1
		6	10	9	9
				1	1
		11	16	19	22
		1	1		
			1	2	2
		2	2	5	5
		1	1		
			1	1	2
		25	34	57	61
				2	2
		6	12	25	33
		2	4	8	8
		14	19	25	29
				1	1
				1	1
		2	2		1
		21	35	45	47
				1	1
		16	22	13	16
			1	5	6
		1	1	1	1
				1	1
				2	2
				2	2
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hyposmia	2	2
Hypotension	25	30
Hypothermia	2	2
Hypotonia	1	1
Hypoxia	1	1
Idiopathic intracranial hypertension	1	1
Ill-defined disorder	1	1
Illness	51	56
Immune system disorder	1	1
Impaired driving ability	2	2
Inappropriate schedule of product administration	7	8
Incoherent	1	1
Incontinence	2	2
Incorrect dose administered	1	1
Incorrect route of product administration	13	22
Increased upper airway secretion	1	2
Increased viscosity of upper respiratory secretion	1	1
Indifference	1	1
Induration	1	1
Infantile vomiting	1	1
Infection	3	3
Inflammation	12	12
Inflammatory marker increased	1	1
Influenza	31	35
Influenza like illness	139	150
Inguinal mass	1	1
Initial insomnia	1	1
Injected limb mobility decreased	1	1
Injection related reaction	2	2
Injection site erythema	1	1
Injection site pain	3	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
		6	8	19	22
				2	2
				1	1
				1	1
				1	1
		17	18	34	38
				1	1
		1	1	1	1
		7	7		1
				1	1
				2	2
		1	1		
		13	22		
			1	1	1
				1	1
				1	1
		1	1		
				3	3
		5	5	7	7
				1	1
		11	15	20	20
		56	61	83	89
				1	1
				1	1
		1	1	1	1
		1	1		
		2	3	1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Injection site pruritus	1	1
Injection site warmth	1	1
Injury associated with device		1
Injury corneal	1	1
Insomnia	53	56
Intentional self-injury	1	1
International normalised ratio increased	1	1
Intranasal hypoaesthesia	1	1
Intraocular pressure increased	1	1
Iridocyclitis	2	2
Irritability	4	4
Irritable bowel syndrome	4	4
Ischaemic stroke	3	4
Itching scar	1	1
Jaundice	1	1
Jaw clicking	1	1
Joint effusion	1	1
Joint range of motion decreased	9	10
Joint stiffness	8	10
Joint swelling	13	15
Joint warmth		1
Labyrinthitis	2	2
Lacrimation increased	10	10
Lacunar infarction	1	1
Lacunar stroke	1	1
Lethargy	105	116
Leukaemia	1	1
Ligament sprain	1	1
Limb discomfort	59	78
Limb mass	1	1
Lip blister	1	2
Lip discolouration	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1		
			1		
				1	1
		23	25	30	31
				1	1
				1	1
				1	1
				2	2
		1	1	3	3
		1	1	3	3
				3	4
				1	1
				1	1
				1	1
		1	2	8	8
			1	8	9
		1	2	12	13
			1		
		1	1	1	1
		2	2	8	8
				1	1
				1	1
		35	40	70	76
				1	1
				1	1
		26	37	33	41
		1	1		
				1	2
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lip disorder		2
Lip dry	2	3
Lip oedema	1	1
Lip pain	3	4
Lip pruritus	1	1
Lip swelling	27	40
Livedo reticularis	1	2
Liver function test increased	2	2
Liver injury	1	1
Localised infection	1	1
Local reaction	4	5
Locked-in syndrome	1	1
Loss of consciousness	22	23
Loss of personal independence in daily activities	3	4
Lower limb fracture	1	1
Lower respiratory tract infection	5	5
Lung opacity	1	1
Lymphadenitis	2	2
Lymphadenopathy	239	277
Lymphatic disorder	1	1
Lymph node pain	55	67
Lymph node palpable	1	1
Lymphoedema	4	4
Maculopathy		1
Malaise	315	370
Malnutrition	1	1
Mass	2	2
Mast cell activation syndrome	1	1
Mastication disorder	2	2
Mastitis	2	2
Maternal exposure during pregnancy	3	4
Maternal exposure timing unspecified	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2		
		1	2	1	1
				1	1
		1	2	2	2
		1	1		
		6	12	21	28
			1	1	1
		1	1	1	1
				1	1
				1	1
		1	2	3	3
				1	1
				22	23
		1	1	2	3
				1	1
				5	5
				1	1
				2	2
		108	132	131	145
		1	1		
		27	34	28	33
		1	1		
				4	4
					1
		106	137	209	233
				1	1
		1	1	1	1
				1	1
				2	2
				2	2
		1	2	2	2
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mechanical urticaria	1	1
Memory impairment	3	4
Menopausal symptoms	2	2
Menorrhagia	3	5
Menstruation irregular	1	2
Mental disorder		1
Mental fatigue	7	7
Mental impairment	3	4
Metamorphopsia	1	2
Metrorrhagia		1
Micturition disorder	1	1
Middle ear inflammation	1	1
Middle insomnia	6	6
Migraine	97	105
Migraine with aura	5	6
Miliaria	1	3
Mobility decreased	20	22
Monoparesis	2	2
Monoplegia	2	2
Mood altered	3	3
Morning sickness	1	1
Motion sickness	2	3
Mouth cyst	1	1
Mouth swelling	5	6
Mouth ulceration	9	13
Movement disorder	5	5
Multiple organ dysfunction syndrome	1	1
Multiple sclerosis	2	2
Multiple sclerosis relapse	2	2
Muscle contractions involuntary	1	1
Muscle fatigue	8	13
Muscle rigidity	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	2	2	2
		2	2		
			2	3	3
			1	1	1
			1		
		3	3	4	4
				3	4
				1	2
			1		
				1	1
				1	1
		4	4	2	2
		32	37	65	68
		1	2	4	4
				1	3
		10	12	10	10
		1	1	1	1
				2	2
		2	2	1	1
				1	1
		2	3		
		1	1		
		1	2	4	4
		2	6	7	7
		1	1	4	4
				1	1
				2	2
				2	2
		1	1		
			2	8	11
				2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Muscle spasms	24	28
Muscle strain	1	1
Muscle swelling	3	3
Muscle tightness		1
Muscle tone disorder	1	1
Muscle twitching	9	10
Muscular weakness	32	40
Musculoskeletal chest pain	7	7
Musculoskeletal discomfort	6	6
Musculoskeletal disorder	3	3
Musculoskeletal pain	8	8
Musculoskeletal stiffness	46	54
Myalgia	523	599
Mydriasis	1	1
Myelitis	1	1
Myocardial infarction	5	6
Myocardial ischaemia	1	1
Myocarditis	3	3
Nail discolouration	2	2
Nasal congestion	7	8
Nasal discharge discolouration	1	1
Nasal discomfort		1
Nasal obstruction	1	1
Nasal odour	1	1
Nasal pruritus	1	1
Nasopharyngitis	28	32
Nausea	616	736
Neck mass	3	3
Neck pain	82	102
Negative thoughts	1	1
Nervousness	5	7
Neuralgia	4	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		8	11	16	17
				1	1
		1	1	2	2
					1
				1	1
		6	7	3	3
		9	16	23	24
		2	2	5	5
		4	4	2	2
		1	1	2	2
		2	2	6	6
		15	19	31	35
3	3	159	210	364	389
				1	1
				1	1
				5	6
				1	1
				3	3
				2	2
		4	5	3	3
		1	1		
			1		
				1	1
		1	1		
		1	1		
		13	16	15	16
2	2	192	272	424	464
		1	1	2	2
		29	45	53	57
				1	1
		2	2	3	5
		1	1	3	4

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Neurogenic shock	2	2
Neuropathy peripheral	2	2
Nightmare	5	5
Night sweats	22	22
Nipple pain	1	2
Nipple swelling		1
No adverse event	1	1
Nocturia	1	1
Nodule		1
Obstructive airways disorder	1	1
Occupational exposure to product		1
Ocular discomfort	1	1
Ocular hyperaemia	7	8
Odynophagia		1
Oedema	3	3
Oedema mouth	2	2
Oedema peripheral	2	2
Oesophageal pain	1	1
Off label use	42	51
Optic neuritis	1	1
Oral blood blister	1	1
Oral candidiasis	2	2
Oral discomfort	4	5
Oral herpes	2	3
Oral mucosal blistering	3	3
Oral mucosal erythema	1	1
Oral pain	4	4
Oral papule	1	1
Oropharyngeal blistering	3	3
Oropharyngeal discomfort	5	5
Oropharyngeal pain	102	120
Orthostatic hypotension	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				2	2
		3	3	2	2
		12	12	10	10
			1	1	1
			1		
		1	1		
		1	1		
			1		
				1	1
			1		
		1	1		
		1	1	6	7
					1
		1	1	2	2
		1	1	1	1
				2	2
		1	1		
		39	48	3	3
				1	1
				1	1
		1	1	1	1
		1	1	3	4
		1	1	1	2
		2	2	1	1
				1	1
		2	2	2	2
				1	1
				3	3
		1	1	4	4
		39	52	63	68
				2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Oscillopsia	1	1
Overdose	2	4
Oxygen saturation decreased	9	14
Pain	326	369
Painful respiration	3	5
Pain in extremity	421	503
Pain in jaw	13	13
Pain of skin	10	10
Pallor	17	25
Palpitations	62	79
Pancytopenia	1	1
Panic attack	3	3
Panic disorder	1	1
Papule	3	3
Paraesthesia	115	141
Paraesthesia oral	75	106
Paralysis	3	3
Paranasal sinus inflammation	1	1
Paranoia	1	1
Parosmia	3	3
Parotid gland enlargement	1	1
Parotitis	3	3
Partial seizures	1	1
Periarthritis	2	2
Pericarditis	2	2
Periorbital oedema	1	1
Periorbital swelling	3	4
Peripheral circulatory failure	1	2
Peripheral coldness	19	24
Peripheral ischaemia	1	1
Peripheral sensory neuropathy	1	1
Peripheral swelling	85	95

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		2	4		
			1	9	13
		117	143	209	226
		1	2	2	3
3	3	162	219	259	284
		4	4	9	9
		2	2	8	8
		5	8	12	17
		15	25	47	54
				1	1
				3	3
				1	1
				3	3
		51	74	64	67
		34	55	41	51
				3	3
				1	1
				1	1
		1	1	2	2
		1	1		
		1	1	2	2
				1	1
		1	1	1	1
				2	2
				1	1
		2	3	1	1
				1	2
		6	8	13	16
				1	1
				1	1
		26	34	59	61

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Petechiae	2	3
Pharyngeal disorder	1	1
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia		2
Pharyngeal inflammation	3	3
Pharyngeal oedema	3	3
Pharyngeal paraesthesia	3	4
Pharyngeal swelling	18	20
Pharyngeal ulceration	1	1
Pharyngitis	1	1
Pharyngitis streptococcal	2	2
Phonophobia	1	1
Photophobia	20	26
Photosensitivity reaction		1
Piloerection	2	3
Pleural effusion	1	1
Pleurisy	2	2
Pleuritic pain	3	3
Plicated tongue	1	1
Pneumonia	2	3
Pneumonia aspiration	1	1
Pneumonitis	1	1
Poisoning	1	1
Pollakiuria	1	1
Polymenorrhoea	2	2
Polymyalgia rheumatica	1	1
Poor peripheral circulation	1	1
Poor quality sleep	8	9
Post lumbar puncture syndrome	1	1
Post viral fatigue syndrome	1	1
Pre-existing condition improved		1
Presyncope	30	38

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			1	2	2
				1	1
				1	1
			1		1
				3	3
				3	3
		1	1	2	3
		7	8	11	12
				1	1
				1	1
				2	2
		1	1		
		5	7	15	19
					1
		1	1	1	2
				1	1
				2	2
				3	3
				1	1
				2	3
				1	1
				1	1
				1	1
		1	1	1	1
				1	1
		1	1		
		3	4	5	5
				1	1
				1	1
			1		
		17	21	13	17

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Primary cough headache	2	2
Procedural nausea	1	1
Proctitis ulcerative	1	1
Product administered at inappropriate site	1	1
Product administered to patient of inappropriate age	6	8
Productive cough	5	6
Product use issue	35	44
Pruritus	134	168
Pseudolymphoma	1	1
Psoriasis	1	1
Psoriatic arthropathy	1	1
Pulmonary oedema	2	2
Pulmonary pain	1	3
Pulmonary thrombosis	1	1
Pupillary reflex impaired	1	1
Pupils unequal	2	2
Purpura	2	2
Pustule	1	1
Pyelonephritis	1	1
Pyrexia	757	856
Q fever	1	1
Radiculopathy	1	1
Rales	1	1
Rash	130	158
Rash erythematous	38	55
Rash macular	29	37
Rash maculo-papular	1	1
Rash morbilliform	1	1
Rash papular	7	13
Rash pruritic	41	45
Rash pustular	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				1	1
				1	1
				1	1
		5	7	1	1
		2	2	3	4
		32	41	3	3
		59	80	75	88
				1	1
				1	1
				1	1
				2	2
			1	1	2
				1	1
				1	1
				1	1
3	3	218	273	539	583
				1	1
				1	1
				1	1
		56	74	74	84
		15	26	23	29
		17	23	12	14
		1	1		
				1	1
		2	7	5	6
		14	16	27	29
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash vesicular	2	2
Raynaud's phenomenon	1	1
Reaction to preservatives	1	1
Rectal haemorrhage	2	2
Red blood cell sedimentation rate increased	1	1
Renal failure	2	2
Renal pain	10	10
Respiration abnormal	1	1
Respiratory arrest	1	1
Respiratory disorder	2	2
Respiratory distress	1	1
Respiratory rate decreased	1	1
Respiratory rate increased	6	7
Respiratory tract irritation	1	1
Restless legs syndrome	4	4
Restlessness	8	14
Retching	6	7
Rhabdomyolysis	2	2
Rheumatoid arthritis	2	2
Rhinitis	4	4
Rhinitis allergic	1	1
Rhinorrhoea	20	22
Right ventricular enlargement	1	1
Salivary gland pain	1	1
Salivary hypersecretion	5	8
SARS-CoV-2 ant body test negative	1	1
SARS-CoV-2 ant body test positive	1	1
SARS-CoV-2 test positive	6	10
Sciatica	1	1
Seasonal allergy	1	1
Secretion discharge	1	1
Sedation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
				1	1
				1	1
				2	2
				1	1
				2	2
		5	5	5	5
				1	1
				1	1
				2	2
				1	1
				1	1
			1	6	6
		1	1		
		1	1	3	3
		6	9	2	5
		1	2	5	5
				2	2
				2	2
		2	2	2	2
				1	1
		11	12	9	10
		1	1		
				1	1
		2	5	3	3
		1	1		
				1	1
				6	10
				1	1
		1	1		
				1	1
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Seizure	13	13
Sensation of foreign body	3	3
Sensitive skin	5	5
Sensory disturbance	8	10
Sensory loss	1	1
Sepsis	3	3
Serositis	1	1
Sinonasal obstruction	1	1
Sinus bradycardia		1
Sinus congestion	2	2
Sinus disorder	1	1
Sinus headache	9	10
Sinusitis	1	1
Sinus pain	10	11
Sinus tachycardia	3	6
Sjogren's syndrome		1
Skin abrasion	1	1
Skin burning sensation	13	13
Skin discolouration	6	6
Skin disorder	1	1
Skin erosion	1	1
Skin exfoliation	4	4
Skin induration	1	1
Skin irritation	4	4
Skin laceration	1	1
Skin lesion	1	1
Skin mass	1	2
Skin reaction	1	2
Skin sensitisation	2	2
Skin swelling	2	3
Skin tightness	4	5
Skin ulcer	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				13	13
				3	3
		1	1	4	4
		6	7	2	3
				1	1
				3	3
				1	1
				1	1
					1
		1	1	1	1
				1	1
			1	9	9
				1	1
		3	3	7	8
		1	3	2	3
					1
				1	1
		3	3	10	10
		1	1	5	5
		1	1		
		1	1		
				4	4
		1	1		
		2	2	2	2
				1	1
		1	1		
			1	1	1
			1	1	1
				2	2
		1	2	1	1
		2	2	2	3
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin warm	16	17
Sleep attacks	1	1
Sleep disorder	20	23
Sleep disorder due to a general medical condition	3	3
Sleep disorder due to general medical condition, insomnia type	3	3
Sleep terror	1	1
Slow response to stimuli	1	1
Sneezing	15	16
Snoring	1	1
Somatic symptom disorder		1
Somnolence	51	57
Speech disorder	4	4
Spinal disorder	1	1
Spinal pain	3	3
Stiff leg syndrome	1	1
Stiff tongue	1	1
Stomatitis	1	1
Stress	2	2
Stridor	1	1
Subarachnoid haemorrhage	1	1
Submaxillary gland enlargement	1	1
Sudden death	4	4
Sudden hearing loss	1	1
Supraventricular tachycardia	4	5
Suspected COVID-19	63	67
Sweating fever	8	9
Swelling	53	60
Swelling face	36	42
Swelling of eyelid	5	8
Swollen tongue	39	44

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		6	6	10	11
				1	1
		11	14	9	9
		1	1	2	2
		2	2	1	1
				1	1
				1	1
		9	10	6	6
				1	1
					1
		18	20	33	37
				4	4
		1	1		
		1	1	2	2
				1	1
				1	1
		1	1		
		2	2		
				1	1
				1	1
		1	1		
				4	4
				1	1
		1	1	3	4
		1	1	62	66
				8	9
		21	26	32	34
		6	8	30	34
		1	3	4	5
		9	10	30	34

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Symphysiolysis	1	1
Symptom recurrence	1	1
Syncope	72	83
Synovitis	1	1
Systemic inflammatory response syndrome	1	1
Systemic lupus erythematosus	1	1
Tachycardia	66	88
Tachypnoea	3	3
Taste disorder	10	11
Tearfulness	1	1
Temperature regulation disorder	1	1
Temporomandibular joint syndrome	2	2
Tenderness	14	15
Tension	1	1
Tension headache	20	21
Therapeutic response unexpected	1	1
Thinking abnormal	1	1
Thirst	13	14
Throat clearing	2	2
Throat irritation	9	12
Throat tightness	28	35
Thrombosis	2	2
Tinnitus	12	18
Tongue discomfort		2
Tongue disorder	1	1
Tongue eruption	1	1
Tongue movement disturbance	1	1
Tongue oedema	1	1
Tongue pruritus	1	1
Tongue ulceration	3	3
Tonsillar hypertrophy	3	4
Tonsillar inflammation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
				72	83
				1	1
				1	1
		17	31	49	57
				3	3
		6	7	4	4
				1	1
				1	1
		2	2		
		9	10	5	5
				1	1
		4	5	16	16
				1	1
				1	1
		6	7	7	7
				2	2
		3	3	6	9
		5	7	23	28
				2	2
		5	8	7	10
			2		
				1	1
				1	1
				1	1
		1	1		
				1	1
		1	1	2	2
		1	1	2	3
		1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Tonsillitis	5	6
Tonsillitis bacterial	1	1
Toothache	3	3
Torticollis	1	1
Toxic skin eruption	1	1
Transient ischaemic attack	4	5
Tremor	77	92
Trigeminal neuralgia	1	1
Tri-iodothyronine decreased	1	1
Troponin increased	1	1
Type IV hypersensitivity reaction	1	2
Underdose	1	2
Unresponsive to stimuli	9	10
Upper-airway cough syndrome	1	1
Upper limb fracture	1	1
Upper respiratory tract congestion	1	1
Urinary incontinence	2	2
Urinary retention	3	3
Urinary tract disorder	1	1
Urinary tract infection	3	3
Urinary tract infection bacterial	1	1
Urticaria	55	69
Vaccination complication	2	3
Vaccination site abscess	1	1
Vaccination site bruising	12	13
Vaccination site cellulitis	6	7
Vaccination site discolouration	3	4
Vaccination site discomfort	10	12
Vaccination site erythema	98	122
Vaccination site haematoma	1	1
Vaccination site haemorrhage	2	3
Vaccination site hyperaesthesia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	4	5
				1	1
		1	1	2	2
				1	1
				1	1
				4	5
		22	28	55	64
				1	1
				1	1
				1	1
				1	2
		1	2		
				9	10
		1	1		
				1	1
				1	1
				2	2
				3	3
				1	1
				3	3
				1	1
		20	31	35	38
			1	2	2
				1	1
1	1	5	5	7	8
		1	1	5	6
		1	2	2	2
		6	8	4	4
		53	69	45	53
				1	1
			1	2	2
		1	1		

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Vaccination site hypoaesthesia	5	7
Vaccination site induration	9	12
Vaccination site infection	2	3
Vaccination site inflammation	12	15
Vaccination site joint movement impairment	6	7
Vaccination site joint pain	4	6
Vaccination site lymphadenopathy	2	2
Vaccination site macule	1	1
Vaccination site mass	18	23
Vaccination site movement impairment	9	14
Vaccination site oedema	1	2
Vaccination site pain	421	510
Vaccination site paraesthesia	6	8
Vaccination site pruritus	33	40
Vaccination site rash	20	26
Vaccination site reaction	8	11
Vaccination site swelling	105	127
Vaccination site urticaria	3	4
Vaccination site vesicles	3	3
Vaccination site warmth	56	71
Vaginal haemorrhage	4	4
Varicose vein	1	1
Vasculitic rash	1	1
Vasculitis	1	1
Vasodilatation	2	2
Vein disorder	1	1
Vein rupture	1	1
Ventricular extrasystoles	1	1
Vertigo	34	39
Vertigo positional	1	1
Vestibular migraine	1	1
Viral pharyngitis	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
			2	5	5
		6	9	3	3
			1	2	2
		5	7	7	8
		2	2	4	5
		1	2	3	4
				2	2
		1	1		
		7	11	11	12
		2	5	7	9
			1	1	1
4	4	183	245	238	265
		3	4	3	4
		20	25	13	15
		8	13	12	13
		2	5	6	6
		47	61	58	66
		1	2	2	2
				3	3
		26	38	30	33
				4	4
		1	1		
				1	1
				1	1
				2	2
				1	1
				1	1
		7	10	27	29
				1	1
				1	1
				1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Viral rash	3	3
Viral tonsillitis	1	1
Vision blurred	36	43
Visual acuity reduced	1	1
Visual brightness	1	1
Visual field defect	2	2
Visual impairment	13	14
Vitreous floaters	1	1
Vocal cord disorder	1	1
Vomiting	172	210
Vomiting projectile	3	3
Vomiting psychogenic	1	1
Vulvovaginal candidiasis	2	2
Vulvovaginal pruritus	1	1
Weight decreased	1	1
Weight loss diet	1	1
Wheezing	22	29
White blood cell count decreased	1	1
Writer's cramp	1	1
Wrong product administered	1	1
	9	11
	14,054	16,547

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	2
				1	1
		14	18	22	25
		1	1		
		1	1		
		1	1	1	1
		3	3	10	11
		1	1		
				1	1
1	1	50	77	122	133
				3	3
				1	1
		1	1	1	1
		1	1		
		1	1		
				1	1
		5	9	17	20
				1	1
				1	1
		1	1		
		9	11		
30	30	4637	6180	9417	10367

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal adhesions	1	1					1	1
Abdominal discomfort	3	4				1	3	3
Abdominal distension	1	1			1	1		
Abdominal pain	11	11			1	1	10	10
Abdominal pain lower	2	2					2	2
Abdominal pain upper	8	8			3	3	5	5
Abnormal dreams	3	4			1	2	2	2
Acidosis	1	1					1	1
Acute cardiac event	1	1					1	1
Acute kidney injury	3	3					3	3
Acute myocardial infarction	2	2					2	2
Acute pulmonary oedema	1	1					1	1
Acute respiratory failure	1	1					1	1
Ageusia	6	6			2	2	4	4
Agitation	4	4			2	2	2	2
Alanine aminotransferase increased	1	1					1	1
Allergic cough	1	1					1	1
Allergic oedema	1	1					1	1
Allergy to vaccine	2	2			1	1	1	1
Alopecia	1	1			1	1		
Altered state of consciousness	1	1					1	1
Anal incontinence	1	1					1	1
Anaphylactic reaction	7	7					7	7
Anaphylactic shock		1						1
Angina pectoris	2	2					2	2
Angioedema	5	6					5	6
Ankylosing spondylitis	1	1					1	1
Anosmia	4	4			1	1	3	3
Anxiety	4	6			1	2	3	4
Aortic aneurysm rupture	1	1					1	1
Apathy	1	1					1	1
Aphasia	2	2					2	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Aphthous ulcer	1	1
Arrhythmia		1
Arthralgia	94	104
Arthritis	3	3
Arthritis reactive	1	1
Arthropathy	1	1
Aspartate aminotransferase increased	1	1
Aspiration	1	1
Asthenia	29	32
Asthenopia	1	1
Asthma	2	2
Asymptomatic COVID-19	1	1
Atrial f brillation	6	7
Aura	1	1
Axillary mass	1	2
Axillary pain	8	11
Back pain	17	18
Balance disorder	7	9
Bedridden	2	2
Bile duct stone	1	1
Biliary sepsis	1	1
Bite	1	1
Bladder pain	1	1
Blindness	2	2
Blood creatine phosphokinase increased	2	2
Blood electrolytes increased	1	1
Blood glucose decreased	1	1
Blood glucose increased	2	2
Blood lactic acid increased	1	1
Blood pressure decreased	1	1
Blood pressure increased	2	4
Blood pressure systolic increased		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
					1
		34	40	60	64
		1	1	2	2
				1	1
				1	1
				1	1
		13	14	16	18
				1	1
		2	2		
				1	1
				6	7
				1	1
		1	2		
		5	8	3	3
		8	9	9	9
1	1	1	2	6	7
				2	2
				1	1
				1	1
				1	1
				1	1
				2	2
		1	1	1	1
		1	1		
				1	1
				1	1
				1	1
		1	2	1	2
			1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Blood sodium decreased	1	1
Blood test abnormal	1	1
Blood urea increased	1	1
Body temperature abnormal	2	3
Body temperature decreased	1	1
Body temperature fluctuation	2	2
Body temperature increased	4	6
Bone pain	8	8
Bradycardia	3	3
Bundle branch block right	1	1
Burning sensation	2	3
Cardiac arrest	10	12
Cardio-respiratory arrest	1	1
Central vision loss	1	1
Cerebellar infarction	1	2
Cerebral infarction	1	1
Cerebrovascular accident	8	9
Chest discomfort	7	8
Chest pain	15	18
Chills	146	166
Choking	1	1
Chromaturia	2	2
Circulatory collapse	9	9
Circumstance or information capable of leading to medication error		1
Clinical death	1	1
Cognitive disorder	1	1
Cold sweat	7	10
Colitis ulcerative	1	1
Coma scale abnormal	2	3
Condition aggravated	3	3
Confusional state	15	17

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		1	1		
			1	2	2
				1	1
		1	1	1	1
		3	4	1	2
		3	3	5	5
				3	3
		1	1		
		1	1	1	2
				10	12
				1	1
				1	1
				1	2
				1	1
				8	9
		3	3	4	5
		6	7	9	11
		41	57	105	109
				1	1
				2	2
				9	9
			1		
				1	1
				1	1
		3	4	4	6
				1	1
				2	3
				3	3
		4	5	11	12

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Conjunctival haemorrhage	1	1
Constipation	2	2
Contusion	1	2
Cough	28	31
COVID-19	43	46
COVID-19 pneumonia	2	2
C-reactive protein increased	1	1
Cyanosis	1	1
Cystitis	1	1
Deafness	2	2
Death	27	27
Decreased appetite	26	29
Deep vein thrombosis	1	1
Dehydration	4	4
Delirium	8	8
Dementia	1	1
Depressed level of consciousness	1	1
Depression	1	2
Dermatitis allergic	1	3
Dermatitis bullous	1	1
Diabetes mellitus inadequate control	1	1
Diarrhoea	41	51
Diplopia	1	1
Discomfort	3	3
Disease recurrence	2	2
Disorientation	1	3
Disturbance in attention	2	3
Dizziness	60	76
Dizziness postural	6	6
Drug ineffective	62	66
Dry eye	1	1
Dry mouth	5	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				2	2
				1	2
		13	15	15	16
				43	46
				2	2
		1	1		
		1	1		
				1	1
				2	2
				27	27
		6	8	20	21
				1	1
		2	2	2	2
				8	8
				1	1
				1	1
				1	2
			2	1	1
				1	1
				1	1
		8	11	33	40
		1	1		
		3	3		
				2	2
			1	1	2
			1	2	2
		21	32	39	44
				6	6
				62	66
				1	1
		1	1	4	4

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Dry skin	2	2
Dysarthria	3	3
Dysgeusia	4	9
Dyskinesia	1	1
Dysphagia	2	2
Dysphonia	1	1
Dyspnoea	42	45
Dyspnoea exertional	3	3
Dysstasia	3	3
Dystonia	1	1
Ear congestion	1	1
Ear disorder	1	1
Ear infection	1	1
Ear pain	4	4
Electrocardiogram ST segment abnormal	1	1
Emotional distress	1	1
Enteritis		1
Enuresis	1	1
Epilepsy	2	2
Epistaxis	2	4
Erectile dysfunction	1	1
Eructation	2	2
Erythema	6	8
Expired product administered	1	1
Extrasystoles	1	1
Eye infection	1	1
Eye irritation	1	1
Eyelid function disorder	1	1
Eye pain	9	12
Eye pruritus	4	4
Eye swelling	4	4
Facial discomfort		1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2		
				3	3
		3	8	1	1
		1	1		
				2	2
				1	1
		14	14	28	31
		1	1	2	2
		2	2	1	1
				1	1
		1	1		
				1	1
		1	1		
		3	3	1	1
				1	1
		1	1		
			1		
				1	1
				2	2
		1	1	1	3
				1	1
				2	2
		4	5	2	3
		1	1		
		1	1		
				1	1
				1	1
				1	1
		2	5	7	7
		1	1	3	3
				4	4
					1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facial pain	1	1
Facial paralysis	10	11
Facial spasm	1	1
Faeces discoloured		1
Faeces pale		1
Fall	11	11
Fatigue	176	205
Feeding disorder	1	1
Feeling abnormal	14	16
Feeling cold	18	20
Feeling drunk	1	1
Feeling hot	14	18
Feeling of body temperature change	4	6
Fixed eruption	1	1
Flank pain	1	1
Flatulence	1	1
Flushing	5	6
Foreign body sensation in eyes	1	1
Formication		1
Frequent bowel movements	1	1
Furuncle	1	1
Gait disturbance	5	6
Gait inability	5	5
Gastroenteritis	1	2
Gastroenteritis viral	1	1
Gastrointestinal pain	1	1
Genital herpes	1	1
Glassy eyes	1	1
Glossodynia	1	1
Gout	2	2
Guillain-Barre syndrome	1	1
Haematemesis	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				10	11
		1	1		
			1		
			1		
		2	2	9	9
1	1	63	82	113	123
		1	1		
1	1	3	4	11	12
		10	12	8	8
				1	1
		7	11	7	7
			1	4	5
		1	1		
				1	1
				1	1
		4	5	1	1
				1	1
					1
				1	1
		1	1		
		2	3	3	3
				5	5
			1	1	1
				1	1
				1	1
				1	1
				2	2
				1	1
				3	3

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemoglobin decreased	1	1
Haemoptysis	1	1
Haemorrhage intracranial	1	1
Hallucination	6	6
Hallucination, visual	3	3
Hand-eye coordination impaired	1	1
Hangover	1	1
Headache	232	265
Head discomfort	2	2
Head injury	2	2
Heart rate decreased	2	2
Heart rate increased	7	8
Heart rate irregular	1	1
Hemiparesis	2	3
Hepatic artery embolism	1	1
Hepatic enzyme increased	1	1
Hepatic pain	1	1
Herpes zoster	4	4
Herpes zoster oticus	1	1
Hordeolum	1	1
Hot flush	5	9
Hyperaesthesia	2	2
Hyperglycaemia	5	5
Hyperhidrosis	26	30
Hypersensitivity	6	7
Hypersensitivity pneumonitis	1	1
Hypersomnia	2	2
Hypertension	6	7
Hypertonic bladder		1
Hyperventilation	1	1
Hypoaesthesia	6	9
Hypoaesthesia oral	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
				1	1
				6	6
				3	3
				1	1
		1	1		
		84	107	148	158
				2	2
		1	1	1	1
				2	2
		2	3	5	5
				1	1
				2	3
				1	1
		1	1		
				1	1
		1	1	3	3
				1	1
				1	1
		2	4	3	5
		2	2		
				5	5
		10	14	16	16
		2	3	4	4
				1	1
		1	1	1	1
				6	7
			1		
				1	1
		1	2	5	7
		1	1	2	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Hypoglycaemia	1	1
Hypokinesia	1	1
Hyponatraemia	1	1
Hypophagia	1	1
Hyposmia	2	2
Hypotension	7	9
Hypothermia	5	5
Hypoxia	3	3
Illness	6	7
Immobile	1	1
Immune-mediated adverse reaction		1
Immune thrombocytopenia	1	1
Inappropriate schedule of product administration	4	4
Incision site pain		1
Incorrect route of product administration	4	5
Increased upper airway secretion	1	1
Increased viscosity of upper respiratory secretion	1	1
Infarction	1	1
Infection	3	3
Inflammation	1	1
Influenza	9	9
Influenza like illness	38	44
Initial insomnia	1	1
Injection site pain	1	1
Insomnia	21	25
International normalised ratio increased	3	3
Ischaemic stroke	2	3
Joint effusion	2	2
Joint lock	1	1
Joint noise	1	1
Joint range of motion decreased	2	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
				1	1
				1	1
		1	1	1	1
		2	3	5	6
				5	5
				3	3
		1	2	5	5
				1	1
			1		
				1	1
		4	4		
					1
		4	5		
				1	1
		1	1		
				1	1
				3	3
				1	1
		3	3	6	6
		14	20	24	24
		1	1		
				1	1
		10	13	11	12
				3	3
				2	3
				2	2
				1	1
				1	1
		2	2		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Joint stiffness	4	4
Joint swelling	2	3
Labyrinthitis		1
Lacrimation increased	3	3
Lacunar infarction	1	1
Lethargy	32	38
Limb discomfort	5	9
Limb immobilisation	1	1
Lip swelling		2
Localised infection	1	1
Local reaction	1	1
Loss of consciousness	9	9
Loss of personal independence in daily activities	6	6
Lower respiratory tract infection	7	7
Lung consolidation	1	1
Lymphadenitis	1	1
Lymphadenopathy	28	36
Lymph node pain	5	6
Lymphoedema	1	1
Malaise	76	88
Medication overuse headache	1	1
Melaena	1	1
Memory impairment	1	1
Middle insomnia	1	1
Migraine	12	12
Migraine with aura	1	1
Miliaria	1	1
Mobility decreased	2	4
Mononeuropathy	1	1
Monoplegia	2	2
Motion sickness	1	1
Mouth swelling	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	2	2	2
		2	3		
					1
		2	2	1	1
				1	1
		10	14	22	24
		3	7	2	2
		1	1		
			2		
				1	1
				1	1
				9	9
		1	1	5	5
				7	7
				1	1
		1	1		
		11	15	17	21
		3	4	2	2
				1	1
		24	32	52	56
				1	1
				1	1
				1	1
		1	1	11	11
		1	1		
		1	1		
		1	2	1	2
				1	1
				2	2
		1	1		
		1	1		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Mouth ulceration	3	3
Movement disorder	3	3
Multiple organ dysfunction syndrome	1	1
Muscle contractions involuntary	1	1
Muscle fatigue	2	2
Muscle rigidity	2	2
Muscle spasms	3	4
Muscle tightness	1	1
Muscle twitching	2	2
Muscular weakness	14	15
Musculoskeletal chest pain	1	1
Musculoskeletal discomfort	1	1
Musculoskeletal pain	2	2
Musculoskeletal stiffness	13	14
Myalgia	155	188
Myocardial infarction	8	8
Myocarditis	1	1
Myoclonus	1	1
Myofascial pain syndrome		1
Narcolepsy	1	1
Nasal congestion	3	4
Nasal discomfort	2	2
Nasal dryness	1	1
Nasal oedema	1	1
Nasopharyngitis	4	5
Nausea	89	105
Neck pain	13	14
Nephrotic syndrome	1	1
Nervousness	2	2
Neuralgia	1	1
Neurogenic shock	2	2
Nightmare	1	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
		1	1	2	2
				1	1
				1	1
		1	1	1	1
				2	2
		2	2	1	2
		1	1		
				2	2
		2	2	12	13
				1	1
		1	1		
		1	1	1	1
		5	5	8	9
		43	65	112	123
				8	8
				1	1
		1	1		
			1		
				1	1
		1	2	2	2
		1	1	1	1
				1	1
		1	1		
		1	2	3	3
1	1	28	42	61	63
		4	4	9	10
				1	1
		1	1	1	1
				1	1
				2	2
			2	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Night sweats	13	15
Nipple pain	1	1
Nipple swelling	1	1
No adverse event	1	1
Obsessive-compulsive symptom	1	1
Occupational exposure to SARS-CoV-2	1	1
Ocular hyperaemia	1	1
Off label use	4	6
Oral herpes	2	3
Oral mucosa erosion		1
Oral mucosal eruption	1	1
Oropharyngeal pain	14	17
Orthopnoea	1	1
Oxygen saturation decreased	2	2
Pain	55	62
Pain in extremity	77	88
Pain in jaw	1	2
Pain of skin		1
Pallor	3	6
Palpitations	7	7
Paraesthesia	12	16
Paraesthesia oral	2	5
Paralysis	4	4
Parosmia	2	2
Penile swelling	1	1
Periorbital swelling		1
Peripheral coldness	2	2
Peripheral swelling	10	12
Peroneal nerve palsy	1	1
Petechiae	2	2
Petit mal epilepsy	2	2
Pharyngeal inflammation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		4	6	9	9
		1	1		
		1	1		
		1	1		
				1	1
		1	1		
		4	6		
		2	2		1
			1		
		1	1		
		9	12	5	5
		1	1		
				2	2
		26	33	29	29
		32	40	45	48
		1	2		
					1
		2	3	1	3
		4	4	3	3
		7	9	5	7
			3	2	2
				4	4
		1	1	1	1
				1	1
			1		
		1	1	1	1
		3	4	7	8
				1	1
				2	2
				2	2
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal oedema	1	1
Pharyngeal paraesthesia	1	1
Photophobia	1	2
Photopsia		1
Pneumonia	2	3
Pneumonia aspiration	2	2
Pollakiuria	1	1
Polyuria	1	1
Poor quality sleep	1	1
Posterior reversible encephalopathy syndrome	1	1
Postoperative ileus	1	1
Posture abnormal	1	1
Post viral fatigue syndrome	1	1
Pre-existing condition improved	1	1
Presyncope	8	9
Primary headache associated with sexual activity	1	1
Product administered to patient of inappropriate age	1	1
Productive cough	2	2
Product use issue	4	6
Prostatomegaly	1	1
Pruritus	14	20
Psychotic behaviour	1	1
Pulmonary embolism	1	1
Pulse abnormal	1	1
Pulseless electrical activity	1	1
Purpura	1	1
Pyrexia	245	276
Rash	17	19
Rash erythematous	5	6
Rash macular	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
				1	2
			1		
				2	3
				2	2
		1	1		
		1	1		
				1	1
				1	1
				1	1
				1	1
		1	1		
		3	3	5	6
				1	1
		1	1		
				2	2
		4	6		
		1	1		
		8	12	6	8
				1	1
				1	1
				1	1
		1	1		
		65	87	180	189
		11	12	6	7
		3	3	2	3
		3	3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Rash maculo-papular	1	2
Rash papular	1	1
Rash pruritic	2	4
Rash vesicular	2	2
Regurgitation	1	1
Respiration abnormal		2
Respiratory arrest	2	2
Respiratory disorder	1	2
Restlessness	3	4
Retching	2	2
Retinal migraine	1	1
Rhabdomyolysis	1	1
Rhinitis		1
Rhinorrhoea	4	4
Sacroiliitis	1	1
SARS-CoV-2 ant body test negative	1	1
SARS-CoV-2 test false positive	1	1
SARS-CoV-2 test positive	4	5
Sciatica	1	1
Scrotal erythema		1
Scrotal exfoliation		1
Scrotal pain	1	2
Scrotal swelling		1
Seizure	6	6
Sepsis	2	2
Serotonin syndrome	1	1
Severe acute respiratory syndrome	1	1
Sinus congestion	1	1
Sinus headache	1	1
Sinusitis	1	1
Sinus tachycardia	1	1
Skin burning sensation	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	2
		1	1		
		1	1	1	3
				2	2
				1	1
			1		1
				2	2
			1	1	1
		1	1	2	3
		2	2		
				1	1
				1	1
			1		
		4	4		
				1	1
		1	1		
		1	1		
				4	5
				1	1
					1
					1
		1	1		1
					1
				6	6
				2	2
				1	1
				1	1
		1	1		
				1	1
				1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Skin cancer	1	1
Skin discolouration	2	2
Skin erosion	1	1
Skin exfoliation	3	3
Skin lesion	1	1
Skin mass	1	1
Skin tightness	1	1
Skin warm	3	4
Skin weeping	1	1
Sleep attacks	1	1
Sleep deficit	1	1
Sleep disorder	9	9
Sleep disorder due to a general medical condition	1	1
Small intestinal obstruction	1	1
Sneezing	3	3
Somnolence	11	14
Spinal pain	1	1
Sputum purulent		1
Stevens-Johnson syndrome	1	1
Stoma site discharge		1
Stoma site extravasation		1
Stoma site haemorrhage		1
Sudden death	3	3
Superficial injury of eye	1	1
Superficial vein prominence	1	1
Supraventricular tachycardia		1
Suspected COVID-19	13	13
Sweating fever	2	2
Swelling	5	5
Swelling face	4	5
Swollen tongue	2	5

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	2		
				1	1
		1	1	2	2
		1	1		
		1	1		
				1	1
		2	2	1	2
				1	1
				1	1
				1	1
		4	4	5	5
				1	1
				1	1
		2	2	1	1
		5	8	6	6
		1	1		
					1
				1	1
			1		
					1
				3	3
				1	1
		1	1		
					1
				13	13
				2	2
		4	4	1	1
				4	5
		1	3	1	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Syncope	10	12
Synovial cyst	1	1
Synovial rupture	1	1
Tachycardia	12	14
Tachypnoea	3	3
Taste disorder	2	2
Temperature regulation disorder	1	1
Tenderness	2	2
Tendon injury	1	1
Tendonitis	1	1
Tension headache	3	3
Therapeutic response unexpected	2	2
Thirst	2	2
Throat irritation	1	2
Throat tightness	3	3
Thrombocytopenia	5	5
Thrombocytosis	1	1
Thrombosis	2	2
Thunderclap headache	1	1
Tinnitus	5	6
Tongue discomfort	1	1
Tongue dry		1
Tongue erythema	1	1
Toothache	2	2
Toxic epidermal necrolysis	1	1
Transient ischaemic attack	1	1
Tremor	19	20
Trismus	1	1
Tunnel vision	1	1
Unresponsive to stimuli	5	6
Upper gastrointestinal haemorrhage	2	2
Urinary incontinence	3	3

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				10	12
		1	1		
		1	1		
			2	12	12
		1	1	2	2
		1	1	1	1
				1	1
				2	2
				1	1
		1	1	2	2
		2	2		
		1	1	1	1
			1	1	1
		1	1	2	2
				5	5
				1	1
				2	2
				1	1
		3	4	2	2
				1	1
			1		
		1	1		
		1	1	1	1
				1	1
		4	5	15	15
				1	1
				1	1
				5	6
				2	2
		1	1	2	2

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Urinary retention	2	2
Urinary tract infection	1	1
Urine output decreased	1	1
Urosepsis	1	1
Urticaria	10	14
Vaccination complication	1	1
Vaccination site bruising	6	6
Vaccination site discolouration	2	2
Vaccination site discomfort	3	3
Vaccination site erythema	8	11
Vaccination site haemorrhage	1	1
Vaccination site hypoaesthesia	1	2
Vaccination site infection	1	1
Vaccination site inflammation		1
Vaccination site joint movement impairment	1	1
Vaccination site joint pain	2	2
Vaccination site mass	2	3
Vaccination site movement impairment	1	1
Vaccination site oedema	1	1
Vaccination site pain	106	135
Vaccination site paraesthesia	1	1
Vaccination site pruritus	2	2
Vaccination site reaction	3	3
Vaccination site swelling	14	20
Vaccination site ulcer	1	1
Vaccination site warmth	4	6
Vena cava thrombosis	1	1
Ventricular extrasystoles	2	2
Ventricular fibrillation	2	3
Vertigo	7	8
Vertigo positional	1	1
Vestibular neuritis	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
				1	1
				1	1
				1	1
		6	10	4	4
		1	1		
		3	3	3	3
				2	2
		1	1	2	2
		2	4	6	7
				1	1
		1	2		
				1	1
			1		
		1	1		
		1	1	1	1
		1	2	1	1
				1	1
		48	73	58	62
		1	1		
		2	2		
		1	1	2	2
		8	12	6	8
				1	1
			2	4	4
				1	1
		1	1	1	1
				2	3
		1	1	6	7
				1	1
				1	2

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Viral labyrinthitis	1	1
Viral upper respiratory tract infection	1	1
Vision blurred	10	10
Visual impairment	3	3
Vitreous floaters		1
Vomiting	33	36
Wheezing	1	3
	4	4
	3,270	3,790

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				1	1
		4	4	6	6
				3	3
			1		
		10	12	23	24
			2	1	1
		4	4		
		4	4		
		1021	1359	2249	2431

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	2	2	2	2		
Ageusia	1	1			1	1
Agitation	1	1			1	1
Arthralgia	9	10	4	5	5	5
Arthritis	1	1			1	1
Asthenia	4	4	1	1	3	3
Atrial f brillation	1	1			1	1
Back pain	3	3	2	2	1	1
Balance disorder	2	2	1	1	1	1
Body temperature increased	3	3	1	1	2	2
Bone pain	1	1	1	1		
Bronchospasm	1	1			1	1
Burning sensation	1	1			1	1
Cellulitis		1				1
Chest discomfort	1	1			1	1
Chest pain	4	4	1	1	3	3
Chills	13	13	5	5	8	8
Circumstance or information capable of leading to medication error	1	1	1	1		
Cold sweat	1	1			1	1
Contusion	2	2	1	1	1	1
Coronavirus infection		1				1
Cough	4	4	3	3	1	1
COVID-19	58	58			58	58
Decreased appetite	2	2	1	1	1	1
Diarrhoea	7	8	3	3	4	5
Discomfort	1	1			1	1
Disturbance in attention	1	1	1	1		
Dizziness	11	11	4	4	7	7
Dizziness postural	2	2	1	1	1	1
Drug eruption	1	1			1	1
Drug ineffective	59	61			59	61

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dry mouth	1	2		1	1	1
Dysgeusia	4	4	4	4		
Dyspnoea	3	3	1	1	2	2
Ear infection	1	1			1	1
Ear pain	3	3	2	2	1	1
Epistaxis		1				1
Erythema	1	1			1	1
Exposure via breast milk	3	3	3	3		
Eye irritation	1	1			1	1
Eye pain	1	1			1	1
Facial pain	1	2	1	1		1
Fall	2	2	1	1	1	1
Fatigue	27	31	12	16	15	15
Feeding disorder	1	1			1	1
Feeling abnormal	1	1	1	1		
Feeling hot	2	3	2	3		
Gastrointestinal pain	1	1	1	1		
Haemorrhage	1	1			1	1
Headache	38	41	16	19	22	22
Head injury	1	1	1	1		
Heart rate decreased	1	1	1	1		
Heart rate increased	2	2	1	1	1	1
Hot flush	2	2	2	2		
Hyperhidrosis	3	3			3	3
Hypersensitivity	4	4	2	2	2	2
Hypertension	1	1			1	1
Hypoaesthesia	2	4		1	2	3
Hypoaesthesia oral		1				1
Hypotension	1	1			1	1
Influenza	4	4	1	1	3	3
Influenza like illness	5	5	4	4	1	1
Injection site pain	1	1	1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Insomnia	3	3	1	1	2	2
Joint swelling	1	1			1	1
Labyrinthitis	1	1			1	1
Lacrimation increased	2	2			2	2
Lethargy	5	5	3	3	2	2
Limb discomfort	1	1	1	1		
Lip swelling	2	2			2	2
Liquid product physical issue		2		2		
Loss of consciousness	1	1			1	1
Lymphadenopathy	7	7	4	4	3	3
Lymph node pain	1	1	1	1		
Malaise	10	11	4	5	6	6
Migraine	2	2	2	2		
Mobility decreased	1	1			1	1
Muscle strain	1	1			1	1
Muscular weakness	5	5	1	1	4	4
Musculoskeletal chest pain	1	1			1	1
Musculoskeletal stiffness	4	4	1	1	3	3
Myalgia	14	15	8	9	6	6
Nasal congestion	1	1	1	1		
Nasopharyngitis		1		1		
Nausea	27	29	11	13	16	16
Neck pain	8	9	5	6	3	3
Night sweats	1	1			1	1
No adverse event	1	1	1	1		
Ocular hyperaemia	1	1			1	1
Oral pain		1				1
Oral pruritus	1	1	1	1		
Oropharyngeal pain	4	5	3	4	1	1
Osteoarthritis	1	1	1	1		
Overdose	2	2	2	2		
Oxygen saturation decreased	2	2			2	2

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Gender

**UNKNOWN**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pain	10	12
Pain in extremity	14	18
Pain in jaw	1	1
Pain of skin		1
Pallor	2	2
Palpitations	2	2
Papule		1
Paraesthesia	4	5
Paraesthesia oral	1	1
Peau d'orange	1	1
Peripheral coldness	2	2
Peripheral swelling	4	5
Pharyngeal hypoaesthesia	1	1
Pharyngeal swelling	2	2
Poor quality product administered	3	9
Poor quality sleep	1	1
Presyncope	1	1
Product label confusion		1
Product packaging quantity issue		4
Product preparation error		3
Product preparation issue	2	2
Product temperature excursion issue	3	3
Pruritus	5	6
Pyrexia	20	23
Rash	2	3
Rash erythematous	1	2
Rash macular		1
Retching	2	2
SARS-CoV-2 test positive	1	2
Sinus pain	1	1
Skin warm		1
Sleep disorder		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
4	6	6	6
7	11	7	7
1	1		
			1
1	1	1	1
		2	2
	1		
		4	5
1	1		
1	1		
2	2		
	1	4	4
		1	1
1	1	1	1
3	9		
		1	1
		1	1
	1		
	4		
	3		
2	2		
3	3		
2	3	3	3
11	14	9	9
1	2	1	1
1	2		
	1		
		2	2
		1	2
1	1		
			1
	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Suspected COVID-19	1	1			1	1
Swelling	1	1	1	1		
Swelling face	2	2			2	2
Syncope	4	4			4	4
Tachycardia	2	2			2	2
Taste disorder	1	1	1	1		
Throat irritation	1	2	1	2		
Throat tightness	1	1			1	1
Tinnitus	1	2			1	2
Tremor	3	3			3	3
Underdose		3		3		
Urinary tract infection	1	1			1	1
Urticaria	2	2	1	1	1	1
Vaccination site bruising	2	2			2	2
Vaccination site cellulitis		1		1		
Vaccination site erythema	3	4	3	4		
Vaccination site mass	2	2	1	1	1	1
Vaccination site movement impairment	1	1			1	1
Vaccination site pain	15	17	8	10	7	7
Vaccination site paraesthesia	1	1			1	1
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	3	6	3	6		
Vaccination site warmth	3	4	2	3	1	1
Vertigo	2	2			2	2
Viral infection	1	1	1	1		
Vision blurred	2	2			2	2
Vomiting	6	7		1	6	6
	1	1	1	1		
	577	655	207	270	370	385

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Country Where Event Occurred  
**UNITED STATES**

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	33	47	33	47		
Abdominal distension	4	8	4	8		
Abdominal pain	45	57	43	53	2	4
Abdominal pain lower	2	6	2	4		2
Abdominal pain upper	49	58	45	54	4	4
Abdominal rigidity	1	2	1	1		1
Abnormal behaviour	1	1			1	1
Abnormal dreams	7	9	7	9		
Abnormal sensation in eye	2	3	2	3		
Abortion spontaneous	6	6			6	6
Acarodermatitis	1	1	1	1		
Accidental exposure to product	6	10	5	9	1	1
Accidental overdose	3	8	3	7		1
Acne	3	4	3	4		
Acute disseminated encephalomyelitis	1	1			1	1
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Adnexa uteri pain	1	1	1	1		
Ageusia	34	50	30	45	4	5
Aggression	1	1	1	1		
Agitation	2	4	2	4		
Alanine aminotransferase increased	1	1			1	1
Allergy to vaccine	12	26	8	17	4	9
Allodynia	1	1	1	1		
Alopecia	2	2	2	2		
Amnesia	4	5	2	3	2	2
Anaesthesia		1		1		
Anal incontinence	1	1	1	1		
Anaphylactic reaction	48	67			48	67
Anaphylactic shock	1	1			1	1
Anaphylactoid reaction	1	3			1	3
Anger	2	2	2	2		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Angioedema	4	11
Animal bite	1	1
Anosmia	28	45
Anxiety	35	54
Aphasia	5	5
Aphonia		1
Appendicitis	3	4
Aptyalism		1
Arrhythmia	2	3
Arthralgia	385	492
Arthritis	13	14
Arthropathy	2	2
Arthropod bite	3	3
Aspartate aminotransferase increased	1	1
Asthenia	186	241
Asthenopia	5	7
Asthma	8	10
Asymptomatic COVID-19	1	4
Atrial f brillation	4	4
Aura	1	1
Auricular swelling	1	1
Autoimmune disorder		3
Autoimmune thyroiditis	1	1
Autonomic nervous system imbalance	1	1
Axillary mass	5	8
Axillary pain	37	41
Back pain	103	133
Balance disorder	14	20
Bedridden	6	6
Bladder discomfort	1	1
Blepharospasm	2	3
Blindness	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		4	11
1	1		
23	39	5	6
31	49	4	5
2	2	3	3
	1		
		3	4
	1		
		2	3
369	470	16	22
13	14		
2	2		
3	3		
1	1		
170	221	16	20
4	6	1	1
7	9	1	1
		1	4
1	1	3	3
1	1		
1	1		
			3
		1	1
		1	1
4	6	1	2
36	40	1	1
96	124	7	9
13	17	1	3
5	5	1	1
1	1		
2	3		
		2	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blindness transient		1				1
Blister	7	12	7	12		
Blood count abnormal		1		1		
Blood disorder	1	1	1	1		
Blood glucose abnormal	2	2	2	2		
Blood glucose decreased	1	2	1	2		
Blood glucose increased	5	5	5	5		
Blood iron decreased	1	1	1	1		
Blood potassium decreased	2	2	1	1	1	1
Blood pressure abnormal	1	2	1	2		
Blood pressure decreased	6	10	4	7	2	3
Blood pressure diastolic decreased	1	1	1	1		
Blood pressure diastolic increased		1				1
Blood pressure fluctuation	2	3	1	2	1	1
Blood pressure increased	49	83	27	49	22	34
Blood pressure systolic increased	5	6	2	2	3	4
Blood testosterone decreased	1	1	1	1		
Blood thyroid stimulating hormone increased	1	1	1	1		
Blood urine present	1	2	1	2		
Body height decreased	3	4	3	4		
Body temperature abnormal	5	6	5	6		
Body temperature decreased	2	3	2	2		1
Body temperature fluctuation	1	1	1	1		
Body temperature increased	25	35	25	35		
Bone pain	25	32	21	28	4	4
Bone swelling	2	4	2	4		
Booster dose missed	2	2	2	2		
Bowel movement irregularity	2	2	2	2		
Brachial plexopathy	1	1			1	1
Bradykinesia		1		1		
Brain injury	2	2			2	2
Brain oedema	1	1			1	1

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast discomfort	2	2	2	2		
Breast mass	1	1	1	1		
Breast milk discolouration	1	1	1	1		
Breast pain	9	9	9	9		
Breast swelling	2	3	2	3		
Breast tenderness	2	3	2	2		1
Bronchitis	1	2	1	1		1
Bronchospasm	3	4	2	3	1	1
Burning sensation	33	46	29	40	4	6
Burn oral cavity	1	1			1	1
Capillary nail refill test abnormal		1		1		
Cardiac arrest	2	2			2	2
Cardiac discomfort		1		1		
Cardiac disorder	3	5	2	4	1	1
Cardiac flutter	2	3			2	3
Cardiac valve sclerosis	1	1			1	1
Cardio-respiratory arrest	1	1			1	1
Cellulitis	3	4			3	4
Central nervous system lesion	1	1	1	1		
Cerebral disorder		1		1		
Cerebral haemorrhage	2	2			2	2
Cerebrovascular accident	7	8			7	8
Chalazion	1	1	1	1		
Chapped lips	2	2	2	2		
Cheilitis		1		1		
Chest discomfort	89	129	60	90	29	39
Chest pain	72	98	50	70	22	28
Chills	870	1,130	836	1087	34	43
Choking	2	2			2	2
Choking sensation	2	2			2	2
Cholecystitis	1	1			1	1
Chromaturia	5	5	5	5		

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Circulatory collapse	3	3
Circumoral swelling	1	1
Circumstance or information capable of leading to device use error	1	1
Circumstance or information capable of leading to medication error	27	33
Cluster headache	1	1
Cognitive disorder	2	3
Cold sweat	17	23
Colitis ulcerative	1	1
Communication disorder		1
Condition aggravated	25	35
Confusional state	18	19
Conjunctival haemorrhage	1	1
Conjunctivitis	2	3
Conjunctivitis allergic	2	2
Conjunctivitis viral	1	1
Constipation	2	3
Contraindication to vaccination	2	2
Contrast media allergy	1	1
Contusion	11	14
Corneal oedema	1	1
Coronavirus test positive	1	1
Costochondritis	1	1
Costovertebral angle tenderness	1	1
Cough	129	180
COVID-19	201	257
COVID-19 pneumonia	2	2
C-reactive protein increased	3	3
Crying	10	12
Crystal urine	1	1
Cyanosis	4	5

Spontaneous			
Nonserious		Serious	
I	C	I	C
		3	3
1	1		
1	1		
27	33		
1	1		
2	3		
13	19	4	4
		1	1
	1		
23	29	2	6
16	17	2	2
		1	1
2	3		
2	2		
1	1		
2	3		
2	2		
1	1		
11	14		
1	1		
		1	1
		1	1
1	1		
110	151	19	29
1	2	200	255
		2	2
2	2	1	1
9	11	1	1
1	1		
2	3	2	2

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cyst	2	2
Deafness	6	8
Deafness neurosensory	1	1
Deafness unilateral	1	3
Death	7	8
Decreased appetite	54	69
Deep vein thrombosis	4	4
Defaecation urgency		1
Dehydration	10	16
Delirium	1	1
Delusional perception	2	2
Demyelinating polyneuropathy	1	1
Dental paraesthesia		2
Dental restoration failure	1	1
Depersonalisation/derealisation disorder	1	1
Depressed level of consciousness	1	2
Depressed mood	5	7
Depression	2	2
Dermatitis	3	3
Dermatitis allergic	3	3
Dermatitis contact	4	4
Dermatitis exfoliative	1	1
Device breakage	1	1
Diabetes mellitus	1	2
Diarrhoea	202	265
Diarrhoea haemorrhagic		1
Diastolic hypotension		1
Diet refusal	1	1
Dilatation ventricular	1	1
Diplopia	2	2
Discomfort	25	33
Disease progression	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
		6	8
		1	1
		1	3
		7	8
50	64	4	5
		4	4
	1		
8	13	2	3
		1	1
1	1	1	1
		1	1
	2		
1	1		
1	1		
		1	2
4	6	1	1
		2	2
3	3		
3	3		
4	4		
		1	1
		1	1
		1	2
195	255	7	10
			1
			1
		1	1
		1	1
1	1	1	1
23	31	2	2
1	1		

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disease recurrence	16	22	14	20	2	2
Disorientation	2	3	2	3		
Dissociation	2	2	1	1	1	1
Disturbance in attention	12	17	11	14	1	3
Dizziness	405	616	358	539	47	77
Dizziness exertional	1	1	1	1		
Dizziness postural	6	8	5	7	1	1
Drooling	1	1	1	1		
Drug eruption		1		1		
Drug hypersensitivity	7	8	7	7		1
Drug ineffective	298	400	3	3	295	397
Drug interaction	4	4	4	4		
Dry eye	3	3	3	3		
Dry mouth	16	28	14	25	2	3
Dry skin	2	3	2	3		
Dry throat	12	17	10	13	2	4
Dysaesthesia		1		1		
Dysarthria	2	5	1	4	1	1
Dysgeusia	60	88	58	86	2	2
Dyskinesia	3	4	2	2	1	2
Dysmenorrhoea	3	4	3	4		
Dyspepsia	7	10	7	10		
Dysphagia	24	31	10	15	14	16
Dysphonia	14	20	7	9	7	11
Dyspnoea	172	232	112	150	60	82
Dyspnoea exertional	6	9	4	7	2	2
Dysstasia	6	7	4	4	2	3
Dystonia	1	1			1	1
Dysuria	2	3	2	3		
Ear congestion	2	2	1	1	1	1
Ear discomfort	11	17	11	17		
Ear disorder	2	2	2	2		

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**FEMALE**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Ear infection	1	2
Ear neoplasm	1	1
Ear pain	34	48
Ear pruritus	3	3
Ear swelling	2	5
Eating disorder	6	9
Eczema		2
Electrocardiogram abnormal	2	2
Electrocardiogram QT prolonged		1
Emotional disorder	3	5
Emotional distress	1	1
Enanthema		1
Encephalopathy	1	1
Energy increased	2	2
Enlarged uvula	3	4
Eosinophil count increased	2	2
Eosinophilia	1	1
Epicondylitis	2	2
Epinephrine increased		1
Episcleritis	2	2
Epistaxis	12	16
Erythema	87	123
Erythema of eyelid	3	4
Escherichia infection	1	1
Exercise lack of	1	1
Expired product administered	1	1
Exposure during pregnancy	12	15
Exposure to SARS-CoV-2	23	30
Exposure via breast milk	3	7
Exposure via eye contact		1
Exposure via skin contact	6	8
Extensive swelling of vaccinated limb		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	2		
1	1		
33	46	1	2
3	3		
2	5		
5	7	1	2
	2		
2	2		
			1
3	5		
		1	1
	1		
		1	1
2	2		
1	1	2	3
		2	2
1	1		
2	2		
11	15	1	1
76	107	11	16
3	4		
		1	1
1	1		
1	1		
11	14	1	1
16	23	7	7
3	7		
	1		
5	7	1	1
	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Extrasystoles	1	2	1	2		
Extremity contracture	1	1	1	1		
Eye allergy	1	1	1	1		
Eye contusion	3	3	3	3		
Eye discharge	1	3	1	3		
Eye disorder	8	11	7	9	1	2
Eye haemorrhage	2	4			2	4
Eye infection		1		1		
Eye inflammation	3	3	1	1	2	2
Eye irritation	12	15	12	14		1
Eyelid disorder	1	2	1	2		
Eyelid function disorder		1		1		
Eyelid irritation	1	1	1	1		
Eyelid oedema	1	1	1	1		
Eyelid pain	1	1	1	1		
Eyelid ptosis	1	2	1	1		1
Eyelid sensory disorder	1	1	1	1		
Eyelids pruritus	2	4	1	3	1	1
Eye movement disorder	1	2	1	1		1
Eye oedema	3	3	3	3		
Eye pain	27	37	22	32	5	5
Eye paraesthesia	1	1			1	1
Eye pruritus	7	14	5	11	2	3
Eye swelling	25	34	22	31	3	3
Face injury	2	3	2	2		1
Face oedema		2		1		1
Facial discomfort		2		2		
Facial nerve disorder	1	1	1	1		
Facial pain	16	20	15	18	1	2
Facial paralysis	29	41			29	41
Facial paresis	5	5	2	2	3	3
Faeces discoloured	1	1	1	1		

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fall	10	16	7	11	3	5
Fatigue	819	1,109	794	1079	25	30
Fear	6	9	6	8		1
Febrile convulsion	1	1			1	1
Feeding disorder	4	5	3	4	1	1
Feeling abnormal	144	189	134	174	10	15
Feeling cold	52	70	49	66	3	4
Feeling drunk	3	3	3	3		
Feeling hot	101	150	89	132	12	18
Feeling jittery	5	8	4	6	1	2
Feeling of body temperature change	14	18	13	17	1	1
Fibrin D dimer increased	1	2	1	2		
Fine motor skill dysfunction	2	3	2	3		
Flank pain	2	2	2	2		
Flatulence	5	7	5	7		
Fluid imbalance	1	1			1	1
Flushing	74	138	52	101	22	37
Food allergy		1		1		
Food aversion	1	1	1	1		
Food poisoning		1		1		
Foreign body aspiration		1				1
Formication	2	2	2	2		
Fracture		1				1
Freezing phenomenon		1		1		
Frequent bowel movements	3	3	3	3		
Frostbite	1	1	1	1		
Frustration tolerance decreased	1	2	1	2		
Fungal infection	3	3	3	3		
Furuncle	1	1	1	1		
Gait disturbance	27	35	22	29	5	6
Gait inability	7	9	6	7	1	2
Gal bladder disorder	1	2		1	1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastric pH decreased	1	1	1	1		
Gastritis	1	1	1	1		
Gastroenteritis viral		1				1
Gastrointestinal disorder	9	11	8	10	1	1
Gastrointestinal pain	5	6	5	6		
Gastrointestinal sounds abnormal	2	2	2	2		
Gastrointestinal viral infection	1	1	1	1		
Gastroesophageal reflux disease	2	2	2	2		
Gastroesophageal sphincter insufficiency	1	1			1	1
General physical health deterioration	1	1			1	1
Giant cell arteritis	1	1	1	1		
Gingival bleeding	1	3	1	3		
Gingival blister	1	1	1	1		
Gingival discomfort		1				1
Gingival disorder	1	1	1	1		
Gingival erythema	2	2	2	2		
Gingival pain	3	4	3	3		1
Gingival swelling	4	4	4	4		
Glare	1	1	1	1		
Glassy eyes		1		1		
Glaucoma	1	1			1	1
Glossitis	2	3	2	3		
Glossodynia	4	6	4	6		
Grip strength decreased	1	2	1	2		
Groin pain	1	1	1	1		
Grunting	1	1			1	1
Guillain-Barre syndrome	2	2			2	2
Haematochezia	6	6			6	6
Haematocrit decreased	1	1	1	1		
Haemoglobin decreased	2	2	1	1	1	1
Haemoglobin increased	1	1	1	1		
Haemoptysis	4	4	2	2	2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Haemorrhage	1	3
Haemorrhoids	1	1
Hallucination		1
Hallucination, auditory	2	2
Hallucination, visual	2	2
Hand-eye coordination impaired	1	1
Hangover	2	3
Headache	1,198	1,605
Head discomfort	19	27
Head injury	3	4
Heart rate abnormal	1	2
Heart rate decreased	1	3
Heart rate increased	126	201
Heart rate irregular	2	5
Hemiparesis	1	1
Hemiplegia	1	1
Hepatic pain		1
Herpes simplex		1
Herpes virus infection	4	5
Herpes zoster	23	27
Hidradenitis	1	2
Hordeolum	1	3
Hot flush	34	52
Hunger	2	4
Hydrophobia	1	1
Hyperacusis	3	4
Hyperaemia		1
Hyperaesthesia	10	13
Hyperaesthesia teeth	2	2
Hyperglycaemia	2	2
Hyperhidrosis	95	135
Hyperpyrexia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	3
1	1		
			1
		2	2
		2	2
		1	1
2	3		
1138	1528	60	77
18	25	1	2
3	4		
1	2		
1	2		1
93	153	33	48
2	4		1
		1	1
		1	1
	1		
	1		
4	5		
22	26	1	1
1	2		
1	3		
30	46	4	6
2	4		
1	1		
3	4		
	1		
9	12	1	1
2	2		
1	1	1	1
89	125	6	10
			1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersensitivity	49	68	37	48	12	20
Hypersomnia	18	25	16	23	2	2
Hypertension	34	55	19	32	15	23
Hypertensive crisis	1	1			1	1
Hypertensive emergency	1	3			1	3
Hypertonia		1		1		
Hyperventilation	4	7	3	4	1	3
Hypoacusis	6	8	6	8		
Hypoesthesia	148	210	119	174	29	36
Hypoesthesia oral	51	74	39	59	12	15
Hypocalcaemia	1	1			1	1
Hypogeusia	1	3	1	3		
Hypoglycaemia	2	3	2	3		
Hypokalaemia	1	1			1	1
Hypokinesia	3	3	3	3		
Hypomagnesaemia	1	1			1	1
Hypopnoea	2	2	1	1	1	1
Hyposmia	1	4	1	4		
Hypotension	12	14	8	10	4	4
Hypothermia	1	1			1	1
Hypothyroidism	2	2			2	2
Hypotonia	1	1	1	1		
Illness	47	64	43	60	4	4
Illness anxiety disorder	1	1	1	1		
Immune-mediated arthritis		1				1
Immune system disorder		1				1
Immunodeficiency	1	2			1	2
Impaired driving ability	2	2	2	2		
Impaired work ability	4	5	4	5		
Impulsive behaviour	1	1	1	1		
Inappropriate schedule of product administration	189	192	189	192		
Incoherent	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Incomplete course of vaccination	5	5	5	5		
Incontinence	1	1	1	1		
Incorrect dose administered	5	6	4	5	1	1
Incorrect route of product administration	28	38	26	36	2	2
Increased appetite	1	1	1	1		
Increased upper airway secretion	3	4	3	3		1
Induration	1	2	1	2		
Infant irritability		1		1		
Infection	1	2	1	2		
Infection parasitic	1	1	1	1		
Inflammation	7	12	7	11		1
Inflammatory pain	1	1	1	1		
Influenza	16	24	16	23		1
Influenza B virus test positive	1	1	1	1		
Influenza like illness	73	91	72	90	1	1
Initial insomnia		1		1		
Injected limb mobility decreased	2	2	2	2		
Injection site erythema	2	2	2	2		
Injection site hypoaesthesia		1		1		
Injection site joint movement impairment	1	1			1	1
Injection site pain	7	11	6	10	1	1
Injection site rash	2	3	2	3		
Injection site swelling	3	3	3	3		
Injection site urticaria		1		1		
Insomnia	65	79	62	76	3	3
International normalised ratio increased	1	1			1	1
Intestinal obstruction		1				1
Intranasal paraesthesia	1	2	1	2		
Intraocular pressure increased	1	1	1	1		
Irregular sleep wake rhythm disorder		1		1		
Irritability	6	7	5	6	1	1
Irritability postvaccinal	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Jaundice	1	1	1	1		
Joint dislocation	1	2			1	2
Joint effusion	1	1	1	1		
Joint instability	1	2			1	2
Joint noise	1	1	1	1		
Joint range of motion decreased	13	20	10	17	3	3
Joint stiffness	9	11	9	10		1
Joint swelling	15	23	13	21	2	2
Kidney infection	1	1			1	1
Labile hypertension	1	1	1	1		
Labyrinthitis		1				1
Lacrimation increased	6	8	6	8		
Laryngeal oedema	1	2			1	2
Laryngeal pain	1	1	1	1		
Laryngitis	1	2	1	2		
Laryngospasm	2	2			2	2
Laziness	1	2	1	2		
Lethargy	34	41	34	41		
Leukocytosis	1	1	1	1		
Ligament injury	2	2	2	2		
Ligament sprain	1	1	1	1		
Limb discomfort	35	50	32	45	3	5
Limb injury	3	4	3	4		
Limb mass	1	1	1	1		
Lip blister	2	3	2	3		
Lip disorder	1	2	1	2		
Lip dry	1	1	1	1		
Lip erythema	1	3	1	3		
Lip exfoliation	1	1	1	1		
Lipids increased		1		1		
Lip injury	2	2	1	1	1	1
Lip oedema	1	3	1	2		1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lip pain		2		1		1
Lip pruritus	3	4	3	4		
Lip swelling	34	50	23	32	11	18
Livedo reticularis	2	3	1	1	1	2
Liver injury	1	1			1	1
Localised oedema	1	2	1	2		
Local reaction		1		1		
Loss of consciousness	26	31			26	31
Loss of personal independence in daily activities	18	23	16	20	2	3
Loss of proprioception	1	1			1	1
Lower respiratory tract congestion		1		1		
Lower respiratory tract infection	1	1			1	1
Lung disorder	2	2	2	2		
Lymphadenitis	4	6	4	6		
Lymphadenopathy	266	326	250	305	16	21
Lymph gland infection	1	1	1	1		
Lymph node pain	58	74	54	70	4	4
Lymph node palpable	1	1	1	1		
Lymphoedema	5	7	5	7		
Macule	1	1	1	1		
Malaise	253	350	238	333	15	17
Mania	1	1			1	1
Mass	5	5	5	5		
Mastitis		1				1
Maternal exposure during pregnancy	48	71	47	70	1	1
Maternal exposure timing unspecified	1	1	1	1		
Mechanical urticaria		1		1		
Memory impairment	7	10	4	6	3	4
Meningism	1	1	1	1		
Menorrhagia	1	1	1	1		
Menstrual disorder	8	9	8	9		
Menstruation irregular	8	8	8	8		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Mental disorder	3	4	2	3	1	1
Mental impairment	8	13			8	13
Metrorrhagia	3	4	3	4		
Microembolism	1	1			1	1
Micturition urgency	1	1	1	1		
Middle insomnia	10	12	10	11		1
Migraine	72	87	66	80	6	7
Migraine with aura	1	1	1	1		
Mixed connective tissue disease	1	1			1	1
Mobility decreased	12	19	11	17	1	2
Mononeuropathy	1	1			1	1
Motion sickness		1		1		
Motor dysfunction	2	2			2	2
Mouth swelling	3	7	2	4	1	3
Mouth ulceration	1	2	1	2		
Movement disorder	12	14	12	14		
Mucosal disorder	1	1	1	1		
Muscle atrophy	1	1	1	1		
Muscle contractions involuntary	1	1			1	1
Muscle discomfort	3	4	3	4		
Muscle disorder	2	2	2	2		
Muscle fatigue	3	4	3	4		
Muscle spasms	52	63	46	57	6	6
Muscle strain		1		1		
Muscle swelling	1	1	1	1		
Muscle tightness	25	33	24	31	1	2
Muscle twitching	11	13	10	12	1	1
Muscular weakness	40	50	32	41	8	9
Musculoskeletal chest pain	7	14	7	14		
Musculoskeletal discomfort	13	17	12	16	1	1
Musculoskeletal disorder	3	4	2	3	1	1
Musculoskeletal pain	5	6	4	5	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Musculoskeletal stiffness	51	61	50	59	1	2
Mutism	1	1			1	1
Myalgia	447	588	429	567	18	21
Mydriasis	1	1	1	1		
Myelitis transverse	1	1			1	1
Myocardial infarction	3	5			3	5
Myocardial necrosis marker increased	1	2			1	2
Myocarditis	1	1			1	1
Myopathy	1	1	1	1		
Myopia	1	1	1	1		
Myositis	1	1			1	1
Nasal congestion	62	92	55	83	7	9
Nasal discomfort	1	3	1	2		1
Nasal disorder		1		1		
Nasal injury	2	2	2	2		
Nasal oedema	4	6	4	5		1
Nasopharyngitis	32	46	30	44	2	2
Nausea	607	827	572	777	35	50
Neck injury		1		1		
Neck mass	2	2	2	2		
Neck pain	114	139	110	134	4	5
Needle issue		1		1		
Neoplasm skin	1	1	1	1		
Nephrolithiasis	1	1			1	1
Nerve compression	5	5	5	5		
Nerve injury		1		1		
Nervousness	14	25	14	24		1
Neuralgia	18	20	17	19	1	1
Neuropathy peripheral	8	9			8	9
Neutrophil count increased	1	1			1	1
Nightmare	5	5	5	5		
Night sweats	24	31	23	29	1	2

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Nipple pain	2	2
Nipple swelling		1
No adverse event	1	1
Nuchal rigidity	1	2
Nystagmus	2	2
Obstructive airways disorder	1	2
Occupational exposure to SARS-CoV-2	4	5
Ocular discomfort	7	8
Ocular hyperaemia	12	17
Odynophagia	4	4
Oedema	4	5
Oedema peripheral	7	8
Off label use	157	206
Oligodipsia	1	1
Optic neuritis	1	1
Oral candidiasis	1	2
Oral discomfort	3	7
Oral disorder	3	5
Oral herpes	7	12
Oral mucosal blistering	1	3
Oral mucosal eruption	2	5
Oral mucosal erythema	1	2
Oral pain	3	6
Oral pruritus	4	7
Oral viral infection		1
Oropharyngeal discomfort	6	14
Oropharyngeal pain	111	164
Orthopnoea	1	1
Orthostatic heart rate response increased	1	1
Orthostatic hypotension	1	1
Osteochondritis	1	1
Overdose	9	13

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
	1		
1	1		
1	2		
1	1	1	1
1	1		1
4	5		
4	5	3	3
12	17		
4	4		
3	4	1	1
6	7	1	1
156	205	1	1
		1	1
		1	1
1	2		
3	6		1
3	5		
6	11	1	1
1	3		
2	5		
1	2		
3	6		
4	7		
	1		
5	9	1	5
102	151	9	13
1	1		
1	1		
		1	1
1	1		
9	13		

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Overweight	1	1	1	1		
Oxygen saturation decreased	10	11	5	6	5	5
Pain	749	959	713	917	36	42
Painful respiration	2	3	2	3		
Pain in extremity	524	707	516	693	8	14
Pain in jaw	20	27	18	25	2	2
Pain of skin	8	10	8	10		
Palatal disorder	1	1	1	1		
Palatal swelling	2	3	2	2		1
Pallor	10	16	8	12	2	4
Palmar erythema	3	4	2	3	1	1
Palpitations	77	125	58	93	19	32
Pancreatitis		1				1
Pancreatitis acute	1	1			1	1
Panic attack	2	4	1	2	1	2
Panic reaction	4	5	4	4		1
Papule	1	2	1	2		
Paraesthesia	167	256	144	223	23	33
Paraesthesia ear		1		1		
Paraesthesia mucosal		1		1		
Paraesthesia oral	65	105	53	87	12	18
Paralysis	4	4			4	4
Paranasal sinus discomfort	10	11	10	11		
Paranasal sinus hypersecretion	1	1	1	1		
Paranoia	1	2	1	2		
Parosmia	7	14	7	13		1
Pelvic pain	2	2	2	2		
Periarthritis	2	2	1	1	1	1
Pericardial effusion	1	1			1	1
Pericarditis	1	1			1	1
Periorbital discomfort		1		1		
Periorbital swelling	3	9	3	8		1

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral coldness	13	27	13	26		1
Peripheral swelling	84	113	83	109	1	4
Peripheral vascular disorder	1	1	1	1		
Pertussis		1				1
Petechiae	8	8	7	7	1	1
Pharyngeal disorder	3	3	3	3		
Pharyngeal erythema	4	4	4	4		
Pharyngeal hypoesthesia	4	7	1	4	3	3
Pharyngeal inflammation	1	1	1	1		
Pharyngeal oedema	2	2			2	2
Pharyngeal paraesthesia	9	16	3	10	6	6
Pharyngeal swelling	32	49	19	28	13	21
Pharyngitis		1		1		
Pharyngitis streptococcal		1		1		
Phlebitis	1	1	1	1		
Photophobia	11	17	10	16	1	1
Photopsia	2	2	2	2		
Photosensitivity reaction	4	7	4	7		
Piloerection	3	5	2	4	1	1
Platelet count decreased	1	1			1	1
Platelet count increased	4	4	2	2	2	2
Pleural effusion	2	2	1	1	1	1
Pleuritic pain	1	2	1	2		
Pneumonia	6	7			6	7
Pneumonitis	1	1	1	1		
PO2 decreased	2	2	1	1	1	1
Pollakiuria	4	4	4	4		
Polydipsia	2	2	2	2		
Polymyalgia rheumatica	1	1			1	1
Polyneuropathy	1	1			1	1
Polyuria	1	1	1	1		
Poor peripheral circulation	1	2		1	1	1

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**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Poor quality product administered	6	6
Poor quality sleep	9	14
Postictal state		1
Post-traumatic stress disorder	1	2
Postural orthostatic tachycardia syndrome	1	1
Pre-existing condition improved	1	1
Premature rupture of membranes	1	1
Presyncope	26	40
Procedural pain	2	2
Product administered at inappropriate site	16	25
Product administered to patient of inappropriate age	1	2
Product administration error	2	2
Product confusion	1	1
Product dose omission issue	1	1
Product formulation issue		1
Productive cough	7	10
Product leakage	2	4
Product preparation error	8	14
Product preparation issue	1	5
Product prescribing error	2	4
Product temperature excursion issue	3	3
Product use issue	150	202
Pruritus	184	268
Pruritus genital	1	1
Psoriasis		1
Psychiatric symptom	1	1
Psychomotor hyperactivity	1	1
Pulmonary congestion	1	2
Pulmonary embolism	1	1
Pulmonary oedema		1
Pulmonary pain	2	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
6	6		
9	14		
	1		
1	2		
1	1		
1	1		
		1	1
19	30	7	10
1	1	1	1
15	24	1	1
1	2		
2	2		
1	1		
1	1		
			1
7	10		
2	4		
8	13		1
1	4		1
2	4		
3	3		
148	200	2	2
162	239	22	29
		1	1
	1		
1	1		
1	1		
		1	2
		1	1
			1
2	3		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pulse abnormal	7	9	5	7	2	2
Pupillary disorder	1	1	1	1		
Purpura	1	1	1	1		
Pustule	1	1	1	1		
Pyrexia	889	1,146	843	1089	46	57
Rash	163	234	141	199	22	35
Rash erythematous	29	41	24	32	5	9
Rash macular	24	34	22	30	2	4
Rash maculo-papular	4	5	4	5		
Rash papular	15	18	15	18		
Rash pruritic	28	40	26	37	2	3
Rash pustular		1		1		
Rash vesicular	7	7	6	6	1	1
Raynaud's phenomenon	1	1	1	1		
Reaction to excipient	3	3	2	2	1	1
Rectal haemorrhage	1	1			1	1
Red blood cell count decreased	1	1	1	1		
Red blood cell sedimentation rate increased	1	1	1	1		
Reduced facial expression		1		1		
Renal impairment	1	1			1	1
Renal pain	4	5	4	5		
Respiration abnormal	1	1	1	1		
Respiratory arrest	1	1			1	1
Respiratory disorder	1	1	1	1		
Respiratory distress	6	7			6	7
Respiratory failure	1	1			1	1
Respiratory rate decreased		1				1
Respiratory rate increased	3	5	1	2	2	3
Respiratory symptom		1				1
Respiratory tract congestion	8	9	8	9		
Respiratory tract infection	1	1			1	1
Restless legs syndrome	2	2	2	2		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Restlessness	10	11
Retching	7	8
Rheumatoid arthritis	1	2
Rhinalgia	3	3
Rhinitis	1	1
Rhinorrhoea	60	78
Rhinovirus infection	1	1
Right ventricular dysfunction	1	1
Rosacea	1	1
Rubber sensitivity	1	1
Salivary gland pain	1	1
Salivary hypersecretion	2	2
SARS-CoV-2 ant body test negative	4	4
SARS-CoV-2 ant body test positive	2	2
SARS-CoV-2 test positive	87	130
Scab		1
Scar	1	1
Sciatica	1	1
Scleritis	1	1
Scratch	3	4
Screaming	2	2
Seasonal allergy	3	3
Secretion discharge		1
Sedation	1	2
Seizure	3	5
Sensation of foreign body	15	20
Sensitisation	1	1
Sensitive skin	6	6
Sensory disturbance	4	4
Sensory loss	3	4
Sepsis	2	2
Serum sickness		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
8	9	2	2
6	7	1	1
		1	2
3	3		
1	1		
55	73	5	5
1	1		
		1	1
1	1		
1	1		
1	1		
2	2		
4	4		
2	2		
3	4	84	126
	1		
1	1		
1	1		
		1	1
1	2	2	2
1	1	1	1
3	3		
	1		
1	2		
		3	5
11	13	4	7
1	1		
6	6		
4	4		
3	4		
		2	2
			1

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Shock symptom	1	2
Sinus congestion	9	11
Sinus disorder	6	7
Sinus headache	2	5
Sinusitis	4	8
Sinus pain	3	3
Sinus tachycardia	5	5
Skin burning sensation	8	8
Skin discolouration	8	12
Skin disorder	9	12
Skin exfoliation	4	4
Skin indentation	1	1
Skin injury	1	1
Skin irritation	6	7
Skin laceration	1	2
Skin lesion	1	1
Skin reaction	3	3
Skin swelling	2	2
Skin tightness	1	3
Skin warm	2	2
Sleep disorder	10	12
Sleep disorder due to a general medical condition	1	2
Sleep disorder due to general medical condition, insomnia type	1	2
Sleep paralysis	1	1
Sluggishness	4	4
Small intestinal obstruction		1
Sneezing	18	22
Snoring	1	2
Soft tissue swelling		1
Somnolence	50	69

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
9	11		
6	7		
2	5		
4	8		
3	3		
2	2	3	3
8	8		
8	10		2
9	11		1
3	3	1	1
1	1		
1	1		
6	7		
1	2		
1	1		
2	2	1	1
2	2		
	2	1	1
2	2		
10	12		
1	2		
1	2		
1	1		
4	4		
			1
18	22		
	1	1	1
	1		
44	63	6	6

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Speech disorder	13	17	11	15	2	2
Spinal fusion surgery	1	1			1	1
Spinal pain	7	10	7	10		
Sputum discoloured	2	2	1	1	1	1
Staring		1				1
Status asthmaticus	1	1			1	1
Stevens-Johnson syndrome	1	1			1	1
Stiff tongue		1				1
Stomatitis	10	11	9	10	1	1
Strawberry tongue		1		1		
Streptococcal infection		1				1
Streptococcus test positive		1		1		
Stress	6	7	6	7		
Stridor	3	4			3	4
Sudden death	1	1			1	1
Sudden hearing loss	2	2			2	2
Sunburn	2	2	2	2		
Superficial vein prominence	1	1	1	1		
Suppressed lactation	1	1	1	1		
Supraventricular tachycardia	2	3	1	1	1	2
Suspected COVID-19	15	21	4	6	11	15
Suture related complication	1	1			1	1
Swelling	75	91	68	82	7	9
Swelling face	47	74	39	61	8	13
Swelling of eyelid	8	14	8	14		
Swollen tongue	28	40	16	23	12	17
Syncope	22	32			22	32
Systemic lupus erythematosus	1	1			1	1
Systemic scleroderma		1				1
Tachycardia	78	124	50	82	28	42
Tachyphrenia	3	3	3	3		
Tachypnoea	2	5	1	2	1	3

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**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Taste disorder	8	17	7	16	1	1
Tearfulness	1	1	1	1		
Tenderness	11	16	11	16		
Tendonitis		1		1		
Tendon pain	2	2	2	2		
Tension headache	1	2	1	2		
Terminal insomnia	2	3	2	3		
Tetany	1	2			1	2
Therapeutic response unexpected	5	5	5	5		
Thinking abnormal	3	5	3	5		
Thirst	13	15	13	15		
Throat clearing	1	2	1	1		1
Throat irritation	46	72	35	57	11	15
Throat tightness	48	77	23	36	25	41
Thrombocytopenia	2	2			2	2
Thrombosis	1	1			1	1
Thyroid disorder	2	2	2	2		
Tic	1	1	1	1		
Tinnitus	33	44	26	36	7	8
Tongue blistering	1	1	1	1		
Tongue discolouration	2	3	2	3		
Tongue discomfort	7	11	6	10	1	1
Tongue disorder	2	7		5	2	2
Tongue dry		1		1		
Tongue erythema	2	2	2	2		
Tongue haematoma		1		1		
Tongue haemorrhage	1	1	1	1		
Tongue injury	1	1	1	1		
Tongue movement disturbance	1	1			1	1
Tongue oedema	1	1			1	1
Tongue pruritus	5	7	5	6		1
Tongue ulceration	1	1	1	1		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tonsillar erythema	1	1	1	1		
Tonsillar hypertrophy	2	3	2	3		
Tonsillolith	1	1	1	1		
Toothache	6	11	6	11		
Tracheomalacia		1				1
Transient ischaemic attack	1	2			1	2
Tremor	75	106	61	87	14	19
Trigeminal neuralgia	2	2	1	1	1	1
Trigeminal neuritis	1	1	1	1		
Trismus	3	3	3	3		
Troponin increased	2	2			2	2
Tryptase increased	1	1	1	1		
Tuberculosis	2	2			2	2
Tunnel vision	2	3			2	3
Type IV hypersensitivity reaction	1	1	1	1		
Ulcer	1	1	1	1		
Underdose	17	26	17	26		
Undifferentiated connective tissue disease		1				1
Unresponsive to stimuli	2	2			2	2
Upper-airway cough syndrome	3	6	3	6		
Upper respiratory tract congestion	10	19	9	18	1	1
Upper respiratory tract infection	1	1	1	1		
Urge incontinence		1		1		
Urinary incontinence	1	2	1	2		
Urinary retention	1	1			1	1
Urinary tract infection	7	9	6	8	1	1
Urine output increased	1	1	1	1		
Urticaria	149	210	112	165	37	45
Uterine contractions during pregnancy	1	1	1	1		
Uterine haemorrhage	1	1			1	1
Vaccination site bruising	16	22	15	21	1	1
Vaccination site cellulitis	3	4	2	2	1	2

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Gender

**FEMALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination site discharge	1	1
Vaccination site discolouration	4	4
Vaccination site discomfort	10	17
Vaccination site erythema	159	208
Vaccination site extravasation	2	2
Vaccination site haemorrhage	5	10
Vaccination site hyperaesthesia	1	1
Vaccination site hypersensitivity	2	2
Vaccination site hypoaesthesia	10	12
Vaccination site induration	15	25
Vaccination site infection	4	4
Vaccination site inflammation	7	8
Vaccination site injury	1	1
Vaccination site irritation	1	1
Vaccination site joint movement impairment	6	6
Vaccination site joint pain	3	3
Vaccination site lymphadenopathy	4	4
Vaccination site macule	2	3
Vaccination site mass	30	32
Vaccination site movement impairment	14	24
Vaccination site nodule	8	10
Vaccination site oedema		1
Vaccination site pain	553	821
Vaccination site pallor	1	1
Vaccination site papule	1	1
Vaccination site paraesthesia	8	16
Vaccination site pruritus	72	92
Vaccination site rash	16	25
Vaccination site reaction	6	7
Vaccination site scab	2	2
Vaccination site swelling	133	171
Vaccination site urticaria	11	17

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
4	4		
9	16	1	1
155	203	4	5
2	2		
5	10		
1	1		
2	2		
10	12		
15	25		
4	4		
7	7		1
1	1		
5	5	1	1
2	2	1	1
4	4		
2	3		
27	29	3	3
14	24		
8	10		
	1		
539	806	14	15
1	1		
1	1		
6	13	2	3
69	89	3	3
16	25		
6	7		
2	2		
130	167	3	4
11	17		

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site vesicles	6	8	6	8		
Vaccination site warmth	70	83	68	81	2	2
Vaginal haemorrhage	6	7	2	3	4	4
Vaginal infection		1		1		
Varicella		1		1		
Varicella zoster virus infection		1		1		
Varicose vein	1	1	1	1		
Vascular pain	1	1	1	1		
Vasodilatation		1		1		
Vein discoloration	1	1	1	1		
Ventricular extrasystoles		5		3		2
Ventricular tachycardia	1	1			1	1
Vertigo	38	50	38	48		2
Vertigo positional	1	2		1	1	1
Viral rash		1		1		
Vision blurred	33	43	27	34	6	9
Visual field defect	1	1	1	1		
Visual impairment	10	16	9	14	1	2
Vomiting	161	224	154	212	7	12
Vomiting projectile	1	2	1	2		
Vulvovaginal mycotic infection	1	1	1	1		
Vulvovaginal pruritus	1	1			1	1
Vulvovaginal rash	1	1			1	1
Vulvovaginal swelling	1	1			1	1
Weight decreased	9	12	6	9	3	3
Weight increased	2	4	2	4		
Wheezing	15	23	7	11	8	12
White blood cell count increased	2	3			2	3
Wound	1	1	1	1		
Wound haemorrhage	1	1			1	1
Wrong product administered	3	4	3	4		
Wrong technique in product usage process	7	11	6	10	1	1

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Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	17,624	23,986	15236	20713	2388	3273

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	8	8	6	6	2	2
Abdominal distension	4	4	3	3	1	1
Abdominal pain	6	11	6	10		1
Abdominal pain lower		1		1		
Abdominal pain upper	10	13	10	13		
Abnormal dreams	1	1	1	1		
Abnormal faeces	1	1	1	1		
Abnormal sensation in eye	1	1	1	1		
Accidental exposure to product	2	3	2	3		
Accidental overdose		3		3		
Accidental underdose	1	2	1	2		
Acoustic neuritis		1				1
Acute myocardial infarction	2	2			2	2
Ageusia	8	13	7	11	1	2
Agitation	1	3	1	3		
Allergy to vaccine	3	5	2	3	1	2
Alopecia	1	1	1	1		
Amnesia	1	1	1	1		
Anaphylactic reaction	1	3			1	3
Anaphylactic shock		2				2
Anger	1	1	1	1		
Angioedema	1	1			1	1
Anosmia	14	19	13	16	1	3
Anxiety	6	8	6	7		1
Aphasia		2		2		
Aphonia	1	1	1	1		
Aphthous ulcer	2	2	2	2		
Appendicitis	1	2			1	2
Arrhythmia	1	1			1	1
Arteriospasm coronary	1	1			1	1
Arthralgia	88	121	84	117	4	4
Arthritis	4	4	3	3	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Arthropathy	1	3
Arthropod bite	1	1
Asthenia	47	63
Asthenopia	1	1
Asthma	1	1
Asymptomatic COVID-19		1
Ataxia		1
Atrial f brillation	3	3
Autoimmune disorder	1	1
Axillary mass	1	2
Axillary pain	7	11
Back pain	30	39
Balance disorder	7	9
Basal ganglia haemorrhage	1	2
Bedridden	1	1
Bilirubin urine present	1	1
Blepharochalasis	1	1
Blepharospasm	1	1
Blindness	1	2
Blister	5	6
Blood creatinine increased	1	1
Blood glucose decreased	1	1
Blood glucose fluctuation	1	1
Blood glucose increased	5	6
Blood pressure abnormal		1
Blood pressure diastolic increased	1	2
Blood pressure increased	9	13
Blood urine present	2	2
Body height decreased	2	2
Body temperature decreased	2	2
Body temperature increased	4	8
Bone pain	3	3

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3		
1	1		
42	57	5	6
1	1		
		1	1
			1
		3	3
		1	1
1	2		
7	11		
28	36	2	3
6	8	1	1
		1	2
1	1		
1	1		
1	1		
1	1		
		1	2
5	6		
1	1		
1	1		
3	4	2	2
	1		
1	2		
6	9	3	4
2	2		
2	2		
2	2		
4	8		
3	3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bradycardia	1	1			1	1
Brain oedema	1	1			1	1
Breath odour	2	2	2	2		
Bronchitis	2	3	2	3		
Burning sensation	7	10	6	8	1	2
Cardiac arrest	5	5			5	5
Cardiac disorder		1		1		
Cardio-respiratory arrest	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	6	8			6	8
Chest discomfort	10	15	8	13	2	2
Chest pain	7	11	6	9	1	2
Chills	257	337	250	325	7	12
Choking	1	1			1	1
Chromaturia		1		1		
Circumstance or information capable of leading to medication error	6	6	6	6		
Coagulopathy	1	1			1	1
Cognitive disorder		1				1
Cold sweat	5	10	5	10		
Coma	1	1			1	1
Condition aggravated	11	12	9	10	2	2
Confusional state	1	4	1	3		1
Conjunctival irritation	1	1	1	1		
Conjunctival oedema	1	1	1	1		
Constipation	1	1	1	1		
Contraindicated product administered	1	1	1	1		
Contusion	4	5	4	5		
Coordination abnormal	2	2	1	1	1	1
Cough	29	53	27	49	2	4
COVID-19	92	117	1	1	91	116
C-reactive protein increased	2	2	2	2		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Cystitis	1	1
Deafness	3	4
Deafness neurosensory	2	4
Death	12	12
Decreased appetite	13	18
Deep vein thrombosis	1	1
Dehydration	4	5
Delirium	2	3
Dental restoration failure	1	1
Depression	1	1
Dermatitis	2	2
Dermatitis allergic	1	1
Diabetes mellitus	2	2
Diarrhoea	33	50
Diplopia	1	1
Discomfort	11	13
Disease recurrence	3	3
Disorientation	4	5
Disturbance in attention	2	4
Dizziness	64	100
Dizziness exertional	1	1
Dizziness postural	4	4
Drug hypersensitivity	2	3
Drug ineffective	144	180
Drug interaction	2	2
Dry mouth	5	11
Dry throat	3	4
Dysarthria	2	2
Dysgeusia	6	11
Dyslexia		1
Dyspepsia	7	9
Dysphagia	5	7

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		3	4
		2	4
		12	12
13	17		1
		1	1
4	5		
		2	3
1	1		
1	1		
2	2		
		1	1
		2	2
33	50		
1	1		
11	13		
3	3		
3	4	1	1
2	3		1
60	92	4	8
1	1		
3	3	1	1
2	3		
		144	180
2	2		
4	10	1	1
2	3	1	1
1	1	1	1
6	10		1
	1		
7	9		
4	6	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dysphemia		1		1		
Dysphonia	2	5	2	4		1
Dyspnoea	32	47	24	32	8	15
Dyspnoea exertional	1	1	1	1		
Dysstasia	3	3	2	2	1	1
Ear discomfort	2	3	2	2		1
Ear disorder	2	2	2	2		
Ear pain	1	1	1	1		
Ear pruritus	1	1	1	1		
Eating disorder		1		1		
Ecchymosis	1	1	1	1		
Ejection fraction abnormal		1		1		
Electrocardiogram abnormal	1	1	1	1		
Epistaxis	5	5	5	5		
Eructation	1	1	1	1		
Erythema	10	16	9	15	1	1
Erythema of eyelid	1	1	1	1		
Exposure to SARS-CoV-2	8	8	6	6	2	2
Exposure via breast milk	4	7	4	7		
Exposure via skin contact	2	3	2	3		
Eye contusion	1	1	1	1		
Eye disorder	4	5	2	3	2	2
Eye haemorrhage	2	2			2	2
Eye inflammation		1		1		
Eye irritation	2	3	2	3		
Eyelid oedema	1	1	1	1		
Eyelid pain	1	1	1	1		
Eye oedema	1	1	1	1		
Eye pain	6	8	6	8		
Eye pruritus	2	2	2	2		
Eye swelling	8	11	7	10	1	1
Face injury	1	1	1	1		

Spontaneous			
Nonserious		Serious	
I	C	I	C
	1		
2	4		1
24	32	8	15
1	1		
2	2	1	1
2	2		1
2	2		
1	1		
1	1		
	1		
1	1		
	1		
1	1		
5	5		
1	1		
9	15	1	1
1	1		
6	6	2	2
4	7		
2	3		
1	1		
2	3	2	2
		2	2
	1		
2	3		
1	1		
1	1		
6	8		
2	2		
7	10	1	1
1	1		

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**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Facet joint syndrome	1	1
Facial pain	2	3
Facial paralysis	14	16
Faeces soft	1	1
Fall	5	5
Fatigue	207	297
Fear		1
Feeding disorder	2	3
Feeling abnormal	42	55
Feeling cold	14	17
Feeling drunk	4	4
Feeling hot	14	21
Feeling jittery	3	3
Fibrin D dimer increased	1	1
Fibromyalgia	1	1
Fine motor skill dysfunction	1	1
Flank pain	1	1
Flatulence	1	1
Fluid intake reduced	1	1
Flushing	5	13
Formication	1	1
Gait disturbance	9	11
Gait inability	4	4
Gastric disorder	1	2
Gastritis	1	2
Gastrointestinal disorder	1	2
Gastrointestinal pain	1	1
Gastroesophageal reflux disease	1	1
Gingival discolouration		1
Gingival pain		1
Gingival swelling	1	1
Glaucoma	1	1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
1	2	1	1
	1	14	15
1	1		
3	3	2	2
202	290	5	7
	1		
2	3		
42	54		1
14	17		
3	3	1	1
14	20		1
3	3		
		1	1
		1	1
1	1		
1	1		
1	1		
1	1		
4	11	1	2
1	1		
8	10	1	1
3	3	1	1
1	2		
1	2		
1	2		
1	1		
			1
			1
1	1		
		1	1

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**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gout	4	4	4	4		
Groin pain	1	1	1	1		
Guillain-Barre syndrome		1				1
Haematuria		1				1
Haemolytic anaemia	1	1			1	1
Haemoptysis	3	3	3	3		
Haemorrhage	2	2			2	2
Haemorrhage intracranial	1	1			1	1
Haemorrhagic stroke	1	1			1	1
Hallucination	1	1			1	1
Hangover	1	1	1	1		
Headache	253	346	247	336	6	10
Head discomfort	3	4	3	4		
Head injury	2	2			2	2
Head titubation	1	1	1	1		
Heart rate abnormal	1	1	1	1		
Heart rate decreased	1	3	1	2		1
Heart rate increased	15	29	14	27	1	2
Heart rate irregular	2	2	2	2		
Hemiparesis	1	2			1	2
Hepatic enzyme increased	1	1	1	1		
Herpes simplex	2	2	2	2		
Herpes zoster	6	8	6	8		
Hiccups	1	2	1	2		
Hordeolum		1		1		
Hot flush	3	3	3	3		
Hunger	1	1	1	1		
Hyperacusis		1				1
Hyperaesthesia	2	3	2	3		
Hyperglycaemia	1	1			1	1
Hyperhidrosis	33	43	30	39	3	4
Hypersensitivity	6	7	5	5	1	2

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**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypersomnia	4	5	4	5		
Hypertension	7	13	5	9	2	4
Hypertensive crisis		1				1
Hyperthermia	1	1	1	1		
Hyperventilation	1	2		1	1	1
Hypervigilance	1	1	1	1		
Hypoacusis	3	4	3	4		
Hypoaesthesia	26	43	24	38	2	5
Hypoaesthesia eye	1	1	1	1		
Hypoaesthesia oral	4	8	4	8		
Hypogeusia	2	2	2	2		
Hypoglycaemia	1	1	1	1		
Hypophagia	2	2	2	2		
Hypopnoea	1	1	1	1		
Hypotension	3	3	1	1	2	2
Hypoxia		2				2
Illness	13	19	13	19		
Immune system disorder		1				1
Immune thrombocytopenia	1	2			1	2
Impaired driving ability		1		1		
Impaired work ability	1	2	1	2		
Inappropriate schedule of product administration	67	70	67	70		
Incision site haemorrhage	1	1			1	1
Incomplete course of vaccination	3	3	3	3		
Incontinence		1				1
Incorrect dose administered	2	2	2	2		
Incorrect route of product administration	9	14	9	14		
Increased appetite	1	1	1	1		
Increased bronchial secretion		1		1		
Infantile vomiting	1	1	1	1		
Infant irritability	1	2	1	2		
Inflammation	1	2	1	2		

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**MALE**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Influenza	3	4
Influenza like illness	34	50
Inhibitory drug interaction	1	1
Initial insomnia	2	2
Injection site extravasation	1	2
Injection site pain	2	4
Injury	1	1
Insomnia	16	21
International normalised ratio decreased	1	1
International normalised ratio increased	2	2
Intervertebral disc protrusion	1	1
Intrusive thoughts	1	1
Irritability	1	1
Irritable bowel syndrome	1	1
Jaundice	1	1
Joint range of motion decreased	1	2
Joint stiffness	1	1
Joint swelling	2	4
Lacrimation increased	1	1
Lethargy	11	16
Leukocytosis	1	1
Limb discomfort	6	10
Limb injury	1	1
Lip disorder	1	1
Lip swelling	8	9
Liver function test abnormal	1	1
Loss of consciousness	5	7
Loss of personal independence in daily activities	2	2
Lung infiltration		1
Lymphadenitis	1	1
Lymphadenopathy	46	57
Lymph node pain	11	11

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	3	1	1
31	46	3	4
1	1		
2	2		
1	2		
2	4		
1	1		
16	21		
1	1		
2	2		
1	1		
1	1		
1	1		
1	1		
1	2		
1	1		
1	3	1	1
		1	1
10	14	1	2
1	1		
5	9	1	1
1	1		
1	1		
8	9		
		1	1
		5	7
2	2		
			1
1	1		
43	53	3	4
11	11		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Lymphoedema	1	1
Malaise	80	118
Malnutrition		1
Memory impairment	2	2
Meningitis		1
Meningitis viral	1	1
Mental fatigue	1	1
Mental impairment	1	1
Middle insomnia	3	3
Migraine	8	9
Mobility decreased	1	2
Monocyte count increased	1	1
Motion sickness	2	2
Motor dysfunction	1	1
Movement disorder	3	3
Mucosal disorder	1	1
Multiple organ dysfunction syndrome	1	1
Muscle discomfort	1	1
Muscle fatigue	1	2
Muscle spasms	7	9
Muscle strain	1	1
Muscle swelling	1	1
Muscle tightness	2	2
Muscle twitching	3	3
Muscular weakness	9	12
Musculoskeletal chest pain	1	2
Musculoskeletal discomfort	3	3
Musculoskeletal disorder	2	2
Musculoskeletal pain	1	3
Musculoskeletal stiffness	7	9
Myalgia	133	187
Myocardial infarction	3	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		
73	110	7	8
	1		
2	2		
			1
		1	1
1	1		
		1	1
3	3		
8	9		
	1	1	1
1	1		
2	2		
1	1		
3	3		
1	1		
		1	1
1	1		
1	2		
5	7	2	2
1	1		
2	2		
3	3		
7	9	2	3
1	2		
3	3		
1	1	1	1
1	2		1
6	8	1	1
128	178	5	9
		3	4

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Myositis	1	1
Nasal congestion	14	27
Nasal discomfort	1	2
Nasal dryness	2	3
Nasopharyngitis	8	10
Nausea	104	145
Neck mass	1	1
Neck pain	18	22
Needle issue	2	3
Nervousness	2	4
Nervous system disorder	1	1
Neuralgia	2	2
Neurological symptom	1	1
Neuropathy peripheral	2	2
Nightmare	1	2
Night sweats	7	9
Nipple pain		1
Nipple swelling		1
Nocturia	1	1
Nodal rhythm	1	1
Nodule	1	1
Noninfective encephalitis	1	1
Noninfective gingivitis	1	1
Occipital neuralgia	1	1
Occupational exposure to SARS-CoV-2	1	1
Ocular discomfort		1
Ocular hyperaemia	1	2
Odynophagia	1	1
Off label use	28	33
Oral discomfort		1
Oral disorder		1
Oral herpes	1	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
14	27		
1	2		
1	2	1	1
8	10		
100	139	4	6
1	1		
17	19	1	3
2	3		
2	4		
		1	1
2	2		
		1	1
		2	2
1	2		
5	6	2	3
	1		
	1		
1	1		
1	1		
1	1		
		1	1
1	1		
1	1		
		1	1
		1	
1	2		
		1	1
28	33		
	1		
	1		
1	2		

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Gender

**MALE**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Oral pain	1	2
Orchitis		1
Organising pneumonia		1
Oropharyngeal discomfort	1	1
Oropharyngeal pain	12	28
Oropharyngeal swelling	1	1
Overdose	1	5
Oxygen saturation decreased	2	2
Pain	163	224
Pain in extremity	124	154
Pain in jaw	3	5
Pain of skin	1	2
Pallor	3	3
Palpitations	10	16
Pancytopenia	1	1
Panic attack		2
Paraesthesia	24	36
Paraesthesia oral	5	8
Paralysis	1	1
Paranasal sinus discomfort		1
Paranasal sinus hypersecretion	1	1
Parosmia	3	3
Penile haemorrhage	1	1
Pericarditis	2	3
Periorbital oedema		1
Periorbital swelling	3	4
Peripheral coldness	1	2
Peripheral swelling	16	21
Peroneal nerve palsy	1	2
Petechiae	1	1
Pharyngeal erythema	1	1
Pharyngeal hypoaesthesia		1

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1		1
	1		
			1
1	1		
12	27		1
		1	1
1	5		
2	2		
159	216	4	8
120	150	4	4
3	5		
1	2		
3	3		
10	14		2
		1	1
	2		
18	28	6	8
5	8		
		1	1
	1		
1	1		
3	3		
		1	1
		2	3
	1		
3	3		1
1	2		
15	20	1	1
	1	1	1
1	1		
		1	1
			1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Pharyngeal inflammation	2	2
Pharyngeal swelling	7	11
Photophobia	2	2
Photopsia	2	2
Platelet count decreased	1	1
Pneumonia	1	1
Pollakiuria	4	5
Polyneuropathy	1	1
Polyuria	2	2
Poor quality product administered	9	10
Poor quality sleep	3	5
Post procedural haemorrhage	1	1
Pressure of speech	1	1
Presyncope	3	4
Procedural pain		1
Product administered at inappropriate site	6	7
Product administered to patient of inappropriate age	2	2
Product administration error	3	3
Productive cough	1	1
Product leakage		2
Product preparation error	5	9
Product preparation issue	2	3
Product prescribing error		1
Product temperature excursion issue	2	2
Product use issue	27	37
Pruritus	23	38
Psychomotor hyperactivity	1	1
Pustule	1	2
Pyrexia	277	358
Rash	30	40
Rash erythematous	2	4

Spontaneous			
Nonserious		Serious	
I	C	I	C
2	2		
4	6	3	5
2	2		
1	1	1	1
		1	1
		1	1
4	5		
		1	1
2	2		
9	10		
3	5		
		1	1
		1	1
3	3		1
	1		
6	7		
2	2		
3	3		
1	1		
	2		
5	9		
2	3		
	1		
2	2		
27	37		
22	36	1	2
		1	1
1	1		1
270	343	7	15
28	36	2	4
2	3		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash macular	2	3	2	3		
Rash maculo-papular	3	4	3	4		
Rash papular	1	1	1	1		
Rash pruritic	10	13	10	13		
Rash vesicular	1	1	1	1		
Raynaud's phenomenon		1		1		
Red blood cell sedimentation rate increased	1	1	1	1		
Red blood cells urine positive	1	1	1	1		
Renal disorder	2	2	2	2		
Renal pain	2	2	2	2		
Respiratory arrest	1	1			1	1
Respiratory distress		1				1
Respiratory rate increased		1		1		
Respiratory tract congestion		1		1		
Restlessness	2	3	1	2	1	1
Retching	2	3	2	3		
Rhinalgia	1	2	1	2		
Rhinitis	1	2	1	2		
Rhinorrhoea	17	24	16	23	1	1
SARS-CoV-1 test positive	1	1			1	1
SARS-CoV-2 ant body test negative	5	5	5	5		
SARS-CoV-2 ant body test positive		1				1
SARS-CoV-2 test false positive	1	1	1	1		
SARS-CoV-2 test positive	46	54			46	54
Seizure	3	4			3	4
Sensation of foreign body		2		1		1
Sensitive skin	1	1	1	1		
Sensory disturbance		2		2		
Sensory loss	2	2	2	2		
Serotonin syndrome	1	1			1	1
Sinus congestion	3	5	2	4	1	1
Sinus disorder	1	3	1	3		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sinus headache	2	2	2	2		
Sinusitis	3	7	2	6	1	1
Sinus pain	3	4	3	4		
Sinus tarsi syndrome	1	1	1	1		
Sitophobia	1	1	1	1		
Skin burning sensation	3	5	3	5		
Skin discolouration	2	3	2	3		
Skin disorder		1		1		
Skin injury		1		1		
Skin irritation	1	1	1	1		
Skin lesion	1	1	1	1		
Skin mass	1	1	1	1		
Skin odour abnormal	1	1	1	1		
Skin reaction		1		1		
Skin swelling	2	2	2	2		
Sleep disorder	6	7	6	6		1
Sleep disorder due to a general medical condition	1	1	1	1		
Sleep talking	1	1	1	1		
Slow response to stimuli		1		1		
Sluggishness	2	3	2	3		
Sneezing	2	5	2	5		
Somatic symptom disorder	1	1	1	1		
Somnolence	14	20	14	20		
Speech disorder	2	3	2	3		
Staphylococcal infection	1	1			1	1
Staphylococcal skin infection		1				1
Stress		1		1		
Substance abuse	1	1			1	1
Suffocation feeling		1		1		
Supraventricular extrasystoles	1	1			1	1
Supraventricular tachycardia	1	2	1	1		1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Suspected COVID-19	8	10
Swelling	14	21
Swelling face	10	12
Swelling of eyelid	6	7
Swollen tongue	1	5
Syncope	2	4
Syringe issue		1
Tachycardia	11	20
Tachyphrenia	1	1
Taste disorder	3	5
Temperature intolerance	1	1
Tenderness		1
Tendonitis	2	2
Tenosynovitis		1
Tension	1	1
Tension headache	3	3
Thinking abnormal	1	1
Thirst	2	2
Throat irritation	4	11
Throat tightness	3	4
Thrombocytopenia	1	1
Thrombosis	1	1
Thrombotic thrombocytopenic purpura		1
Tinnitus	10	17
Tongue coated		1
Tongue disorder	1	1
Tongue pruritus	1	1
Tonsillitis	1	1
Toothache	2	3
Transient global amnesia	1	1
Transient ischaemic attack	2	2
Tremor	18	19

Spontaneous			
Nonserious		Serious	
I	C	I	C
		8	10
12	18	2	3
9	11	1	1
6	7		
	2	1	3
		2	4
	1		
11	18		2
1	1		
3	5		
1	1		
	1		
1	1	1	1
	1		
1	1		
3	3		
1	1		
2	2		
3	10	1	1
3	4		
		1	1
		1	1
			1
8	12	2	5
	1		
1	1		
1	1		
1	1		
2	3		
1	1		
		2	2
17	18	1	1

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Trigeminal nerve disorder		1		1		
Type IV hypersensitivity reaction	1	1	1	1		
Underdose	8	13	8	13		
Unresponsive to stimuli	1	1			1	1
Upper-airway cough syndrome	3	5	3	5		
Upper airway obstruction	1	1			1	1
Upper respiratory tract congestion	1	1	1	1		
Upper respiratory tract infection	1	1	1	1		
Urticaria	19	25	18	24	1	1
Uvulitis	1	1	1	1		
Vaccination site bruising	3	3	3	3		
Vaccination site coldness		2		2		
Vaccination site discolouration	2	2	2	2		
Vaccination site discomfort		2		2		
Vaccination site erythema	7	8	7	8		
Vaccination site haemorrhage	2	5	2	5		
Vaccination site hypoaesthesia		2		2		
Vaccination site induration	1	1	1	1		
Vaccination site inflammation	1	1	1	1		
Vaccination site irritation	1	1	1	1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site mass	4	4	4	4		
Vaccination site movement impairment	4	5	4	5		
Vaccination site pain	161	234	161	233		1
Vaccination site paraesthesia	1	2	1	2		
Vaccination site pruritus	2	2	2	2		
Vaccination site rash	3	5	3	5		
Vaccination site reaction	4	4	4	4		
Vaccination site swelling	11	15	11	15		
Vaccination site ulcer	1	1	1	1		
Vaccination site urticaria	3	4	3	4		
Vaccination site warmth	5	6	5	6		

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Gender

**MALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ventricular extrasystoles	1	1	1	1		
Ventricular fibrillation	1	1			1	1
Ventricular tachycardia		1				1
Vertigo	8	10	8	9		1
Viral infection	1	1	1	1		
Vision blurred	9	12	8	10	1	2
Visual impairment	3	3	3	3		
Vomiting	30	45	27	41	3	4
Weight decreased	3	3	3	3		
Wheezing	1	2	1	2		
White blood cell count increased	1	1			1	1
Wound	1	1	1	1		
Wrong product administered	1	1	1	1		
Wrong technique in product usage process	3	3	3	3		
	4,121	5,655	3512	4819	609	836

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Gender

UNKNOWN

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	2	1	2		
Abnormal sensation in eye	1	1	1	1		
Accidental exposure to product	2	2	2	2		
Accidental overdose	5	14	5	14		
Adverse event	1	1	1	1		
Ageusia		2		1		1
Aggression	1	1	1	1		
Allergy to vaccine	3	5	3	5		
Anaesthesia		1		1		
Anaphylactic reaction	8	16			8	16
Anger	1	1	1	1		
Anosmia		1				1
Anxiety	3	3	3	3		
Aphasia		1		1		
Aphthous ulcer	1	1	1	1		
Arthralgia	15	19	15	19		
Asthenia	7	11	7	11		
Asthenopia	1	1	1	1		
Axillary pain	1	1	1	1		
Back pain	5	6	5	6		
Blood glucose decreased	1	1			1	1
Blood glucose increased	1	1	1	1		
Blood potassium decreased	1	1	1	1		
Blood pressure decreased		1		1		
Blood pressure increased	1	1	1	1		
Blood sodium decreased	1	1	1	1		
Blood thyroid stimulating hormone increased	1	1	1	1		
Body temperature abnormal	1	2	1	2		
Body temperature decreased	2	2	2	2		
Body temperature increased	2	3	2	3		
Bone pain	1	2	1	2		
Burning sensation	1	1	1	1		

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**UNKNOWN**

Preferred Term	Interval Total #	Cumulative Total #
	Spontaneous AE	Spontaneous AE
Chest discomfort	1	3
Chest pain	1	1
Chillblains	1	1
Chills	33	45
Circumstance or information capable of leading to medication error	5	8
Cognitive disorder		1
Cold sweat	2	2
Condition aggravated	1	2
Confusional state		1
Conjunctivitis	1	1
Contusion		1
Cough	6	8
COVID-19	82	93
Cyanosis	1	1
Death	10	10
Decreased appetite	2	3
Deep vein thrombosis	1	1
Dehydration	2	2
Depressed mood	1	1
Diabetes mellitus	1	1
Diarrhoea	10	13
Diplopia	1	1
Discomfort		1
Disturbance in attention	1	3
Dizziness	20	26
Drug ineffective	121	147
Drug interaction	1	1
Dry mouth	1	1
Dry throat	1	3
Dysarthria		1
Dysgeusia	5	8

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	3		
1	1		
1	1		
33	45		
5	8		
	1		
2	2		
1	2		
	1		
1	1		
	1		
6	8		
		82	93
1	1		
		10	10
2	3		
		1	1
1	1	1	1
		1	1
9	12	1	1
1	1		
	1		
1	3		
20	26		
		121	147
1	1		
1	1		
1	3		
	1		
5	8		

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**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesia		1		1		
Dyspepsia	1	1	1	1		
Dysphagia	2	2	1	1	1	1
Dysphonia		1		1		
Dyspnoea	6	8	5	7	1	1
Dysuria	1	1	1	1		
Epistaxis	1	1	1	1		
Erythema	5	7	4	6	1	1
Euphoric mood	1	1	1	1		
Exposure to SARS-CoV-2	5	5	3	3	2	2
Exposure via breast milk	34	57	34	57		
Exposure via eye contact	1	1	1	1		
Exposure via skin contact	2	2	2	2		
Eye irritation	1	1	1	1		
Eye pruritus	2	2	2	2		
Eye swelling		1		1		
Facial asymmetry		1		1		
Facial pain	1	1	1	1		
Facial paralysis	7	10			7	10
Fatigue	65	85	64	83	1	2
Febrile neutropenia	1	1			1	1
Feeding disorder	1	1	1	1		
Feeling abnormal	3	11	3	11		
Feeling cold	5	6	5	6		
Feeling hot	4	4	3	3	1	1
Feeling jittery	1	1	1	1		
Feeling of body temperature change		1		1		
Flushing	4	9	3	8	1	1
Gait disturbance	1	1	1	1		
Gait inability	2	2	2	2		
Gastrointestinal disorder	2	4	2	4		
Gingival bleeding	1	1	1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gingival pain	1	1	1	1		
Gingival swelling	1	1	1	1		
Glassy eyes	1	1	1	1		
Gout	1	1	1	1		
Groin pain	1	1	1	1		
Haematochezia		1				1
Hangover	1	1	1	1		
Headache	74	94	73	92	1	2
Heart rate decreased		1		1		
Heart rate increased	14	15	14	15		
Heart rate irregular	1	1	1	1		
Herpes zoster	3	3	3	3		
Hiccups	1	1	1	1		
Hyperhidrosis	1	2	1	2		
Hypersensitivity	6	16	6	14		2
Hypertension	3	3	2	2	1	1
Hypoacusis	3	3	3	3		
Hypoaesthesia	5	6	5	6		
Hypoaesthesia eye	1	1	1	1		
Hypoaesthesia oral	4	4	4	4		
Hypokinesia	2	3	2	3		
Hypotonia	1	1	1	1		
Illness	12	12	12	12		
Immune thrombocytopenia	1	1			1	1
Inappropriate schedule of product administration	11	11	11	11		
Incorrect dose administered	3	5	3	5		
Incorrect route of product administration	6	12	5	11	1	1
Induration	1	1			1	1
Infantile vomiting		1		1		
Infection	1	1	1	1		
Influenza	3	4	3	4		
Influenza like illness	10	11	10	11		

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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infrequent bowel movements	1	1	1	1		
Injection site erythema	1	1	1	1		
Injection site pain	1	1	1	1		
Insomnia	3	3	3	3		
Intentional product misuse	1	1	1	1		
Irritability	1	1	1	1		
Lethargy	5	7	5	7		
Leukocytosis	1	1			1	1
Limb discomfort	2	3	2	3		
Limb mass	1	1			1	1
Lip oedema	1	1	1	1		
Lip pain	1	1	1	1		
Lip pruritus	1	2	1	1		1
Lip swelling	1	1	1	1		
Liquid product physical issue	5	5	5	5		
Localised infection	1	1	1	1		
Loss of consciousness		1				1
Loss of personal independence in daily activities	2	2	2	2		
Lung neoplasm malignant	1	1			1	1
Lymphadenitis	1	1	1	1		
Lymphadenopathy	15	16	15	16		
Lymph node pain	2	3	2	3		
Malaise	20	26	19	25	1	1
Maternal exposure during breast feeding	1	1	1	1		
Middle insomnia	1	1	1	1		
Migraine	2	4	2	4		
Mobility decreased	1	1	1	1		
Mouth swelling		1		1		
Movement disorder	4	4	4	4		
Mucous stools		1		1		
Muscle spasms	5	5	5	5		
Muscle strain		1		1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Muscular weakness		1		1		
Musculoskeletal chest pain	3	3	3	3		
Musculoskeletal stiffness	3	3	2	2	1	1
Myalgia	14	23	14	23		
Nasal congestion	5	7	5	7		
Nasal discomfort	1	1	1	1		
Nasal oedema	1	1	1	1		
Nasopharyngitis	2	2	2	2		
Nausea	19	24	19	24		
Neck mass	2	2	2	2		
Neck pain	2	3	2	3		
Needle issue	1	2	1	2		
Nerve compression	1	1	1	1		
Nervousness	2	3	2	3		
Neuralgia	2	2	2	2		
Neuritis	1	1	1	1		
Neuropathy peripheral	1	1			1	1
Night sweats	3	4	3	4		
No adverse event	3	3	3	3		
Occupational exposure to product	1	1	1	1		
Ocular hyperaemia	1	1	1	1		
Oesophageal pain	1	1	1	1		
Off label use	3	3	3	3		
Oral dysaesthesia	1	1			1	1
Oral herpes	2	2	2	2		
Oral mucosal blistering	1	1	1	1		
Oropharyngeal pain	4	5	4	5		
Overdose	23	32	23	32		
Oxygen consumption	1	1	1	1		
Oxygen saturation decreased	1	1	1	1		
Pain	53	65	53	65		
Pain in extremity	53	68	52	67	1	1

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pain in jaw		1		1		
Palpitations	4	4	3	3	1	1
Panic attack	1	1	1	1		
Paraesthesia	8	9	7	8	1	1
Paraesthesia oral		1		1		
Pericarditis	1	1			1	1
Peripheral swelling	19	21	19	21		
Pharyngeal hypoaesthesia	1	1	1	1		
Pharyngeal paraesthesia		2		2		
Pharyngeal swelling	1	4		3	1	1
Plantar erythema	1	1	1	1		
Platelet count decreased		1		1		
Platelet count increased	1	1	1	1		
Pleurisy	1	1			1	1
Poor feeding infant		1		1		
Poor quality product administered	76	176	76	176		
Poor quality sleep	1	1	1	1		
Presyncope	1	1	1	1		
Product administered at inappropriate site	1	3	1	3		
Product administered to patient of inappropriate age	1	1	1	1		
Product administration error	6	6	6	6		
Product complaint		1		1		
Product dose omission issue	1	1	1	1		
Productive cough	1	1			1	1
Product leakage	3	3	3	3		
Product packaging quantity issue		4		4		
Product preparation error	51	63	51	63		
Product preparation issue	45	56	45	56		
Product temperature excursion issue	10	100	10	100		
Product use issue	2	2	2	2		
Pruritus	6	10	6	10		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Psoriatic arthropathy	1	1
Pulmonary congestion	2	2
Pulmonary embolism	1	2
Pyrexia	54	77
Rash	8	16
Rash erythematous	2	4
Renal pain	1	1
Rhinalgia	1	1
Rhinorrhoea	2	3
SARS-CoV-2 ant body test positive		3
SARS-CoV-2 test positive	35	50
Sensation of foreign body		2
Sinus disorder	1	1
Sinusitis	2	2
Skin discolouration	2	2
Skin disorder	1	1
Skin laceration	1	1
Sleep disorder	2	3
Sneezing	1	2
Somnolence	1	3
Sputum discoloured	1	1
Suspected COVID-19	4	4
Swelling	3	3
Swelling face	1	1
Syncope	2	3
Tachycardia	1	6
Tenderness	1	1
Therapeutic response unexpected	1	2
Throat irritation	3	5
Throat tightness	1	3
Thrombocytopenia	1	1
Thrombosis	2	2

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	1
		2	2
		1	2
53	75	1	2
8	16		
2	4		
1	1		
1	1		
2	3		
	3		
		35	50
	2		
1	1		
2	2		
1	1	1	1
1	1		
1	1		
1	2	1	1
1	2		
1	3		
1	1		
		4	4
3	3		
1	1		
		2	3
	4	1	2
1	1		
1	2		
2	3	1	2
1	3		
		1	1
		2	2

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tinnitus	1	1	1	1		
Tongue disorder	1	1	1	1		
Tongue erythema	1	1	1	1		
Tongue ulceration	1	1	1	1		
Tooth infection	1	1	1	1		
Tremor	4	4	4	4		
Tunnel vision		1				1
Underdose	45	69	45	69		
Upper respiratory tract congestion	1	1	1	1		
Urticaria	8	11	8	11		
Vaccination complication	2	2	2	2		
Vaccination site discharge	2	2	2	2		
Vaccination site discolouration	2	2	2	2		
Vaccination site erythema	5	8	5	8		
Vaccination site extravasation	1	1	1	1		
Vaccination site induration	2	2	1	1	1	1
Vaccination site mass	1	1	1	1		
Vaccination site movement impairment		1		1		
Vaccination site pain	26	47	26	47		
Vaccination site pruritus	2	2	2	2		
Vaccination site rash	3	3	3	3		
Vaccination site reaction	2	3	2	3		
Vaccination site swelling	5	6	5	6		
Vertigo	2	4	2	4		
Vessel puncture site haemorrhage		1		1		
Vessel puncture site injury		1		1		
Vision blurred	1	2	1	2		
Vomiting	7	8	7	8		
Von Willebrand's disease		1				1
Weight decreased	1	1	1	1		
Wheezing	1	2	1	2		
Wrong product administered	1	1	1	1		

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Gender

**UNKNOWN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Wrong technique in product usage process	13	33	13	33		
	1,531	2,231	1216	1837	315	394

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Country Where Event Occurred  
**UNITED STATES MINOR OUTLYING ISLA**

Gender

**FEMALE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Discomfort	1	1	1	1
Inappropriate schedule of product administration	1	1	1	1
Joint range of motion decreased	1	1	1	1
Lymphadenopathy	1	1	1	1
Vaccination site pain		1		1
	4	5	4	5

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**APPENDIX 2.5.4: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per Patient with Relevant Co-Morbidities by Preferred Term per Country**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 2,535 (Interval) / 3,148 (Cumulative)

Total Number of Adverse Events (PT): 10,964 (Interval) / 13,739 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AUSTRIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Asthenia	2	2			2	2
Death	3	3			3	3
Fatigue	1	1			1	1
Myocardial infarction	1	1			1	1
Nausea	2	2	2	2		
Pulmonary embolism	1	1			1	1
Rales	1	1			1	1
Respiratory depression	1	1			1	1
Somnolence	1	1			1	1
Urinary retention	1	1			1	1
Vaginal discharge	1	1	1	1		
Vomiting	2	2	2	2		
	18	18	5	5	13	13

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Country Where Event Occurred

**BELGIUM**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Acute respiratory failure	1	1			1	1
Agitation	2	2			2	2
Amnesia	1	1			1	1
Bradycardia	1	1			1	1
Cardiovascular disorder	4	4			4	4
Confusional state	2	2			2	2
Depressed level of consciousness	1	1			1	1
Disorientation	1	1			1	1
Dyspnoea	1	1			1	1
Eye movement disorder	1	1			1	1
Fatigue	1	1	1	1		
General physical health deterioration	1	1			1	1
Hypoglycaemia	1	1			1	1
Hypotension	1	1			1	1
Hypovolaemic shock	1	1			1	1
Intestinal ischaemia	1	1			1	1
Liver function test abnormal	1	1			1	1
Lung infiltration	1	1			1	1
Malaise	3	3			3	3
Metabolic acidosis	1	1			1	1
Nervous system disorder	1	1			1	1
Neutropenia	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Patient elopement	1	1			1	1
Pneumonitis	1	1			1	1
Presyncope	2	2			2	2
Pulmonary embolism	1	1			1	1
Pyrexia	1	1			1	1
Renal disorder	1	1			1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Respiratory disorder	2	2			2	2
Septic shock	1	1			1	1
Staring	1	1			1	1
Sudden death	2	2			2	2
Tachycardia	1	1			1	1
Tachypnoea	1	1			1	1
	46	46	1	1	45	45

\* I=Interval, C=Cumulative

\* AE=Adverse Event

\* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

Country Where Event Occurred

**BULGARIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Blood pressure diastolic decreased	1	1	1	1		
Body temperature increased	1	1	1	1		
Chills	1	1			1	1
Diarrhoea	1	1	1	1		
Dizziness	1	1			1	1
Dizziness postural	1	1	1	1		
Dyspnoea	1	1			1	1
Fatigue	1	1	1	1		
Headache	2	2	1	1	1	1
Head discomfort	1	1			1	1
Hyperhidrosis	1	1			1	1
Myalgia	1	1	1	1		
Nausea	1	1			1	1
Pain	1	1	1	1		
Pallor	1	1	1	1		
Paraesthesia	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Peripheral coldness	1	1	1	1		
Rash	1	1	1	1		
Rash erythematous	1	1	1	1		
Rash pruritic	1	1	1	1		
Swelling	1	1	1	1		
Vaccination site pain	1	1	1	1		
Vertigo	1	1			1	1
	27	27	19	19	8	8

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Country Where Event Occurred

**CANADA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse event	1	1	1	1		
Agitation	1	1	1	1		
Anaphylactic reaction	1	1	1	1		
Aphthous ulcer	1	1	1	1		
Arthralgia	3	3	2	2	1	1
Body temperature increased	1	1	1	1		
Buttock injury	1	1	1	1		
Cellulitis	1	1			1	1
Chills	2	3	2	3		
Deafness	1	1			1	1
Decreased appetite	1	1	1	1		
Diarrhoea	5	5	5	5		
Dizziness	2	2	2	2		
Dysphagia	1	1	1	1		
Ear discomfort	1	1	1	1		
Erythema	1	1			1	1
Exposure during pregnancy	2	2	2	2		
Face oedema	1	1			1	1
Facial paralysis		1				1
Fatigue	7	7	6	6	1	1
Feeling abnormal	1	1	1	1		
Feeling cold	1	1	1	1		
Fibromyalgia	1	1	1	1		
Flushing	1	1			1	1
Genital blister	1	1	1	1		
Headache	6	7	6	7		
Herpes zoster	2	2	2	2		
Hypertension	1	1			1	1
Illness	1	1	1	1		
Inappropriate schedule of product administration	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Influenza like illness	1	1	1	1		
Joint swelling	1	1	1	1		
Lethargy	1	1	1	1		
Leukoplakia	1	1	1	1		
Localised infection	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	2	2	2	2		
Maternal exposure during pregnancy	2	2	2	2		
Myalgia	5	5	4	4	1	1
Nasopharyngitis	1	1	1	1		
Off label use	5	5	5	5		
Oropharyngeal pain	1	1	1	1		
Overdose	1	1	1	1		
Pain	2	3	2	3		
Pain in extremity	2	3	2	3		
Paraesthesia	1	2			1	2
Paraesthesia oral	1	2	1	1		1
Peripheral swelling	1	1	1	1		
Petechiae	1	1	1	1		
Pharyngeal swelling	1	1			1	1
Product use issue	4	4	4	4		
Pruritus	2	2	1	1	1	1
Pyrexia	4	4	4	4		
Rash	2	2	1	1	1	1
Rash macular	1	1	1	1		
Rheumatoid arthritis	1	1			1	1
Sinus pain	1	1	1	1		
Skin lesion	1	1	1	1		
Somnolence	1	1	1	1		
Swelling	1	1			1	1
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachycardia	2	2	1	1	1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat irritation	1	1	1	1		
Urticaria	1	1	1	1		
Vaccination site pain	5	5	4	4	1	1
Varicella	1	1	1	1		
Vital functions abnormal	1	1			1	1
Vomiting	2	2	2	2		
Vulval disorder	1	1			1	1
	117	124	96	100	21	24

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Country Where Event Occurred

**CHILE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1			1	1
Headache	1	1	1	1		
Lymph node pain	1	1	1	1		
Muscle spasms	1	1	1	1		
Nasal congestion	1	1	1	1		
Nausea	1	1			1	1
Pain in extremity	1	1	1	1		
Pancreatitis	1	1			1	1
Sensory loss	1	1	1	1		
Urine analysis abnormal	1	1			1	1
	10	10	6	6	4	4

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Country Where Event Occurred

**COLOMBIA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Candida infection	1	1	1	1
Gingivitis	1	1	1	1
Hypersensitivity	1	1	1	1
Leukocytosis	1	1	1	1
Mouth swelling	1	1	1	1
Stomatitis	1	1	1	1
	6	6	6	6

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Country Where Event Occurred

**COSTA RICA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Headache	1	1	1	1
Heart rate irregular	1	1	1	1
Insomnia	1	1	1	1
Red blood cell sedimentation rate increased	1	1	1	1
Sleep disorder	1	1	1	1
Vasculitis	1	1	1	1
	6	6	6	6

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 \* AE=Adverse Event  
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Country Where Event Occurred

**CROATIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain upper	1	1	1	1		
Anaphylactic reaction	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Bronchospasm	1	1			1	1
Chills	1	1	1	1		
Dysgeusia	1	1			1	1
Dyspnoea	1	1			1	1
Eyelid ptosis	1	1			1	1
Facial paresis	1	1			1	1
Fatigue	1	1	1	1		
Headache	3	3	2	2	1	1
Hypoaesthesia oral	1	1			1	1
Lip disorder	1	1			1	1
Multi-organ disorder	1	1			1	1
Pain	1	1	1	1		
Paraesthesia	1	1			1	1
Pharyngeal paraesthesia	1	1			1	1
Pyrexia	2	2	2	2		
Respiratory tract oedema	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Tachypnoea	1	1			1	1
Tongue oedema	1	1			1	1
Tremor	1	1			1	1
Vaccination site oedema	1	1			1	1
Vaccination site pain	1	1			1	1
Wheezing	1	1			1	1
	31	31	8	8	23	23

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Country Where Event Occurred

**CYPRUS**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cervix oedema	1	1	1	1		
Facial paresis	1	1	1	1		
Headache	1	1	1	1		
Hypersensitivity	1	1	1	1		
Hypertension	1	1			1	1
Myocardial infarction		1				1
Rash	1	1	1	1		
Tachyarrhythmia	1	1			1	1
Tachycardia	1	1			1	1
	8	9	5	5	3	4

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Country Where Event Occurred

**CZECH REPUBLIC**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergy to vaccine	2	2			2	2
Anaphylactic reaction	1	1			1	1
Angioedema	1	1			1	1
Anxiety	1	1	1	1		
Arthralgia	1	1	1	1		
Asthenia	1	1	1	1		
Blood pressure increased	1	1			1	1
Chills	1	1			1	1
Dizziness	2	2	1	1	1	1
Dyspnoea	2	2	1	1	1	1
Erythema	2	2	2	2		
Fatigue	2	2	2	2		
Headache	1	1	1	1		
Hypertension	1	1	1	1		
Hyperventilation	1	1	1	1		
Hypoaesthesia	1	1	1	1		
Joint stiffness	1	1	1	1		
Lip swelling	1	1			1	1
Malaise	1	1	1	1		
Musculoskeletal pain	1	1	1	1		
Musculoskeletal stiffness	1	1	1	1		
Nausea	2	2	1	1	1	1
Paraesthesia	2	2	1	1	1	1
Peripheral swelling	1	1			1	1
Photophobia	1	1	1	1		
Pruritus	1	1	1	1		
Rash	1	1	1	1		
Swelling	1	1			1	1
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	1	1			1	1
Throat tightness	1	1			1	1
Vision blurred	1	1	1	1		
Vomiting	1	1			1	1
	41	41	23	23	18	18

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Country Where Event Occurred

**DENMARK**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aggression	1	1			1	1
Anaphylactic reaction	1	1			1	1
Angioedema	2	2			2	2
Aspiration	1	1			1	1
Asthenia	1	1	1	1		
Bacteraemia	1	1			1	1
Blood pressure systolic increased	1	1	1	1		
Bronchospasm	1	1			1	1
Cardiac arrest	1	1			1	1
Chest discomfort	1	1			1	1
Chills	1	1			1	1
Chronic obstructive pulmonary disease	1	1			1	1
Coma	1	1			1	1
Condition aggravated	1	1			1	1
Cough	1	1			1	1
Death	1	1			1	1
Depressed level of consciousness	1	1			1	1
Discomfort	2	2			2	2
Disturbance in attention	1	1			1	1
Dizziness	3	3	1	1	2	2
Dry eye	1	1	1	1		
Dyspnoea	4	4			4	4
Dyspnoea at rest	1	1			1	1
Eye pain	1	1	1	1		
Eye pruritus	1	1	1	1		
Fatigue	3	3			3	3
Fluid intake reduced	1	1	1	1		
Flushing	1	1			1	1
Foaming at mouth	1	1	1	1		
General physical health deterioration	3	3			3	3

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headache	3	3	1	1	2	2
Heart rate increased	1	1			1	1
Hemiparesis	1	1			1	1
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1			1	1
Hypophagia	1	1	1	1		
Hypotension	2	2			2	2
Incorrect route of product administration	1	1	1	1		
Malaise	3	3	2	2	1	1
Mobility decreased	1	1			1	1
Myalgia	3	3	2	2	1	1
Nausea	2	2	2	2		
Obstructive airways disorder	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pain	1	1			1	1
Pallor	1	1	1	1		
Palpitations	1	1			1	1
Pneumonia aspiration	1	1			1	1
Prolonged expiration	1	1			1	1
Pruritus	1	1	1	1		
Pulmonary oedema	1	1			1	1
Pyrexia	6	6	2	2	4	4
Rales	1	1			1	1
Rash	2	2	1	1	1	1
Rash erythematous	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory failure	1	1			1	1
Sepsis	1	1			1	1
Somnolence	1	1			1	1
Stridor	1	1			1	1
Sudden death	1	1			1	1
Swelling face	1	1			1	1
Syncope	1	1			1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	1	1			1	1
Urticaria	1	1	1	1		
Vaccination site erythema	1	1	1	1		
Vaccination site pain	7	7	5	5	2	2
Vaccination site pruritus	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vomiting	4	4	1	1	3	3
	104	104	33	33	71	71

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Country Where Event Occurred

**FINLAND**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic shock	1	1			1	1
Chest discomfort	2	2			2	2
Cough	1	1			1	1
Death	1	1			1	1
Derealisation	1	1	1	1		
Dyspnoea	2	2			2	2
Erythema	1	1			1	1
Fatigue	1	1			1	1
Feeling cold	1	1	1	1		
Headache	2	2			2	2
Heart rate increased	1	1			1	1
Hypoaesthesia	1	1	1	1		
Hypokalaemia	2	2			2	2
Malaise	3	3	2	2	1	1
Migraine	1	1			1	1
Myalgia	1	1	1	1		
Nausea	1	1			1	1
Pain in extremity	1	1	1	1		
Paraesthesia	1	1			1	1
Pharyngeal oedema	1	1			1	1
Pharyngeal swelling	1	1			1	1
Presyncope	1	1	1	1		
Pyrexia	1	1	1	1		
Rash	1	1			1	1
Rash erythematous	1	1	1	1		
Seizure	1	1			1	1
Syncope	1	1			1	1
Tremor	1	1			1	1
Urticaria	1	1			1	1
Vomiting	1	1			1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	36	36	10	10	26	26

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Country Where Event Occurred

**FRANCE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Anaphylactic shock	1	1			1	1
Angioedema	1	1			1	1
Anxiety	2	2			2	2
Arrhythmia	1	1			1	1
Arrhythmia supraventricular	1	1			1	1
Atrial f brillation	2	2			2	2
Blood pressure systolic increased	1	1			1	1
Blood uric acid increased	1	1	1	1		
Bronchial obstruction	1	1			1	1
Cardiac arrest	1	1			1	1
Cardiac failure	2	2			2	2
Cardio-respiratory arrest	1	1			1	1
Cerebrovascular accident	2	2			2	2
Chest pain	1	1			1	1
Cognitive disorder	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	1	1			1	1
Constipation	1	1	1	1		
C-reactive protein increased	2	2	1	1	1	1
Death	5	5			5	5
Depressed level of consciousness	1	1			1	1
Diarrhoea	2	2			2	2
Dysarthria	1	1			1	1
Dysphagia	1	1			1	1
Dyspnoea	2	2			2	2
Fall	1	1			1	1
Fear	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glycosylated haemoglobin increased	1	1	1	1		
Haemorrhagic stroke	1	1			1	1
Headache	2	2	2	2		
Hyperleukocytosis	1	1			1	1
Hypersensitivity	1	1			1	1
Hypertension	1	1	1	1		
Hypertensive crisis	1	1			1	1
Hypertonia	1	1			1	1
Hypotension	1	1			1	1
Increased bronchial secretion	1	1			1	1
Injection site pain	1	1	1	1		
International normalised ratio abnormal	1	1			1	1
Ischaemic stroke	1	1			1	1
Loss of consciousness	1	1			1	1
Lymphopenia	1	1	1	1		
Malaise	3	3			3	3
Nausea	2	2			2	2
Oedema peripheral	1	1			1	1
Oropharyngeal discomfort	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Palpitations	1	1	1	1		
Petit mal epilepsy	1	1			1	1
Productive cough	1	1			1	1
Pruritus	1	1	1	1		
Pyrexia	2	2	1	1	1	1
Rales	1	1			1	1
Renal failure	1	1			1	1
Sudden death	6	6			6	6
Tachycardia	1	1			1	1
Thrombocytopenia	1	1			1	1
Urticaria	2	2			2	2
Vaccination site pain	1	1	1	1		
Vomiting	2	2			2	2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	86	86	13	13	73	73

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Country Where Event Occurred

**GERMANY**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain lower	2	2	2	2		
Abdominal pain upper	1	1	1	1		
Accidental overdose	1	1	1	1		
Acute kidney injury	3	3			3	3
Acute myocardial infarction	2	2			2	2
Allergy to vaccine	1	1			1	1
Anaphylactic shock	3	3			3	3
Angina pectoris	1	1			1	1
Arrhythmia	1	1			1	1
Arthralgia	4	4	4	4		
Asthenia	7	7	5	5	2	2
Atrial f brillation	1	1			1	1
Back pain	1	1	1	1		
Bedridden	1	1			1	1
Blister	1	1	1	1		
Blood glucose fluctuation	1	1	1	1		
Blood urine present	1	1			1	1
Body temperature increased	3	3	1	1	2	2
Bone pain	1	1	1	1		
Cardiac arrest	1	1			1	1
Cardiac failure	5	5			5	5
Cardiac fibrillation	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills	6	6	6	6		
Chronic kidney disease	1	1			1	1
Circulatory collapse	3	3			3	3
Cough	3	3	3	3		
COVID-19	9	9			9	9
COVID-19 pneumonia	2	2			2	2
Crepitations	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cyanosis	1	1			1	1
Death	13	13			13	13
Decreased appetite	1	1			1	1
Dementia	1	1			1	1
Dementia of the Alzheimer's type, with delirium	1	1			1	1
Depressed level of consciousness	1	1			1	1
Diarrhoea	5	5	4	4	1	1
Diet refusal	2	2			2	2
Disorientation	1	1	1	1		
Dizziness	7	7	6	6	1	1
Drug ineffective	13	13			13	13
Dry skin	1	1	1	1		
Dyspepsia	1	1	1	1		
Dysphonia	2	2	2	2		
Dyspnoea	4	4	3	3	1	1
Epilepsy		1				1
Erythema	1	1	1	1		
Eye pruritus	2	2	1	1	1	1
Eye swelling	1	1			1	1
Fall	1	1			1	1
Fatigue	14	14	12	12	2	2
Feeling cold	1	1	1	1		
Feeling hot	1	1	1	1		
Femoral neck fracture	1	1			1	1
Food refusal	2	2			2	2
General physical condition abnormal	1	1			1	1
General physical health deterioration	4	4	1	1	3	3
Haematoma	1	1	1	1		
Headache	11	11	9	9	2	2
Hyperhidrosis	1	1	1	1		
Hyperpyrexia	1	1			1	1
Hypersensitivity	1	1			1	1
Hypertension	2	2			2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hypotension	1	1			1	1
Hypotonia	1	1			1	1
Incorrect route of product administration	2	2	2	2		
Infective exacerbation of chronic obstructive airways disease	1	1			1	1
Influenza like illness	4	4	4	4		
Irregular breathing	1	1			1	1
Jaw clicking	1	1			1	1
Laryngeal oedema	1	1			1	1
Limb discomfort	1	1	1	1		
Lip swelling	1	1			1	1
Livedo reticularis	1	1	1	1		
Local reaction	1	1	1	1		
Lymphadenopathy	3	3	3	3		
Malaise	4	4	1	1	3	3
Mobility decreased	1	1	1	1		
Muscle swelling	1	1	1	1		
Muscular weakness	1	1	1	1		
Myalgia	5	5	5	5		
Nausea	4	4	2	2	2	2
Neck pain	1	1	1	1		
Off label use	3	3	3	3		
Otitis media	1	1	1	1		
Oxygen saturation decreased	3	3			3	3
Pain in extremity	6	6	6	6		
Palpitations	1	1	1	1		
Paraesthesia	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Pathogen resistance	1	1			1	1
Peripheral vascular disorder	2	2	1	1	1	1
Personality change	1	1			1	1
Pharyngeal inflammation	1	1	1	1		
Pharyngeal swelling	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pneumonia	4	4	1	1	3	3
Poor quality sleep	1	1			1	1
Product preparation issue	1	1	1	1		
Product use issue	3	3	3	3		
Pruritus	1	1	1	1		
Psoriasis	1	1	1	1		
Pulmonary embolism	1	1			1	1
Pyrexia	14	14	11	11	3	3
Rash	1	1			1	1
Renal failure	2	2			2	2
Respiratory distress	3	3	1	1	2	2
Respiratory failure	1	1			1	1
Retching	1	1	1	1		
Rhinalgia	1	1	1	1		
Rhinorrhoea	1	1			1	1
Rhonchi	1	1			1	1
Rosacea	1	1			1	1
SARS-CoV-2 test positive	2	2			2	2
Seizure	1	1			1	1
Somnolence	2	2	2	2		
Staphylococcal sepsis	1	1			1	1
Sudden death	6	6			6	6
Suspected COVID-19	1	1			1	1
Swelling	1	1	1	1		
Swelling face	1	1			1	1
Swollen tongue	1	1			1	1
Syncope	1	1			1	1
Tachyarrhythmia	2	2			2	2
Tachycardia	5	5	2	2	3	3
Tachypnoea	1	1	1	1		
Throat irritation	1	1	1	1		
Throat tightness	1	1			1	1
Transient ischaemic attack	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tremor	1	1	1	1		
Unresponsive to stimuli	2	2			2	2
Vaccination site dermatitis	1	1	1	1		
Vaccination site erythema	2	2	2	2		
Vaccination site induration	1	1	1	1		
Vaccination site pain	13	13	12	12	1	1
Vaccination site paraesthesia	1	1	1	1		
Vaccination site rash	1	1	1	1		
Vaccination site reaction	2	2	2	2		
Vaccination site swelling	3	3	3	3		
Vaccination site warmth	2	2	2	2		
Ventricular fibrillation	1	1			1	1
Visual impairment	1	1			1	1
Vomiting	5	5	1	1	4	4
	329	330	167	167	162	163

\* I=Interval, C=Cumulative  
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Country Where Event Occurred

**GREECE**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Acute respiratory distress syndrome	1	1			1	1
Acute respiratory failure	1	1			1	1
Anaphylactic shock	1	1			1	1
Atrial fibrillation	1	1			1	1
Auscultation	1	1	1	1		
Cardiac arrest	2	2			2	2
Cardiac disorder	1	1			1	1
Cardiac valve disease	1	1			1	1
Chest pain	2	2	1	1	1	1
Condition aggravated	1	1			1	1
Diastolic hypertension	1	1			1	1
Dizziness	4	4	2	2	2	2
Drug interaction	1	1			1	1
Dysphagia	1	1	1	1		
Dyspnoea	2	2	1	1	1	1
Fall	1	1			1	1
Fatigue	1	1			1	1
Gait disturbance	1	1	1	1		
Headache	1	1	1	1		
Hypoaesthesia	1	1			1	1
Leukocytosis	1	1			1	1
Myalgia	1	1	1	1		
Pneumonia	1	1			1	1
Presyncope	1	1			1	1
Pruritus	2	2	1	1	1	1
Pyrexia	1	1			1	1
Rash	2	2	2	2		
Respiratory tract infection	1	1			1	1
Seizure	1	1			1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachycardia	1	1			1	1
Tremor	1	1			1	1
	40	40	12	12	28	28

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Country Where Event Occurred

**HUNGARY**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ageusia	2	2	2	2		
Anosmia	1	1	1	1		
Asthenia	2	3	2	3		
Back pain	1	1	1	1		
Blood glucose increased		1		1		
Blood pressure increased		1				1
Chills		1		1		
COVID-19	1	1			1	1
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dry mouth		1				1
Fatigue	1	2	1	2		
Feeling hot	1	2	1	1		1
Haemorrhage	1	1			1	1
Headache	3	3	3	3		
Heart rate increased	1	2	1	2		
Incorrect route of product administration	1	1	1	1		
Malaise	2	2	2	2		
Micturition urgency		1		1		
Myalgia	2	2	2	2		
Nasopharyngitis	1	1	1	1		
Oropharyngeal pain	1	1	1	1		
Pain in extremity	1	1	1	1		
Paraesthesia		1				1
Peripheral swelling	1	1	1	1		
Pyrexia	2	2	2	2		
Somnolence	1	1	1	1		
Thirst		1				1
Tremor		1				1
Vaccination site nodule	2	2	2	2		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	3	3	3	3		
	33	45	30	36	3	9

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Country Where Event Occurred

**ICELAND**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysm	1	1			1	1
Asthenia	2	2	2	2		
Back pain	1	1	1	1		
Cardiac failure	2	2			2	2
Cough	2	2	1	1	1	1
Death	2	2			2	2
Disease progression	1	1			1	1
Headache	1	1	1	1		
Malaise	2	2			2	2
Migraine	1	1	1	1		
Myocardial infarction	1	1			1	1
Nasopharyngitis	3	3	3	3		
Nausea	1	1	1	1		
Pneumonia	2	2			2	2
Pyrexia	6	6	4	4	2	2
Rhinorrhoea	1	1	1	1		
Sepsis	1	1			1	1
Vaccination site erythema	1	1	1	1		
	31	31	16	16	15	15

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Country Where Event Occurred

**IRELAND**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Death	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**ISRAEL**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Allergy to vaccine	2	2			2	2
Anaphylactic reaction	1	1			1	1
Angina pectoris	1	1			1	1
Arthralgia	1	1	1	1		
Asthenia	7	8	7	8		
Asthma	1	1	1	1		
Atrial fibrillation	1	2			1	2
Balance disorder		1		1		
Blood chloride increased	2	2	1	1	1	1
Blood glucose increased	2	2	1	1	1	1
Blood pressure increased	2	2	1	1	1	1
Cardiac arrest	3	4			3	4
Cardiac failure		1				1
Chest discomfort		1		1		
Chills	2	2	2	2		
Circulatory collapse	1	1			1	1
Contusion	1	1			1	1
Cough	1	1	1	1		
COVID-19	1	1			1	1
C-reactive protein increased	1	1	1	1		
Crying	1	1	1	1		
Death	3	4			3	4
Disease recurrence	1	2	1	1		1
Dizziness	4	5	4	5		
Drug ineffective	1	1			1	1
Dysgeusia	1	1	1	1		
Dysphagia	2	2	1	1	1	1
Dyspnoea	7	7	4	4	3	3
Dyspnoea exertional	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eosinophilic oesophagitis	1	1	1	1		
Erythema	3	4	3	4		
Eye irritation	2	2	1	1	1	1
Facial paralysis	1	1			1	1
Fall	1	1			1	1
Fatigue	2	2	2	2		
Feeling abnormal	1	2			1	2
Feeling hot	2	3	2	3		
Glomerular filtration rate decreased	1	1			1	1
Haemolytic anaemia	1	1			1	1
Headache	7	7	6	6	1	1
Heart rate increased	2	2	2	2		
Hypoaesthesia	2	2	2	2		
Hypoaesthesia oral	1	2		1	1	1
Hypotension	1	1	1	1		
Hypoventilation	1	1			1	1
Inflammatory marker increased		1				1
Influenza like illness	1	1	1	1		
Jaundice	1	1	1	1		
Lacrimation increased	2	2	1	1	1	1
Leukocytosis	1	1			1	1
Lip swelling	1	1	1	1		
Loss of consciousness		1				1
Lymphocyte count increased	1	1	1	1		
Lymphocytosis	1	1	1	1		
Lymphopenia	1	1			1	1
Malaise	1	1	1	1		
Mean cell haemoglobin concentration decreased	1	1	1	1		
Mean cell haemoglobin decreased	2	2	1	1	1	1
Mean cell volume decreased	1	1	1	1		
Multiple sclerosis relapse	3	3			3	3
Myalgia	4	4	4	4		
Nausea	1	2	1	2		

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\* AE=Adverse Event

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neutrophil count increased	1	1			1	1
Off label use	1	1	1	1		
Oropharyngeal discomfort		1		1		
Oropharyngeal pain	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pain	1	1	1	1		
Pain in extremity	2	2	2	2		
Palpitations	2	2	2	2		
Paraesthesia	4	4	3	3	1	1
Paraesthesia oral	2	3	2	3		
Pericarditis		1				1
Personality change	1	1	1	1		
Pharyngeal swelling		1		1		
Pleural effusion	1	1			1	1
Pleuritic pain		1				1
Product use issue	1	1	1	1		
Pruritus	1	1			1	1
Pulse abnormal	1	1			1	1
Pyrexia	4	4	3	3	1	1
Rash	1	1			1	1
Red blood cell count increased	1	1	1	1		
Respiratory arrest	1	1			1	1
Respiratory distress	1	1			1	1
Sepsis	1	1			1	1
Suffocation feeling	1	1	1	1		
Swollen tongue	2	2			2	2
Tachycardia	1	1	1	1		
Therapeutic response unexpected	1	1	1	1		
Throat tightness	1	1			1	1
Tinnitus	1	1	1	1		
Tremor	1	1	1	1		
Urticaria	1	1			1	1
Vaccination site movement impairment	1	1	1	1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site pain	3	4	3	4		
Vaccination site swelling	1	1	1	1		
Vision blurred	1	1	1	1		
Vomiting	1	1	1	1		
	148	170	94	106	54	64

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Country Where Event Occurred

**ITALY**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Abdominal pain upper	2	2	2	2		
Acute coronary syndrome	1	1			1	1
Acute myocardial infarction	1	1			1	1
Agitation	1	1	1	1		
Allergic respiratory symptom	1	1			1	1
Allergy to vaccine	1	1			1	1
Anaphylactic reaction	1	1			1	1
Angioedema	1	1			1	1
Arteriosclerosis	1	1			1	1
Arthralgia	3	4	3	4		
Asphyxia	1	1			1	1
Asthenia	3	4	2	3	1	1
Atrioventricular block complete	1	1			1	1
Back pain	2	2	1	1	1	1
Balance disorder	1	1	1	1		
Blood pressure increased	1	1			1	1
Bradycardia	1	1			1	1
Burning sensation	1	1	1	1		
Cerebellar haemorrhage	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills	2	2	2	2		
Circulatory collapse	1	1			1	1
Coma scale abnormal	1	1			1	1
Condition aggravated	1	1			1	1
Cough	2	2	2	2		
Death	2	2			2	2
Deep vein thrombosis	1	1			1	1
Dehydration	1	1			1	1
Dermatitis allergic	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis exfoliative generalised	1	1			1	1
Dizziness	2	2	2	2		
Drug ineffective	1	1			1	1
Dysphagia	3	3	1	1	2	2
Dyspnoea	5	5	1	1	4	4
Erythema	2	2	1	1	1	1
Extremity contracture	1	1	1	1		
Eye pain	1	1	1	1		
Facial spasm	1	1			1	1
Fall	1	1			1	1
Fatigue	1	1	1	1		
Flushing	2	2	2	2		
Gastrointestinal disorder	1	1	1	1		
General physical health deterioration	1	1			1	1
Headache	7	8	7	8		
Hemiparesis	1	1			1	1
Hot flush	1	1	1	1		
Hyperhidrosis	2	2	2	2		
Hypersensitivity	1	1			1	1
Hypertension	4	4	2	2	2	2
Influenza like illness	1	2	1	2		
Laryngeal oedema	3	3			3	3
Laryngospasm	1	1			1	1
Limb discomfort	1	1	1	1		
Lymphadenopathy	2	2	2	2		
Malaise	4	4	4	4		
Migraine	1	1	1	1		
Muscle contractions involuntary	1	1			1	1
Muscle rigidity	1	1			1	1
Muscle spasms	1	1	1	1		
Musculoskeletal pain	2	2	2	2		
Myalgia	2	2	2	2		
Myocardial ischaemia	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea	5	5	4	4	1	1
Neck pain	1	1	1	1		
Nuchal rigidity	1	1			1	1
Off label use	1	1	1	1		
Oral herpes	1	1	1	1		
Oropharyngeal swelling	1	1	1	1		
Oxygen saturation decreased	2	2	1	1	1	1
Pain in extremity	1	1	1	1		
Palatal swelling	1	1	1	1		
Paraesthesia	1	1	1	1		
Paraesthesia oral	2	2	2	2		
Presyncope	1	1	1	1		
Product use issue	1	1	1	1		
Pruritus	3	3	3	3		
Pulmonary embolism	1	1			1	1
Pyrexia	5	5	5	5		
Q fever	1	1			1	1
Rash	3	3	2	2	1	1
Rash pruritic	1	1	1	1		
Reduced facial expression	1	1			1	1
Renal failure	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory distress	1	1			1	1
Restlessness	1	1			1	1
SARS-CoV-2 test positive	1	1			1	1
Skin reaction	1	1	1	1		
Somnolence	1	1	1	1		
Spinal pain	1	1	1	1		
Swelling face	1	1			1	1
Systolic hypertension	1	1			1	1
Tachycardia	3	3	1	1	2	2
Tachypnoea	1	1	1	1		
Throat irritation	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Throat tightness	4	4	2	2	2	2
Tongue oedema	1	1			1	1
Underdose	1	1	1	1		
Urticaria	4	4	3	3	1	1
Vaccination site erythema	2	2	2	2		
Vaccination site movement impairment	1	1	1	1		
Vaccination site oedema	1	1	1	1		
Vaccination site pain	7	7	7	7		
Vaccination site paraesthesia	1	1	1	1		
Vaccination site swelling	1	1	1	1		
Vertigo	1	1	1	1		
Vomiting	2	2	1	1	1	1
Weight decreased	1	1			1	1
	176	180	108	112	68	68

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Country Where Event Occurred

**LATVIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthralgia	2	2	1	1	1	1
Asthenia	2	2	2	2		
Asthma	1	1	1	1		
Chest pain	1	1	1	1		
Cough	1	1	1	1		
Dyspnoea	1	1	1	1		
Fatigue	2	2	2	2		
Headache	1	1			1	1
Neuralgia	1	1			1	1
Pain in extremity	1	1			1	1
Paraesthesia	1	1			1	1
Pyrexia	1	1	1	1		
Throat irritation	1	1	1	1		
Vaccination site pain	2	2	2	2		
	18	18	13	13	5	5

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Country Where Event Occurred

**LUXEMBOURG**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Herpes zoster	1	1	1	1
Oral herpes	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**MALTA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyspnoea	1	1			1	1
Nausea	1	1	1	1		
Rash pruritic	1	1			1	1
Wheezing	1	1			1	1
	4	4	1	1	3	3

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Country Where Event Occurred

**MEXICO**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1	1	1		
Anaphylactic shock		1				1
Angioedema		1				1
Asthma	1	1	1	1		
COVID-19 pneumonia	1	1			1	1
Cyanosis		1		1		
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea		1		1		
Encephalitis post immunisation		1				1
Eye swelling		1		1		
Hypersensitivity		1		1		
Loss of consciousness		1				1
Masticatory pain	1	1	1	1		
Muscle spasms		1				1
Myelitis transverse		1				1
Nasal congestion		1		1		
Paraesthesia		1				1
Paralysis		1				1
Parotid gland enlargement	1	1	1	1		
Parotitis	1	1	1	1		
Pruritus		1		1		
Rash		1				1
Respiratory distress		1				1
Seizure		1				1
Sneezing		1		1		
Throat irritation		1		1		
Vaccination site pain	1	1	1	1		
	9	28	7	15	2	13

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Country Where Event Occurred

**NETHERLANDS**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaphylactic reaction	1	1			1	1
Angioedema	1	1			1	1
Erythema	1	1	1	1		
Paraesthesia oral	1	1	1	1		
Tongue oedema	1	1			1	1
Urticaria	1	1	1	1		
	6	6	3	3	3	3

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Country Where Event Occurred

**NORWAY**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Anxiety	1	1	1	1		
Apathy	1	1			1	1
Blood pressure decreased	2	2			2	2
Blood pressure diastolic decreased	1	1	1	1		
Body temperature decreased	1	1	1	1		
Cardiac failure	1	1			1	1
Cardiovascular disorder	1	1			1	1
Cerebral haemorrhage	1	1			1	1
Cerebrovascular accident	2	2			2	2
Cold sweat	2	2			2	2
Concomitant disease aggravated	1	1			1	1
Condition aggravated	1	1			1	1
Confusional state	3	3			3	3
Coordination abnormal	1	1			1	1
Cough	1	1			1	1
Death	7	7			7	7
Decreased appetite	2	2			2	2
Delirium	1	1			1	1
Depressed level of consciousness	2	2			2	2
Diarrhoea	2	2			2	2
Disease recurrence	1	1			1	1
Dysphagia	1	1			1	1
Dyspnoea	3	3			3	3
Fatigue	4	4	1	1	3	3
Feeling hot	1	1			1	1
Gastrointestinal haemorrhage	1	1			1	1
General physical health deterioration	7	7			7	7
Hallucination	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate increased	1	1			1	1
Hyperventilation	1	1	1	1		
Hypotension	1	1			1	1
Infection	1	1			1	1
Influenza like illness	1	1			1	1
Local reaction	1	1			1	1
Loss of consciousness	1	1			1	1
Malaise	2	2			2	2
Malignant hypertension	1	1			1	1
Nausea	1	1			1	1
Oxygen saturation decreased	1	1			1	1
Pallor	2	2			2	2
Pneumonia	1	1			1	1
Pupil fixed	2	2			2	2
Pyrexia	4	4			4	4
Rales	1	1			1	1
Respiratory arrest	1	1			1	1
Respiratory rate increased	2	2			2	2
Restlessness	1	1	1	1		
Somnolence	2	2			2	2
Sudden death	2	2			2	2
Syncope	2	2			2	2
Tremor	1	1			1	1
Vaccination site erythema	1	1			1	1
Vaccination site pain	1	1			1	1
Vaccination site swelling	1	1			1	1
Vomiting	4	4	1	1	3	3
	95	95	7	7	88	88

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Country Where Event Occurred

**POLAND**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disease recurrence	1	1			1	1
Inflammation	1	1	1	1		
Iritis	1	1	1	1		
Paraparesis	1	1			1	1
Pyrexia	1	1	1	1		
Rash macular	1	1	1	1		
Vaccination site pain	1	1	1	1		
	7	7	5	5	2	2

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Country Where Event Occurred

**PORTUGAL**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1	1	1		
Balance disorder		1				1
Cardio-respiratory arrest	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	2	2			2	2
Circumoral oedema	1	1			1	1
Cough	1	1			1	1
Death	1	1			1	1
Dizziness		1				1
Dysgeusia	1	1			1	1
Erythema		1				1
Fatigue	1	1			1	1
Generalised tonic-clonic seizure	1	1			1	1
Hypersensitivity		1				1
Hypothyroidism	1	1			1	1
Incorrect route of product administration	1	1	1	1		
Laryngeal oedema	1	1			1	1
Lip oedema	2	2			2	2
Malaise		1				1
Myalgia	2	2			2	2
Nasal obstruction	1	1			1	1
Nausea	1	2			1	2
Oropharyngeal discomfort	1	1			1	1
Pain	1	1	1	1		
Pain in extremity	1	1			1	1
Pain in jaw	1	1			1	1
Palmar-plantar erythrodysesthesia syndrome	1	1			1	1
Palpitations	1	1	1	1		
Peripheral coldness	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Pruritus	2	3	1	1	1	2
Pyrexia	1	1			1	1
Rash	1	2			1	2
Rhinorrhoea	1	1			1	1
Sensory loss	1	1			1	1
Sinus tachycardia		1				1
Tachypnoea	1	1			1	1
Tenosynovitis	1	1	1	1		
Thyroid function test abnormal	1	1	1	1		
Tongue dry	1	1			1	1
Vaccination site pain	1	1			1	1
Vaccination site pruritus		1				1
	39	49	7	7	32	42

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Country Where Event Occurred

**PUERTO RICO**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	1	1	1	1		
Arthralgia		2		2		
Chills	1	1	1	1		
Dyskinesia	1	1			1	1
Facial paralysis	1	1			1	1
Fatigue		1		1		
Gait disturbance		1		1		
Headache	1	2	1	2		
Heart rate decreased	1	1			1	1
Hypertension		1		1		
Hypoaesthesia		1		1		
Joint range of motion decreased		1		1		
Limb discomfort		1		1		
Migraine	1	1			1	1
Musculoskeletal stiffness		1		1		
Neuralgia		1		1		
Night sweats	1	1			1	1
Pain		1		1		
Pain in extremity		2		2		
Palpitations		1		1		
Rash	1	1	1	1		
Sinus arrhythmia	1	1			1	1
Tachycardia		1		1		
Vaccination site induration		1		1		
	10	27	4	21	6	6

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Country Where Event Occurred

**ROMANIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety	1	1			1	1
Arthralgia	1	1			1	1
Asthenia	1	1			1	1
Chest pain	1	1			1	1
Chills	1	1			1	1
Cough	1	1			1	1
Dizziness	1	1	1	1		
Fatigue	1	1			1	1
Flushing	1	1	1	1		
Headache	1	1			1	1
Maternal exposure during pregnancy	1	1	1	1		
Migraine	1	1			1	1
Myalgia	2	2	1	1	1	1
Nausea	1	1			1	1
Off label use	1	1	1	1		
Palpitations	1	1			1	1
Paraesthesia	2	2	1	1	1	1
Product use issue	1	1	1	1		
Rash	1	1	1	1		
Somnolence	1	1	1	1		
Systolic hypertension	1	1			1	1
Tachycardia	1	1			1	1
Vaccination site erythema	1	1	1	1		
Vaccination site pain	2	2	2	2		
Vomiting	1	1			1	1
	28	28	12	12	16	16

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Country Where Event Occurred

**SAUDI ARABIA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Fatigue	1	1	1	1
Headache	1	1	1	1
Movement disorder	1	1	1	1
Musculoskeletal stiffness	1	1	1	1
Nasopharyngitis	1	1	1	1
Pain	1	1	1	1
Rhinorrhoea	1	1	1	1
Vaccination site pain	1	1	1	1
	8	8	8	8

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Country Where Event Occurred

**SERBIA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Pyrexia	1	1	1	1
Vaccination site pain	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**SLOVAKIA**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoaesthesia	1	1	1	1
Lymphadenopathy	1	1	1	1
Pain in extremity	2	2	2	2
Product administered at inappropriate site	1	1	1	1
Rash	1	1	1	1
Rash pruritic	1	1	1	1
Vaccination site urticaria	1	1	1	1
	8	8	8	8

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Country Where Event Occurred

**SLOVENIA**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute myocardial infarction	1	1			1	1
Asthenia	1	1	1	1		
Disease recurrence	1	1			1	1
Sudden death	1	1			1	1
	4	4	1	1	3	3

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Country Where Event Occurred

**SPAIN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	1	1			1	1
Acute respiratory failure	1	1			1	1
Anaphylactic shock	1	1			1	1
Angular cheilitis	1	1	1	1		
Arthralgia	2	2	2	2		
Aspiration	1	1			1	1
Cardio-respiratory distress	1	1			1	1
Chest discomfort	1	1			1	1
Chest pain	1	1			1	1
Chills	2	2	2	2		
Depressed mood	1	1	1	1		
Diarrhoea	3	3	2	2	1	1
Discomfort	1	1	1	1		
Dizziness	3	3	2	2	1	1
Drug interaction	1	1	1	1		
Dyspnoea	6	6			6	6
Facial paralysis	1	1			1	1
Fatigue	1	1			1	1
Feeling cold	1	1			1	1
Flatulence	1	1			1	1
Formication	1	1	1	1		
Haematoma muscle	1	1			1	1
Headache	4	4	2	2	2	2
Hyperglycaemia	1	1	1	1		
Hyperhidrosis	1	1	1	1		
Hypersensitivity	1	1			1	1
Hypoxia	1	1			1	1
Inappropriate schedule of product administration	1	1	1	1		
Incorrect dose administered	1	1	1	1		
Insulin resistance	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laryngeal oedema	1	1			1	1
Lymphadenopathy	1	1	1	1		
Malaise	1	1			1	1
Migraine	1	1			1	1
Mobility decreased	1	1			1	1
Musculoskeletal stiffness	1	1			1	1
Myalgia	1	1	1	1		
Nasopharyngitis	1	1	1	1		
Nausea	2	2	1	1	1	1
Neck pain	1	1			1	1
Pain in extremity	1	1	1	1		
Palpitations	1	1			1	1
Paraesthesia	1	1	1	1		
Peripheral ischaemia	1	1			1	1
Pneumonia	1	1			1	1
Pyrexia	7	7	5	5	2	2
Rash	2	2	2	2		
Rectal haemorrhage	1	1			1	1
Respiratory distress	1	1			1	1
Respiratory failure	1	1			1	1
Sepsis	1	1			1	1
Stomatitis	1	1	1	1		
Sudden death	2	2			2	2
Troponin T increased	1	1			1	1
Vaccination site joint erythema	1	1	1	1		
Vaccination site movement impairment	1	1	1	1		
Vaccination site pain	3	3	3	3		
Vaccination site warmth	1	1	1	1		
Vomiting	2	2	2	2		
	85	85	42	42	43	43

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Country Where Event Occurred

**SWEDEN**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour	1	1	1	1		
Acute kidney injury	1	1			1	1
Anaphylactic shock	1	1			1	1
Anxiety	1	1			1	1
Blood pressure abnormal	1	1			1	1
Blood pressure decreased	1	1	1	1		
Blood pressure diastolic decreased	1	1	1	1		
Cardiac arrest	3	4			3	4
Cardiac disorder	1	1			1	1
Cardiac failure	1	1			1	1
Cerebrovascular accident	1	1			1	1
Chills	1	1	1	1		
Chronic obstructive pulmonary disease	2	2			2	2
Circulatory collapse	1	1			1	1
Confusional state	1	1			1	1
Cough	1	1			1	1
COVID-19	1	1			1	1
C-reactive protein increased	1	1			1	1
Crepitations	1	1	1	1		
Death	8	8			8	8
Dehydration	1	1			1	1
Depressed level of consciousness	1	1			1	1
Dermatitis	1	1	1	1		
Diarrhoea	3	3	1	1	2	2
Dizziness	1	1	1	1		
Drug ineffective	1	1			1	1
Dyspnoea	6	6			6	6
Dysstasia	1	1	1	1		
Epistaxis	1	1	1	1		
Erythema	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Escherichia sepsis	1	1			1	1
Facial paresis	1	1			1	1
Fatigue	4	4	2	2	2	2
General physical health deterioration	4	4	1	1	3	3
Headache	1	1	1	1		
Hypotension	2	2			2	2
Infection	3	3			3	3
Insomnia	1	1	1	1		
Ischaemic stroke	2	2			2	2
Loss of consciousness	1	1			1	1
Myalgia	1	1			1	1
Myocardial infarction	1	1			1	1
Nausea	1	1	1	1		
Oropharyngeal pain	1	1			1	1
Oropharyngeal spasm	1	1			1	1
Oxygen saturation decreased	2	2	2	2		
Palpitations	2	2	2	2		
Paraesthesia	1	1			1	1
Pharyngitis	1	1	1	1		
Pneumonia	1	1			1	1
Pneumonia bacterial	1	1			1	1
Productive cough	2	2			2	2
Pulmonary oedema	2	2			2	2
Pyrexia	5	5	1	1	4	4
Respiratory distress	2	2			2	2
Respiratory rate increased	1	1			1	1
Sensation of foreign body	1	1			1	1
Sepsis	1	1			1	1
Sudden death	2	2			2	2
Swelling	1	1	1	1		
Swelling face	1	1	1	1		
Systemic inflammatory response syndrome	1	1			1	1
Tachycardia	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tachypnoea	1	1	1	1		
Throat tightness	1	1			1	1
Upper respiratory tract infection	1	1			1	1
Urinary tract infection	1	1			1	1
Urosepsis	2	2			2	2
Urticaria	1	1	1	1		
Vomiting	1	1	1	1		
Wheezing	1	1	1	1		
	109	110	29	29	80	81

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Country Where Event Occurred

**SWITZERLAND**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal pain	2	2	2	2		
Anal haemorrhage	1	1	1	1		
Back pain	1	1	1	1		
Blood pressure decreased	2	2	1	1	1	1
Coma	1	1			1	1
C-reactive protein increased	1	1			1	1
Death	1	1			1	1
Fatigue	1	1	1	1		
Gastric disorder	1	1	1	1		
General physical health deterioration	2	2			2	2
Heart rate decreased	1	1			1	1
Heart rate increased	1	1	1	1		
Malaise	1	1	1	1		
Oxygen saturation decreased	1	1			1	1
Pneumonia	1	1			1	1
Respiratory failure	1	1			1	1
Restlessness	1	1	1	1		
Somnolence	1	1			1	1
Tachypnoea	1	1			1	1
Urethral pain	1	1	1	1		
Vaccination site pain	3	3	3	3		
	26	26	14	14	12	12

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Country Where Event Occurred

**UNITED ARAB EMIRATES**

<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Diarrhoea	1	1	1	1
Off label use		1		1
Product use issue		1		1
	1	3	1	3

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Country Where Event Occurred

**UNITED KINGDOM**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal discomfort	4	5			1	2	3	3
Abdominal distension	2	3			1	2	1	1
Abdominal pain	12	14			6	8	6	6
Abdominal pain lower	1	1					1	1
Abdominal pain upper	18	23			8	11	10	12
Abnormal dreams		2				2		
Acidosis	2	2			1	1	1	1
Acute kidney injury	3	3					3	3
Acute myocardial infarction	2	3					2	3
Acute respiratory failure	1	1					1	1
Ageusia	4	5			1	2	3	3
Agitation	3	3			1	1	2	2
Allergic oedema	1	1					1	1
Allodynia	1	1					1	1
Altered state of consciousness	1	1					1	1
Anal haemorrhage		1						1
Anal incontinence	1	1					1	1
Anaphylactic reaction	12	13					12	13
Anger	1	1					1	1
Angioedema	5	6					5	6
Ankylosing spondylitis	1	1					1	1
Anosmia	2	2			1	1	1	1
Anxiety	5	9			1	4	4	5
Aphasia	2	2					2	2
Aphonia	1	2					1	2
Arrhythmia	1	2					1	2
Arthralgia	106	123	1	1	29	39	77	84
Arthritis	3	4			1	2	2	2
Arthritis reactive	1	1					1	1
Asthenia	33	38			11	12	22	26

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Asthenopia	1	1
Asthma	12	15
Asthma prophylaxis	1	1
Atrial fibrillation	7	7
Aura	1	1
Axillary mass	2	3
Axillary pain	10	11
Back pain	22	26
Balance disorder	9	11
Blister	1	1
Blood creatine phosphokinase increased	1	1
Blood glucose decreased	1	1
Blood glucose increased	5	5
Blood ketone body present	1	1
Blood lactic acid increased	2	2
Blood potassium abnormal	1	1
Blood pressure decreased	1	1
Blood pressure increased	3	7
Blood pressure systolic decreased	1	1
Blood pressure systolic increased		1
Body temperature abnormal	3	3
Body temperature increased	11	13
Bone pain	4	4
Bone swelling	1	1
Bradycardia	3	3
Breast pain	3	3
Breast swelling	1	1
Bronchospasm	3	3
Bundle branch block right	1	1
Burning sensation	6	7
Cardiac arrest	6	8
Cardiac disorder	1	1
Cardiac failure congestive	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		3	4	9	11
				1	1
				7	7
				1	1
		1	2	1	1
		1	2	9	9
		9	13	13	13
1	1	2	2	7	9
		1	1		
				1	1
				1	1
		1	1	4	4
				1	1
		1	1	1	1
				1	1
				1	1
			2	3	5
				1	1
			1		
		1	1	2	2
1	1	3	4	8	9
		3	3	1	1
				1	1
				3	3
				3	3
		1	1		
				3	3
		1	1		
				6	7
				6	8
				1	1
				1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Cardiopulmonary failure	1	1
Cardio-respiratory arrest	1	1
Cataplexy		1
Cellulitis	4	4
Cerebral haemorrhage	2	2
Cerebral infarction	1	1
Cerebral venous sinus thrombosis	1	1
Cerebrovascular accident	8	8
Cheilitis	1	1
Chest discomfort	17	21
Chest pain	27	29
Chillblains	1	1
Chills	146	168
Cholecystitis infective	1	1
Chromaturia	1	1
Chronic fatigue syndrome		1
Circulatory collapse	12	13
Circumstance or information capable of leading to medication error		1
Clinical death	1	1
Cognitive disorder	1	1
Cold sweat	10	12
Colitis ulcerative	1	1
Coma scale abnormal	1	1
Communication disorder	1	1
Condition aggravated	12	14
Confusional state	12	13
Conjunctivitis	1	1
Contusion	3	4
Coronary artery disease	1	1
Cortisol decreased	1	1
Costochondritis	1	1
Cough	38	40

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
				1	1
					1
				4	4
				2	2
				1	1
				1	1
				8	8
				1	1
		4	6	13	15
		4	4	23	25
				1	1
		43	57	103	111
				1	1
				1	1
			1		
				12	13
			1		
				1	1
				1	1
		3	3	7	9
				1	1
				1	1
		2	3	10	11
		4	4	8	9
				1	1
				3	4
				1	1
				1	1
				1	1
		10	11	28	29

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
COVID-19	19	20
COVID-19 pneumonia	1	1
C-reactive protein increased	1	1
Crying	2	2
Cyanosis	3	3
Deafness	1	1
Death	23	23
Decreased appetite	26	27
Decreased interest	1	1
Deep vein thrombosis	2	2
Defaecation urgency	1	1
Dehydration	3	4
Delirium	5	5
Dementia	2	2
Depressed level of consciousness	1	1
Depression	2	2
Dermatitis	2	2
Dermatitis allergic		2
Diabetes mellitus inadequate control	1	2
Diabetic complication	1	1
Diabetic ketoacidosis	2	3
Diarrhoea	45	57
Diplopia	1	1
Discomfort	5	5
Disease recurrence	4	4
Disorientation	1	2
Dissociation		1
Disturbance in attention	2	3
Dizziness	73	91
Dizziness postural	7	10
Drug eruption	2	2
Drug hypersensitivity	1	1
Drug ineffective	46	48

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				19	20
				1	1
		1	1		
		1	1	1	1
		1	1	2	2
				1	1
				23	23
		3	4	23	23
				1	1
				2	2
				1	1
		2	3	1	1
				5	5
				2	2
				1	1
				2	2
		2	2		
			2		
				1	2
				1	1
				2	3
		10	15	35	42
				1	1
		2	2	3	3
				4	4
			1	1	1
			1		
				2	3
1	1	20	31	53	60
		1	3	6	7
				2	2
				1	1
				46	48

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous				
			Serious		Nonserious		Serious		
			I	C	I	C	I	C	
Dry eye		1				1			
Dry mouth	7	10				2	7	8	
Dry skin	3	3			3	3			
Dry throat	2	3				1	2	2	
Dysarthria	6	6					6	6	
Dysgeusia	11	13			7	8	4	5	
Dyskinesia	2	2			1	1	1	1	
Dysmenorrhoea	1	1			1	1			
Dyspepsia	1	1			1	1			
Dysphagia	7	7			1	1	6	6	
Dysphonia	1	1					1	1	
Dyspnoea	53	62			13	17	40	45	
Dyspnoea exertional	3	4				1	3	3	
Dysstasia	2	2			2	2			
Ear infection	1	1					1	1	
Ear pain	9	10			4	4	5	6	
Eating disorder	1	1					1	1	
Eczema	3	3			2	2	1	1	
Electrocardiogram ST segment elevation	1	1					1	1	
Epilepsy	4	4					4	4	
Epistaxis	3	5				1	3	4	
Erectile dysfunction	1	1					1	1	
Eructation	3	3					3	3	
Erythema	22	24			12	12	10	12	
Exposure during pregnancy	1	1			1	1			
Exposure to SARS-CoV-2	1	1					1	1	
Extrasystoles	2	2			2	2			
Eye allergy	1	1					1	1	
Eye disorder	2	3				1	2	2	
Eye irritation	1	1					1	1	
Eyelid ptosis		1				1			
Eye movement disorder	1	1					1	1	
Eye pain	11	12			2	3	9	9	

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Eye pruritus	3	3
Eye swelling	7	8
Facial discomfort	1	1
Facial pain	6	6
Facial paralysis	10	10
Facial paresis	2	2
Faeces discoloured	2	2
Fall	8	8
Fatigue	215	256
Feeling abnormal	14	18
Feeling cold	31	33
Feeling drunk	1	1
Feeling hot	22	24
Feeling of body temperature change	8	11
Fibromyalgia	1	1
Fluid intake reduced	1	1
Flushing	10	13
Frequent bowel movements		3
Gait disturbance	11	12
Gait inability	1	1
Gastritis		1
Gastroenteritis	1	1
Gastroenteritis viral	1	1
Gastrointestinal disorder	1	1
Gastrointestinal pain	1	1
Gastrointestinal stoma complication	1	1
Gastrooesophageal reflux disease	2	2
Generalised tonic-clonic seizure	1	1
General physical health deterioration	1	1
Gingival blister	1	1
Gingival pain	1	1
Glossodynia	2	2
Grip strength decreased	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				3	3
		1	1	6	7
				1	1
		2	2	4	4
				10	10
				2	2
		1	1	1	1
		2	2	6	6
3	3	63	89	152	167
1	1	4	6	10	12
		14	15	17	18
				1	1
		9	10	13	14
		2	4	6	7
				1	1
				1	1
		4	7	6	6
			2		1
		3	4	8	8
				1	1
			1		
				1	1
				1	1
		1	1		
				1	1
				1	1
				2	2
				1	1
				1	1
		1	1		
				1	1
		1	1	1	1
		2	2		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Haematemesis	4	4
Haematochezia	1	1
Haematoma	1	1
Haemoglobin decreased	2	2
Haemoptysis	1	1
Haemorrhage intracranial	1	1
Haemorrhagic stroke	1	1
Hallucination	4	4
Hallucination, visual	2	2
Hangover	2	2
Headache	269	317
Head discomfort	2	3
Head injury	2	2
Heart rate decreased	2	2
Heart rate increased	11	13
Heat illness	1	1
Heat stroke	1	1
Hemiparesis	5	5
Hepatic artery embolism	1	1
Hepatic enzyme increased	1	1
Hepatic pain	1	1
Herpes virus infection		1
Herpes zoster	5	7
Hot flush	11	12
Hyperacusis	1	1
Hyperaesthesia	3	3
Hyperglycaemia	5	6
Hyperhidrosis	17	19
Hypersensitivity	7	11
Hypersensitivity pneumonitis	1	1
Hypersomnia	5	5
Hypertension	8	10
Hypertonia	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				4	4
				1	1
		1	1		
		1	1	1	1
				1	1
				1	1
				1	1
				4	4
				2	2
		1	1	1	1
3	3	75	106	194	211
		1	2	1	1
		1	1	1	1
				2	2
		1	2	10	11
				1	1
		1	1		
				5	5
				1	1
					1
		3	5	2	2
		1	2	10	10
				1	1
		1	1	2	2
			1	5	5
		2	2	15	17
		1	3	6	8
				1	1
				5	5
			1	8	9
				1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Hyperventilation	1	1
Hypoaesthesia	15	18
Hypoaesthesia oral	8	8
Hypoglycaemia	6	8
Hyponatraemia	1	1
Hypophagia	1	1
Hypopnoea	1	1
Hyporeflexia	1	1
Hyporesponsive to stimuli	1	1
Hyposmia	1	1
Hypotension	9	11
Hypothermia	3	3
Hypotonia	1	1
Hypoxia	3	3
Idiopathic intracranial hypertension	1	1
Illness	6	7
Immune system disorder	1	1
Immune thrombocytopenia	1	1
Inappropriate schedule of product administration	3	4
Incoherent	1	1
Incorrect route of product administration	2	3
Increased upper airway secretion	1	1
Increased viscosity of upper respiratory secretion	1	1
Infarction	1	1
Infection	2	2
Inflammation	2	2
Influenza	6	6
Influenza like illness	52	54
Injection site pain		1
Injury corneal	1	1
Insomnia	20	21
Iridocyclitis	2	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		4	6	11	12
		6	6	2	2
		1	2	5	6
				1	1
				1	1
				1	1
				1	1
				1	1
		2	2	7	9
				3	3
				1	1
				3	3
				1	1
		2	2	4	5
				1	1
				1	1
		3	3		1
				1	1
		2	3		
				1	1
				1	1
				2	2
		1	1	1	1
		2	2	4	4
		25	26	27	28
			1		
				1	1
		6	7	14	14
				2	2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Irritability	1	1
Irritable bowel syndrome	2	2
Ischaemic stroke	3	3
Joint effusion	1	1
Joint range of motion decreased	2	2
Joint stiffness	4	5
Joint swelling	7	9
Labyrinthitis	1	1
Lacrimation increased	6	6
Lethargy	36	38
Leukaemia	1	1
Limb discomfort	14	20
Limb immobilisation	1	1
Lip blister	1	1
Lip disorder		1
Lip dry	1	1
Lip swelling	10	13
Livedo reticularis	1	1
Liver function test increased	1	1
Local reaction	3	3
Loss of consciousness	7	7
Loss of personal independence in daily activities	3	3
Lower respiratory tract infection	11	11
Lung consolidation	1	1
Lymphadenitis	1	1
Lymphadenopathy	48	57
Lymph node pain	14	16
Lymphoedema	1	1
Malaise	105	131
Mastication disorder	2	2
Mastitis	1	1
Memory impairment	1	1
Menopausal symptoms	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1	1	1
				3	3
				1	1
		1	1	1	1
		1	2	3	3
		1	2	6	7
				1	1
		2	2	4	4
		10	11	26	27
				1	1
		4	6	10	14
		1	1		
			1	1	1
				1	1
		3	5	7	8
				1	1
				1	1
		1	1	2	2
				7	7
		1	1	2	2
				11	11
				1	1
				1	1
		20	26	28	31
		4	5	10	11
				1	1
		28	44	77	87
				2	2
				1	1
				1	1
		1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Menorrhagia	1	1					1	1
Mental fatigue	2	2			1	1	1	1
Mental impairment	2	2					2	2
Micturition disorder	1	1					1	1
Middle ear inflammation	1	1					1	1
Migraine	26	26			7	7	19	19
Migraine with aura	3	3					3	3
Mobility decreased	8	9			4	4	4	5
Monoplegia	1	1					1	1
Mood altered	1	1			1	1		
Mouth swelling	2	2					2	2
Mouth ulceration	5	8			2	5	3	3
Movement disorder	1	1			1	1		
Multiple sclerosis	1	1					1	1
Multiple sclerosis relapse	2	2					2	2
Muscle contractions involuntary	1	1			1	1		
Muscle fatigue	1	2					1	2
Muscle rigidity	2	2					2	2
Muscle spasms	9	9			2	2	7	7
Muscle strain	1	1					1	1
Muscle swelling	1	1					1	1
Muscle tone disorder	1	1					1	1
Muscle twitching	1	2				1	1	1
Muscular weakness	14	16			3	4	11	12
Musculoskeletal chest pain	1	1					1	1
Musculoskeletal disorder	1	1					1	1
Musculoskeletal pain	1	1					1	1
Musculoskeletal stiffness	16	18			5	5	11	13
Myalgia	154	177	2	2	39	54	115	123
Mydriasis	1	1					1	1
Myocardial infarction	8	8					8	8
Myocardial ischaemia	1	1					1	1
Nail discolouration	1	1					1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Nasal congestion	3	3
Nasal discharge discolouration	1	1
Nasal obstruction	1	1
Nasopharyngitis	13	13
Nausea	151	183
Neck pain	24	30
Negative thoughts	1	1
Nephrotic syndrome	1	1
Nervousness	2	4
Neuralgia		1
Neurogenic shock	1	1
Neuropathy peripheral	1	1
Nightmare	1	2
Night sweats	4	4
Nipple pain	1	1
Nipple swelling	1	1
Obsessive-compulsive symptom	1	1
Occupational exposure to SARS-CoV-2	1	1
Ocular hyperaemia	4	4
Odynophagia		1
Oedema	3	3
Oedema peripheral	1	1
Off label use	8	11
Optic neuritis	1	1
Oral blood blister	1	1
Oral discomfort	2	2
Oral herpes	2	3
Oral mucosal blistering	3	3
Oral mucosal erythema	1	1
Oral pain	1	1
Oropharyngeal blistering	1	1
Oropharyngeal pain	27	32
Orthopnoea	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	2	2
		1	1		
				1	1
		7	7	6	6
2	2	41	61	110	122
		7	11	17	19
				1	1
				1	1
		1	1	1	3
					1
				1	1
			1	1	1
		2	2	2	2
		1	1		
		1	1		
				1	1
		1	1		
				1	1
		1	1	3	3
					1
		1	1	2	2
				1	1
		8	11		
				1	1
				1	1
		1	1	1	1
		2	2		1
		2	2	1	1
				1	1
				1	1
		15	20	12	12
		1	1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Overdose	1	1
Oxygen saturation decreased	3	5
Pain	100	113
Pain in extremity	110	130
Pain in jaw	2	2
Pain of skin	2	2
Pallor	5	7
Palpitations	13	17
Papule	1	1
Paraesthesia	34	41
Paraesthesia oral	17	19
Paralysis	3	3
Parosmia	3	3
Periarthritis	1	1
Pericarditis	1	1
Periorbital swelling	1	3
Peripheral circulatory failure	1	1
Peripheral coldness	8	9
Peripheral swelling	20	22
Petechiae	3	3
Pharyngeal erythema	1	1
Pharyngeal hypoesthesia	1	1
Pharyngeal inflammation	2	2
Pharyngeal paraesthesia	1	1
Pharyngeal swelling	8	9
Pharyngitis	1	1
Pharyngitis streptococcal	1	1
Photophobia	7	8
Piloerection	1	2
Pleural effusion	1	1
Pleurisy	1	1
Plicated tongue	1	1
Pneumonia	1	2

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
				3	5
		35	43	65	70
1	1	45	59	65	71
		1	1	1	1
				2	2
		1	1	4	6
		3	5	10	12
				1	1
		8	15	26	26
		5	6	12	13
				3	3
		1	1	2	2
				1	1
				1	1
		1	3		
				1	1
		1	2	7	7
		7	8	13	14
				3	3
				1	1
				1	1
				2	2
				1	1
				1	1
		2	2	6	7
				1	1
				1	1
		1	1	6	7
		1	1		1
				1	1
				1	1
				1	1
				1	1
				1	2

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Pneumonitis	1	1
Polymenorrhoea	1	1
Polymyalgia rheumatica	1	1
Polyuria	1	1
Poor quality sleep	2	2
Post viral fatigue syndrome	1	1
Pre-existing condition improved		1
Presyncope	4	6
Proctitis ulcerative	1	1
Product administered to patient of inappropriate age	4	5
Productive cough	3	4
Product use issue	9	12
Prostatomegaly	1	1
Pruritus	32	40
Psoriasis	1	1
Psoriatic arthropathy	1	1
Psychotic behaviour	1	1
Pulmonary oedema	1	1
Pulmonary thrombosis	1	1
Pulseless electrical activity	1	1
Pyelonephritis	1	1
Pyrexia	218	258
Q fever	1	1
Rales	1	1
Rash	23	25
Rash erythematous	3	3
Rash macular	9	10
Rash papular	1	2
Rash pruritic	9	10
Rash vesicular	1	1
Raynaud's phenomenon	1	1
Renal failure	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		1	1		
				1	1
		1	1		
				2	2
				1	1
			1		
				4	6
				1	1
		4	5		
				3	4
		9	12		
		1	1		
		13	19	19	21
				1	1
				1	1
				1	1
				1	1
				1	1
1	1	59	83	159	175
				1	1
				1	1
		9	9	14	16
		2	2	1	1
		6	7	3	3
		1	1		1
		3	3	6	7
		1	1		
				1	1
				1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Renal pain	2	2			1	1	1	1
Respiration abnormal	1	1					1	1
Respiratory arrest	3	3					3	3
Respiratory distress	1	1					1	1
Respiratory rate increased	5	5					5	5
Restless legs syndrome	1	1					1	1
Restlessness	2	4			1	2	1	2
Retching	4	5			2	3	2	2
Rhabdomyolysis	1	1					1	1
Rheumatoid arthritis	2	2					2	2
Rhinitis	1	1			1	1		
Rhinorrhoea	6	6			3	3	3	3
Right ventricular enlargement	1	1			1	1		
Sacroiliitis	1	1					1	1
Salivary hypersecretion	2	3			1	2	1	1
SARS-CoV-2 ant body test negative	1	1			1	1		
SARS-CoV-2 test positive	5	5					5	5
Seasonal allergy	1	1			1	1		
Secretion discharge	1	1					1	1
Seizure	8	8					8	8
Sensation of foreign body	2	2					2	2
Sensitive skin	1	1					1	1
Sensory disturbance	2	3			1	2	1	1
Sepsis	1	1					1	1
Serotonin syndrome	1	1					1	1
Severe acute respiratory syndrome	1	1					1	1
Sinus headache	2	3				1	2	2
Sinus pain	3	3			1	1	2	2
Sjogren's syndrome		1						1
Skin burning sensation	4	4			2	2	2	2
Skin cancer	1	1					1	1
Skin discolouration	3	3			2	2	1	1
Skin disorder	1	1			1	1		

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Skin erosion	2	2
Skin exfoliation	2	2
Skin induration	1	1
Skin irritation	2	2
Skin sensitisation	1	1
Skin tightness	2	3
Skin ulcer	1	1
Skin warm	4	6
Skin weeping	1	1
Sleep attacks	1	1
Sleep disorder	6	7
Sleep disorder due to a general medical condition	3	3
Sleep disorder due to general medical condition, insomnia type	1	1
Sneezing	5	6
Somnolence	24	26
Speech disorder	1	1
Spinal disorder	1	1
Spinal pain	1	1
Stoma site discharge		1
Subarachnoid haemorrhage	1	1
Sudden death	4	4
Suspected COVID-19	21	22
Sweating fever	1	1
Swelling	10	11
Swelling face	8	11
Swelling of eyelid	1	2
Swollen tongue	11	12
Syncope	14	15
Synovial cyst	1	1
Synovitis	1	1
Systemic inflammatory response syndrome	1	1

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1	1	1
				2	2
		1	1		
		1	1	1	1
				1	1
		1	1	1	2
				1	1
		2	2	2	4
				1	1
				1	1
		4	5	2	2
		1	1	2	2
		1	1		
		5	6		
		6	6	18	20
				1	1
		1	1		
				1	1
					1
				1	1
				4	4
				21	22
				1	1
		2	3	8	8
		1	1	7	10
				1	2
		3	3	8	9
				14	15
		1	1		
				1	1
				1	1

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Systemic lupus erythematosus	1	1
Tachycardia	19	26
Tachypnoea	2	2
Taste disorder	2	3
Temperature regulation disorder	1	1
Temporomand bular joint syndrome	1	1
Tenderness	2	2
Tension headache	4	4
Therapeutic response unexpected	2	2
Thirst	3	3
Throat clearing	1	1
Throat irritation	6	9
Throat tightness	10	13
Thrombocytopenia	3	3
Thrombosis	2	2
Tinnitus	4	6
Tongue discomfort		1
Tongue pruritus	1	1
Tongue ulceration	1	1
Tonsillar hypertrophy	1	1
Toothache	1	1
Transient ischaemic attack	1	1
Tremor	25	26
Tri-iodothyronine decreased	1	1
Type IV hypersensitivity reaction	1	2
Unresponsive to stimuli	6	7
Upper-airway cough syndrome	1	1
Urinary retention	2	2
Urinary tract disorder	1	1
Urinary tract infection	2	2
Urinary tract infection bacterial	1	1
Urosepsis	1	1
Urticaria	20	21

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				1	1
		2	8	17	18
				2	2
		1	2	1	1
				1	1
		1	1		
		2	2		
		1	1	3	3
		1	1	1	1
		1	1	2	2
				1	1
		1	2	5	7
				10	13
				3	3
				2	2
		1	3	3	3
			1		
				1	1
				1	1
				1	1
		1	1		
		6	6	19	20
				1	1
				1	2
				6	7
		1	1		
				2	2
				1	1
				2	2
				1	1
				1	1
		4	5	16	16

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<i>Preferred Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Vaccination complication	1	1
Vaccination site bruising	5	5
Vaccination site discolouration	2	2
Vaccination site discomfort	3	4
Vaccination site erythema	24	28
Vaccination site haemorrhage	1	2
Vaccination site hypoaesthesia	1	1
Vaccination site induration	3	3
Vaccination site infection	2	2
Vaccination site inflammation	3	3
Vaccination site joint movement impairment	2	2
Vaccination site joint pain		1
Vaccination site lymphadenopathy	2	2
Vaccination site mass	6	6
Vaccination site movement impairment	2	3
Vaccination site pain	103	131
Vaccination site paraesthesia	2	2
Vaccination site pruritus	6	7
Vaccination site rash	5	6
Vaccination site reaction	3	3
Vaccination site swelling	24	28
Vaccination site ulcer	1	1
Vaccination site urticaria	1	1
Vaccination site warmth	12	15
Vaginal haemorrhage	1	1
Vasculitis	1	1
Vein rupture	1	1
Ventricular extrasystoles	3	3
Ventricular f brillation		1
Vertigo	4	6
Vertigo positional	1	1
Viral labyrinthitis	1	1
Vision blurred	10	10

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1	4	4
				2	2
		2	3	1	1
		12	15	12	13
			1	1	1
				1	1
		1	1	2	2
				2	2
		2	2	1	1
		1	1	1	1
					1
				2	2
		3	3	3	3
		1	1	1	2
3	3	42	62	61	69
				2	2
		2	3	4	4
		1	2	4	4
		1	1	2	2
		7	9	17	19
				1	1
				1	1
		2	4	10	11
				1	1
				1	1
		1	1	2	2
					1
			1	4	5
				1	1
		1	1		
		2	2	8	8

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Visual impairment	4	4			1	1	3	3
Vitreous floaters	1	1			1	1		
Vocal cord disorder	1	1					1	1
Vomiting	53	64			15	20	38	44
Vomiting psychogenic	1	1					1	1
Vulvovaginal candidiasis	1	1			1	1		
Weight loss diet	1	1					1	1
Wheezing	7	11				2	7	9
White blood cell count decreased	1	1					1	1
	3	4			3	4		
	4,181	4,861	20	20	1151	1547	3030	3314

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Country Where Event Occurred

**UNITED STATES**

Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal discomfort	10	14	10	14		
Abdominal distension	1	2	1	2		
Abdominal pain	10	20	10	17		3
Abdominal pain lower	2	3	2	3		
Abdominal pain upper	7	10	7	10		
Abdominal rigidity		1				1
Abnormal behaviour	1	1			1	1
Abnormal dreams		1		1		
Abnormal sensation in eye	1	1	1	1		
Accidental exposure to product	2	3	1	2	1	1
Accidental overdose		1		1		
Acne	2	2	2	2		
Acute kidney injury	1	1			1	1
Acute myocardial infarction	1	1			1	1
Ageusia	9	14	9	13		1
Aggression	1	1	1	1		
Agitation	1	3	1	3		
Allergy to vaccine	2	9	1	4	1	5
Alopecia	1	1	1	1		
Amnesia	1	1	1	1		
Anaphylactic reaction	18	26			18	26
Anaphylactoid reaction		1				1
Anger	3	3	3	3		
Angioedema	1	3			1	3
Anosmia	7	11	7	9		2
Anxiety	10	15	8	13	2	2
Aphonia	1	2	1	2		
Appendicitis	2	3			2	3
Arrhythmia	2	2			2	2
Arthralgia	129	170	118	158	11	12

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthritis	10	11	9	10	1	1
Arthropathy	1	1	1	1		
Arthropod bite	1	1	1	1		
Asthenia	62	80	55	71	7	9
Asthenopia	2	3	1	2	1	1
Asthma	5	7	3	5	2	2
Ataxia		1				1
Autoimmune disorder		1				1
Axillary mass	2	3	2	3		
Axillary pain	7	7	7	7		
Back pain	35	42	33	39	2	3
Balance disorder	4	6	3	4	1	2
Bedridden	2	2	1	1	1	1
Blindness	1	2			1	2
Blindness transient		1				1
Blister	1	2	1	2		
Blood glucose abnormal	1	1	1	1		
Blood glucose fluctuation	1	1	1	1		
Blood glucose increased	7	8	5	6	2	2
Blood potassium decreased	1	1	1	1		
Blood pressure abnormal		1		1		
Blood pressure decreased	1	2		1	1	1
Blood pressure diastolic increased	1	2	1	1		1
Blood pressure fluctuation		1		1		
Blood pressure increased	27	40	16	26	11	14
Blood pressure systolic increased		1				1
Blood urine present	1	1	1	1		
Body height decreased	1	2	1	2		
Body temperature abnormal	1	1	1	1		
Body temperature increased	8	11	8	11		
Bone pain	8	8	5	5	3	3
Brain oedema	1	1			1	1
Breast pain	4	4	4	4		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast swelling	1	1	1	1		
Breast tenderness	1	1	1	1		
Bronchitis	1	1	1	1		
Bronchospasm		1		1		
Burning sensation	8	13	7	10	1	3
Burn oral cavity	1	1			1	1
Cardiac arrest	3	3			3	3
Cardiac disorder	2	2	2	2		
Cardio-respiratory arrest	1	1			1	1
Cellulitis	2	3			2	3
Cerebral disorder		1		1		
Cerebrovascular accident	1	1			1	1
Chest discomfort	35	53	20	34	15	19
Chest pain	17	26	10	16	7	10
Chills	213	289	200	271	13	18
Choking	2	2			2	2
Choking sensation	1	1			1	1
Circumstance or information capable of leading to device use error	1	1	1	1		
Circumstance or information capable of leading to medication error	2	3	2	3		
Cognitive disorder	1	2	1	2		
Cold sweat	8	10	6	8	2	2
Condition aggravated	6	9	5	5	1	4
Confusional state	6	7	6	6		1
Conjunctival haemorrhage	1	1			1	1
Contraindication to vaccination	2	2	2	2		
Contusion	3	3	3	3		
Coordination abnormal	1	1	1	1		
Cough	43	71	34	56	9	15
COVID-19	38	47	1	1	37	46
COVID-19 pneumonia	1	1			1	1
C-reactive protein increased	1	1			1	1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Crying	3	3	3	3		
Crystal urine	1	1	1	1		
Cyanosis	2	2	1	1	1	1
Deafness	2	2			2	2
Deafness neurosensory		1				1
Deafness unilateral		2				2
Death	5	6			5	6
Decreased appetite	14	20	12	16	2	4
Deep vein thrombosis	1	1			1	1
Dehydration	4	4	3	3	1	1
Delirium	3	4			3	4
Delusional perception	2	2	1	1	1	1
Depressed mood		1		1		
Dermatitis allergic	1	1	1	1		
Diabetes mellitus	2	3			2	3
Diarrhoea	58	76	56	72	2	4
Diarrhoea haemorrhagic		1				1
Diet refusal	1	1			1	1
Diplopia	1	1			1	1
Discomfort	6	8	5	7	1	1
Disease recurrence	8	9	7	8	1	1
Disturbance in attention	7	9	7	8		1
Dizziness	124	182	106	151	18	31
Dizziness postural	2	3	1	2	1	1
Drug eruption		1		1		
Drug hypersensitivity	1	1	1	1		
Drug ineffective	54	70	2	2	52	68
Drug interaction	3	3	3	3		
Dry eye	1	1	1	1		
Dry mouth	4	8	3	7	1	1
Dry skin	1	1	1	1		
Dry throat		1		1		
Dysaesthesia		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
Dysarthria		1		1			
Dysgeusia	10	20	10	19			1
Dyskinesia	1	2			1		2
Dyslexia		1		1			
Dysmenorrhoea		1		1			
Dyspepsia	3	5	3	5			
Dysphagia	6	8	2	2	4		6
Dysphonia	5	8	3	5	2		3
Dyspnoea	61	84	37	51	24		33
Dyspnoea exertional	4	4	3	3	1		1
Dysstasia	4	4	3	3	1		1
Ear discomfort		3		3			
Ear disorder	1	1	1	1			
Ear pain	8	12	7	11	1		1
Ear swelling	1	1	1	1			
Eating disorder	1	3		1	1		2
Eczema		1		1			
Electrocardiogram abnormal	1	1	1	1			
Emotional disorder	2	2	2	2			
Encephalopathy	1	1			1		1
Energy increased	2	2	2	2			
Enlarged uvula		1					1
Eosinophil count increased	1	1			1		1
Eosinophilia	1	1	1	1			
Epicondylitis	1	1	1	1			
Epistaxis	3	3	3	3			
Erythema	27	46	21	37	6		9
Erythema of eyelid	2	3	2	3			
Exposure during pregnancy		1		1			
Exposure to SARS-CoV-2	2	4	2	4			
Exposure via skin contact	2	2	1	1	1		1
Extensive swelling of vaccinated limb		1		1			
Eye contusion	2	2	2	2			

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eye disorder	3	4	3	4		
Eye haemorrhage	1	3			1	3
Eye infection		1		1		
Eye inflammation	2	2	1	1	1	1
Eye irritation	1	2	1	2		
Eyelid disorder	1	1	1	1		
Eyelid function disorder		1		1		
Eyelid irritation	1	1	1	1		
Eyelid oedema	2	2	2	2		
Eyelid pain	1	1	1	1		
Eyelids pruritus	2	3	1	2	1	1
Eye oedema	1	1	1	1		
Eye pain	9	11	7	9	2	2
Eye paraesthesia	1	1			1	1
Eye pruritus	4	6	2	4	2	2
Eye swelling	9	12	8	11	1	1
Face oedema		1				1
Facial discomfort		1		1		
Facial nerve disorder	1	1	1	1		
Facial pain	6	9	5	7	1	2
Facial paralysis	13	15			13	15
Facial paresis	2	2	1	1	1	1
Fatigue	247	339	234	322	13	17
Fear	2	5	2	4		1
Febrile convulsion	1	1			1	1
Feeding disorder	4	5	3	4	1	1
Feeling abnormal	46	67	43	61	3	6
Feeling cold	18	21	17	19	1	2
Feeling drunk	4	4	4	4		
Feeling hot	30	46	28	40	2	6
Feeling jittery		2		1		1
Feeling of body temperature change	3	4	2	3	1	1
Fibrin D dimer increased	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Fibromyalgia	1	1			1	1
Flatulence	1	1	1	1		
Flushing	18	40	14	28	4	12
Foreign body aspiration		1				1
Frequent bowel movements	2	2	2	2		
Frustration tolerance decreased		1		1		
Gait disturbance	12	16	8	12	4	4
Gait inability	4	4	2	2	2	2
Gallbladder disorder	1	1			1	1
Gastroenteritis viral		1				1
Gastrointestinal disorder	4	5	3	4	1	1
Gastrointestinal pain	2	2	2	2		
Gastrointestinal viral infection	1	1	1	1		
Gastroesophageal sphincter insufficiency	1	1			1	1
General physical health deterioration	1	1			1	1
Gingival bleeding	1	1	1	1		
Gingival discomfort		1				1
Gingival disorder	1	1	1	1		
Gingival erythema	2	2	2	2		
Gingival pain	1	2	1	1		1
Gingival swelling	2	2	2	2		
Glossitis	2	2	2	2		
Glossodynia	1	1	1	1		
Grip strength decreased		1		1		
Grunting	1	1			1	1
Haematochezia	1	1			1	1
Haemoptysis	1	1			1	1
Haemorrhage	1	1			1	1
Hallucination	1	1			1	1
Hallucination, visual	1	1			1	1
Hangover	1	1	1	1		
Headache	338	465	311	428	27	37
Head discomfort	8	11	8	10		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Head injury	1	1	1	1		
Heart rate abnormal		1		1		
Heart rate decreased	1	2	1	2		
Heart rate increased	39	61	31	51	8	10
Heart rate irregular		1		1		
Hepatic pain		1		1		
Herpes zoster	5	7	5	7		
Hordeolum		1		1		
Hot flush	13	19	10	16	3	3
Hunger		1		1		
Hyperacusis	1	1	1	1		
Hyperaesthesia	6	8	5	7	1	1
Hyperaesthesia teeth	1	1	1	1		
Hyperglycaemia	3	3	1	1	2	2
Hyperhidrosis	31	45	27	40	4	5
Hypersensitivity	17	26	11	14	6	12
Hypersomnia	6	9	6	9		
Hypertension	8	20	3	10	5	10
Hypertensive emergency	1	1			1	1
Hyperventilation		1				1
Hypervigilance	1	1	1	1		
Hypoacusis	1	1	1	1		
Hypoaesthesia	49	73	37	57	12	16
Hypoaesthesia oral	16	24	13	19	3	5
Hypogeusia		1		1		
Hypoglycaemia	2	2	2	2		
Hypokinesia	2	2	2	2		
Hypophagia	1	1	1	1		
Hypopnoea	1	1			1	1
Hyposmia		1		1		
Hypotension	6	7	3	4	3	3
Hypothyroidism	1	1			1	1
Hypoxia		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Illness	14	19	14	19		
Immunodeficiency	1	1			1	1
Impaired work ability	2	2	2	2		
Inappropriate schedule of product administration	32	32	32	32		
Incision site haemorrhage	1	1			1	1
Incomplete course of vaccination	2	2	2	2		
Incontinence		1				1
Incorrect route of product administration	5	5	4	4	1	1
Increased upper airway secretion		1				1
Inflammation	2	3	2	2		1
Inflammatory pain	1	1	1	1		
Influenza	6	11	6	10		1
Influenza B virus test positive	1	1	1	1		
Influenza like illness	25	36	23	33	2	3
Initial insomnia	1	1	1	1		
Injection site pain	2	3	2	3		
Injection site rash	1	2	1	2		
Injection site urticaria		1		1		
Insomnia	20	22	18	20	2	2
International normalised ratio increased	1	1	1	1		
Intranasal paraesthesia		1		1		
Intrusive thoughts	1	1	1	1		
Irritability	2	2	2	2		
Joint dislocation	1	1			1	1
Joint effusion	1	1	1	1		
Joint instability	1	2			1	2
Joint range of motion decreased	5	8	4	7	1	1
Joint stiffness	3	5	3	4		1
Joint swelling	7	10	6	9	1	1
Labile hypertension	1	1	1	1		
Lacrimation increased	3	3	2	2	1	1
Laryngitis	1	2	1	2		
Laryngospasm	2	2			2	2

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Laziness		1		1		
Lethargy	9	11	9	10		1
Leukocytosis	2	2	2	2		
Limb discomfort	8	14	6	11	2	3
Limb injury	3	3	3	3		
Lip dry	1	1	1	1		
Lip erythema	1	2	1	2		
Lipids increased		1		1		
Lip injury	1	1	1	1		
Lip oedema	1	2	1	1		1
Lip pain		1				1
Lip pruritus	2	2	2	2		
Lip swelling	10	20	5	10	5	10
Livedo reticularis	1	2	1	1		1
Localised oedema	1	1	1	1		
Loss of consciousness	7	8			7	8
Loss of personal independence in daily activities	6	7	5	6	1	1
Loss of proprioception	1	1			1	1
Lower respiratory tract congestion		1		1		
Lung disorder	1	1	1	1		
Lymphadenitis	1	1	1	1		
Lymphadenopathy	58	75	51	65	7	10
Lymph node pain	17	22	15	20	2	2
Lymphoedema	1	1	1	1		
Malaise	70	108	66	103	4	5
Maternal exposure during pregnancy	3	4	3	4		
Mechanical urticaria		1		1		
Memory impairment	2	3	2	3		
Menstrual disorder	1	2	1	2		
Mental disorder	2	2	1	1	1	1
Mental impairment	4	5			4	5
Metrorrhagia	2	2	2	2		
Middle insomnia	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Migraine	15	20	15	20		
Migraine with aura	1	1	1	1		
Mobility decreased	3	5	2	4	1	1
Motor dysfunction	2	2	1	1	1	1
Mouth swelling		2		1		1
Movement disorder	3	3	3	3		
Mucosal disorder	1	1	1	1		
Muscle discomfort	1	1	1	1		
Muscle spasms	22	25	19	22	3	3
Muscle tightness	7	10	7	9		1
Muscle twitching	3	3	3	3		
Muscular weakness	12	15	8	11	4	4
Musculoskeletal chest pain	4	5	4	5		
Musculoskeletal discomfort	7	9	6	8	1	1
Musculoskeletal disorder	1	1	1	1		
Musculoskeletal pain	2	2	1	1	1	1
Musculoskeletal stiffness	12	13	12	13		
Mutism	1	1			1	1
Myalgia	115	164	108	155	7	9
Myocardial infarction	2	2			2	2
Myocardial necrosis marker increased	1	1			1	1
Myocarditis	1	1			1	1
Nasal congestion	17	25	14	22	3	3
Nasal discomfort		2		1		1
Nasal dryness		1		1		
Nasal oedema		1				1
Nasopharyngitis	5	6	4	5	1	1
Nausea	169	244	155	221	14	23
Neck injury		1		1		
Neck pain	29	40	27	37	2	3
Nephrolithiasis	1	1			1	1
Nerve compression	2	2	2	2		
Nervousness	3	6	3	5		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuralgia	10	10	10	10		
Neurological symptom	1	1			1	1
Neuropathy peripheral	5	5			5	5
Neutrophil count increased	1	1			1	1
Night sweats	3	5	3	5		
Nipple pain	1	2	1	2		
Nipple swelling		1		1		
Nocturia	1	1	1	1		
Noninfective encephalitis	1	1			1	1
Nuchal rigidity		1		1		
Nystagmus	1	1	1	1		
Obstructive airways disorder		1				1
Ocular discomfort	5	5	3	3	2	2
Ocular hyperaemia	4	8	4	8		
Odynophagia	3	3	2	2	1	1
Oedema	3	3	2	2	1	1
Oedema peripheral	1	1	1	1		
Off label use	35	43	35	43		
Oligodipsia	1	1			1	1
Oral discomfort	1	5	1	4		1
Oral herpes	1	2	1	2		
Oral mucosal erythema	1	2	1	2		
Oral pain	2	3	2	3		
Oral pruritus	1	1	1	1		
Oral viral infection		1		1		
Organising pneumonia		1				1
Oropharyngeal discomfort	1	3	1	2		1
Oropharyngeal pain	28	40	23	34	5	6
Orthopnoea	1	1	1	1		
Osteochondritis	1	1	1	1		
Overdose	1	1	1	1		
Overweight	1	1	1	1		
Oxygen consumption	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oxygen saturation decreased	4	4	3	3	1	1
Pain	222	281	205	262	17	19
Pain in extremity	142	187	137	181	5	6
Pain in jaw	5	6	4	5	1	1
Pain of skin	3	5	3	5		
Palatal disorder	1	1	1	1		
Palatal swelling		1				1
Pallor	5	7	4	6	1	1
Palmar erythema	2	2	1	1	1	1
Palpitations	20	35	17	23	3	12
Panic reaction		1				1
Paraesthesia	50	76	39	60	11	16
Paraesthesia oral	13	25	9	20	4	5
Paranasal sinus discomfort	2	2	2	2		
Paranoia	1	1	1	1		
Parosmia	1	4	1	3		1
Penile haemorrhage	1	1			1	1
Periarthritis	1	1			1	1
Pericardial effusion	1	1			1	1
Pericarditis	1	1			1	1
Periorbital discomfort		1		1		
Periorbital swelling		2		2		
Peripheral coldness	6	11	6	10		1
Peripheral swelling	20	34	19	31	1	3
Peroneal nerve palsy	1	2		1	1	1
Petechiae	3	3	2	2	1	1
Pharyngeal disorder	2	2	2	2		
Pharyngeal hypoaesthesia	2	3		1	2	2
Pharyngeal inflammation	1	1	1	1		
Pharyngeal oedema	1	1			1	1
Pharyngeal paraesthesia	5	8		3	5	5
Pharyngeal swelling	9	15	2	4	7	11
Phlebitis	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Photophobia	4	7	3	6	1	1
Photopsia	1	1	1	1		
Photosensitivity reaction	1	1	1	1		
Piloerection		1		1		
Platelet count decreased	1	1			1	1
Platelet count increased	2	2			2	2
Pleural effusion	1	1			1	1
Pneumonia	4	4			4	4
PO2 decreased	1	1			1	1
Pollakiuria	2	3	2	3		
Polydipsia	1	1	1	1		
Poor peripheral circulation	1	1			1	1
Poor quality sleep	4	5	4	5		
Presyncope	7	12	4	7	3	5
Procedural pain	2	2	1	1	1	1
Product administered at inappropriate site	2	2	1	1	1	1
Product confusion	1	1	1	1		
Productive cough	1	2	1	2		
Product preparation error	1	2	1	2		
Product prescribing error	1	1	1	1		
Product use issue	33	42	32	41	1	1
Pruritus	45	73	36	61	9	12
Pruritus genital	1	1			1	1
Psoriatic arthropathy	1	1			1	1
Psychomotor hyperactivity	1	1			1	1
Pulmonary congestion	1	1			1	1
Pulmonary oedema		1				1
Pulse abnormal	2	3	1	2	1	1
Pupillary disorder	1	1	1	1		
Pyrexia	230	302	210	277	20	25
Rash	53	79	45	63	8	16
Rash erythematous	10	15	8	10	2	5
Rash macular	4	8	4	7		1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Rash maculo-papular	3	3	3	3		
Rash papular	4	5	4	5		
Rash pruritic	14	19	13	17	1	2
Rash vesicular	1	1	1	1		
Raynaud's phenomenon	1	2	1	2		
Reaction to excipient	2	2	1	1	1	1
Red blood cell sedimentation rate increased	1	1	1	1		
Reduced facial expression		1		1		
Renal pain	1	2	1	2		
Respiratory distress	2	2			2	2
Respiratory failure	1	1			1	1
Respiratory rate decreased		1				1
Respiratory rate increased	2	3			2	3
Respiratory tract congestion	2	2	2	2		
Restlessness	6	6	3	3	3	3
Retching	4	5	4	5		
Rheumatoid arthritis	1	1			1	1
Rhinalgia	1	2	1	2		
Rhinitis	1	1	1	1		
Rhinorrhoea	16	21	13	18	3	3
Rosacea	1	1	1	1		
Salivary hypersecretion	1	1	1	1		
SARS-CoV-1 test positive	1	1			1	1
SARS-CoV-2 ant body test negative	4	4	4	4		
SARS-CoV-2 test positive	11	16	1	1	10	15
Scab		1		1		
Scratch		1		1		
Screaming	1	1	1	1		
Sedation	1	1	1	1		
Seizure	2	2			2	2
Sensation of foreign body	4	6	4	4		2
Sensitive skin	3	3	3	3		
Sensory loss		1		1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sepsis	1	1			1	1
Sinus congestion	2	3	2	3		
Sinus disorder	1	1	1	1		
Sinus headache	1	1	1	1		
Sinusitis	1	2	1	2		
Sinus pain	3	3	3	3		
Sinus tachycardia	1	1			1	1
Skin burning sensation	1	1	1	1		
Skin discolouration	4	5	4	5		
Skin disorder		2		1		1
Skin exfoliation	1	1	1	1		
Skin injury	1	2	1	2		
Skin irritation	1	1	1	1		
Skin lesion	1	1	1	1		
Skin swelling	1	1	1	1		
Sleep disorder	4	5	4	4		1
Sleep disorder due to a general medical condition	1	1	1	1		
Sleep disorder due to general medical condition, insomnia type	1	1	1	1		
Sleep paralysis	1	1	1	1		
Sleep talking	1	1	1	1		
Sluggishness		1		1		
Small intestinal obstruction		1				1
Sneezing	4	7	4	7		
Snoring		1		1		
Soft tissue swelling		1		1		
Somnolence	17	24	14	21	3	3
Speech disorder	5	7	4	6	1	1
Spinal fusion surgery	1	1			1	1
Sputum discoloured	1	1			1	1
Status asthmaticus	1	1			1	1
Stiff tongue		1				1

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis	3	3				
Stress	1	1	2	2	1	1
Stridor	1	2	1	1		
Sudden death	1	1			1	2
Suspected COVID-19	2	5		1	1	1
Suture related complication	1	1			2	4
Swelling	19	25			1	1
Swelling face	13	29	16	20	3	5
Swelling of eyelid	3	6	8	19	5	10
Swollen tongue	11	16	3	6		
Syncope	3	5	6	8	5	8
Systemic lupus erythematosus	1	1			3	5
Systemic scleroderma		1			1	1
Tachycardia	25	39				1
Tachyphrenia	1	1	16	23	9	16
Tachypnoea	1	2	1	1		
Taste disorder	2	5	1	1		1
Tenderness	2	4	1	4	1	1
Tension headache	1	1	2	4		
Therapeutic response unexpected	3	4	1	1		
Thirst	2	4	3	4		
Throat clearing		1	2	4		
Throat irritation	11	17				1
Throat tightness	13	25	6	12	5	5
Thyroid disorder	2	2	3	5	10	20
Tinnitus	14	19	2	2		
Tongue blistering	1	1	11	14	3	5
Tongue discomfort	1	2	1	1		
Tongue disorder	2	2	1	2		
Tongue erythema	2	2	1	1	1	1
Tongue oedema	1	1	2	2		
Tongue pruritus	1	1			1	1
Tongue ulceration	1	1	1	1		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Toothache	1	4	1	4		
Tracheomalacia		1				1
Transient ischaemic attack	1	1			1	1
Tremor	17	24	15	20	2	4
Trigeminal nerve disorder		1		1		
Trigeminal neuralgia	1	1			1	1
Trismus	1	1	1	1		
Troponin increased	2	2			2	2
Tryptase increased	1	1	1	1		
Underdose	2	4	2	4		
Undifferentiated connective tissue disease		1				1
Unresponsive to stimuli	2	2			2	2
Upper-airway cough syndrome	2	4	2	4		
Upper respiratory tract congestion	2	4	1	3	1	1
Upper respiratory tract infection	1	1	1	1		
Urinary tract infection	1	1			1	1
Urticaria	44	64	32	49	12	15
Vaccination site bruising	5	6	5	6		
Vaccination site cellulitis	1	1	1	1		
Vaccination site discolouration	4	4	4	4		
Vaccination site discomfort	1	1			1	1
Vaccination site erythema	44	58	41	55	3	3
Vaccination site haemorrhage	1	2	1	2		
Vaccination site hypoaesthesia	2	2	2	2		
Vaccination site induration	2	5	2	5		
Vaccination site infection	1	1	1	1		
Vaccination site inflammation	3	3	3	3		
Vaccination site joint movement impairment	2	2	2	2		
Vaccination site joint pain	1	1	1	1		
Vaccination site lymphadenopathy	1	1	1	1		
Vaccination site macule		1		1		
Vaccination site mass	6	6	4	4	2	2
Vaccination site movement impairment	3	7	3	7		

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Preferred Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vaccination site nodule	1	1	1	1		
Vaccination site oedema		1		1		
Vaccination site pain	176	242	165	230	11	12
Vaccination site pallor	1	1	1	1		
Vaccination site papule	1	1	1	1		
Vaccination site paraesthesia	2	2	1	1	1	1
Vaccination site pruritus	26	33	23	30	3	3
Vaccination site rash	4	6	4	6		
Vaccination site scab	1	1	1	1		
Vaccination site swelling	40	55	38	53	2	2
Vaccination site urticaria	3	6	3	6		
Vaccination site vesicles	1	1	1	1		
Vaccination site warmth	19	22	18	21	1	1
Vaginal haemorrhage	3	3	1	1	2	2
Varicella zoster virus infection		1		1		
Ventricular extrasystoles		2		1		1
Vertigo	11	16	11	14		2
Vision blurred	11	15	9	11	2	4
Visual field defect	1	1	1	1		
Visual impairment	5	7	4	5	1	2
Vomiting	40	60	38	56	2	4
Vulvovaginal pruritus	1	1			1	1
Vulvovaginal rash	1	1			1	1
Vulvovaginal swelling	1	1			1	1
Weight decreased	6	8	5	7	1	1
Weight increased	1	1	1	1		
Wheezing	7	16	3	8	4	8
White blood cell count increased	1	1			1	1
Wound	1	1	1	1		
Wrong technique in product usage process		1		1		
	5,008	7,007	4162	5798	846	1209

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**APPENDIX 2.6: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Sources Organized per MedDRA System Organ Class by High Level Term**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval) / 18,061 (Cumulative)

Total Number of Adverse Events (PT): 51,740 (Interval) / 63,975 (Cumulative)

MedDRA Version: v.23.1J

*System Organ Class*

**Blood and lymphatic system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC	2	2			2	2
Coagulopathies	1	1			1	1
Eosinophilic disorders	2	2	2	2		
Haematological disorders	2	2	1	1	1	1
Leukocytoses NEC	9	9	4	4	5	5
Leukopenias NEC	3	4	1	1	2	3
Lymphatic system disorders NEC	877	1,030	658	782	219	248
Marrow depression and hypoplastic anaemias	2	2			2	2
Neutropenias	2	2			2	2
Spleen disorders	1	1			1	1
Thrombocytopenias	13	15			13	15
Thrombocytoses	1	1			1	1
	915	1,071	666	790	249	281

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System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	2	2	1	1	1	1
Cardiac disorders NEC	22	25	8	11	14	14
Cardiac signs and symptoms NEC	219	295	136	190	83	105
Cardiac valve disorders NEC	2	2			2	2
Coronary artery disorders NEC	2	2			2	2
Heart failures NEC	20	21			20	21
Ischaemic coronary artery disorders	58	65			58	65
Myocardial disorders NEC	3	3	1	1	2	2
Noninfectious myocarditis	5	5			5	5
Noninfectious pericarditis	7	9			7	9
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	320	414	152	213	168	201
Supraventricular arrhythmias	54	66	12	14	42	52
Ventricular arrhythmias and cardiac arrest	56	68	3	6	53	62
	771	978	313	436	458	542

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coagulation disorders congenital		1		1
Neurological disorders congenital NEC	4	4	4	4
	4	5	4	5

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	119	149	97	121	22	28
External ear disorders NEC	2	2	1	1	1	1
Hearing losses	41	52	14	17	27	35
Hyperacusia	5	8	3	5	2	3
Inner ear disorders NEC	1	1	1	1		
Inner ear signs and symptoms	203	254	139	176	64	78
Middle ear infections and inflammations	1	1			1	1
	372	467	255	321	117	146

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	1	1			1	1
Thyroid disorders NEC	2	2	2	2		
Thyroid hypofunction disorders	3	3			3	3
	6	6	2	2	4	4

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amblyopic vision impairment	1	1	1	1		
Choroid and vitreous structural change, deposit and degeneration	1	2	1	2		
Colour blindness (incl acquired)	1	1			1	1
Conjunctival and corneal bleeding and vascular disorders	5	6			5	6
Conjunctival infections, irritations and inflammations	5	5	5	5		
Corneal infections, oedemas and inflammations	1	1	1	1		
Eyelid movement disorders	11	15	6	9	5	6
Glaucomas (excl congenital)	3	3			3	3
Iris and uveal tract infections, irritations and inflammations	3	3	1	1	2	2
Lacrimation disorders	37	40	22	25	15	15
Lid, lash and lacrimal infections, irritations and inflammations	38	49	30	40	8	9
Lid, lash and lacrimal structural disorders	1	1			1	1
Ocular bleeding and vascular disorders NEC	6	8			6	8
Ocular disorders NEC	214	270	130	179	84	91
Ocular infections, inflammations and associated manifestations	99	123	64	83	35	40
Ocular nerve and muscle disorders	6	7	1	1	5	6
Ocular sensation disorders	64	81	36	48	28	33
Pupil disorders	8	8	2	2	6	6
Refractive and accommodative disorders	1	1	1	1		
Retinal structural change, deposit and degeneration	1	2			1	2
Scleral infections, irritations and inflammations	5	5	4	4	1	1
Structural change, deposit and degeneration of eye NEC	1	1	1	1		
Visual disorders NEC	126	151	80	97	46	54
Visual impairment and blindness (excl colour blindness)	43	52	20	25	23	27
	681	836	406	525	275	311

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System Organ Class

**Gastrointestinal disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Abdominal findings abnormal	3	3
Acute and chronic pancreatitis	4	5
Benign oral cavity neoplasms	1	1
Colitis (excl infective)	2	2
Dental pain and sensation disorders	18	27
Diarrhoea (excl infective)	573	712
Duodenal and small intestinal stenosis and obstruction	1	2
Dyspeptic signs and symptoms	39	44
Faecal abnormalities NEC	11	15
Flatulence, bloating and distension	28	37
Gastritis (excl infective)	5	8
Gastrointestinal and abdominal pains (excl oral and throat)	316	383
Gastrointestinal atonic and hypomotility disorders NEC	22	23
Gastrointestinal disorders NEC	22	29
Gastrointestinal dyskinetic disorders	3	3
Gastrointestinal inflammatory disorders NEC		1
Gastrointestinal mucosal dystrophies and secretion disorders	1	1
Gastrointestinal signs and symptoms NEC	155	183
Gastrointestinal spastic and hypermotility disorders	12	18
Gastrointestinal stenosis and obstruction NEC		1
Gastrointestinal vascular occlusion and infarction	4	4
Gingival disorders, signs and symptoms NEC	25	30
Gingival haemorrhages	6	8
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1	1
Intestinal haemorrhages	5	6
Nausea and vomiting symptoms	2,259	2,806
Non-site specific gastrointestinal haemorrhages	18	20

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		3	3		
				4	5
		1	1		
				2	2
		15	24	3	3
		410	524	163	188
				1	2
		31	36	8	8
		9	13	2	2
		20	27	8	10
		3	6	2	2
		222	275	94	108
		14	15	8	8
		18	25	4	4
		3	3		
			1		
		1	1		
		88	113	67	70
		5	8	7	10
					1
				4	4
		20	21	5	9
		4	6	2	2
		1	1		
		1	1	4	5
4	4	1483	1951	776	855
				18	20

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System Organ Class

**Gastrointestinal disorders**

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Oesophagitis (excl infective)	1	1
Oral dryness and saliva altered	81	117
Oral soft tissue disorders NEC	21	31
Oral soft tissue haemorrhages	1	1
Oral soft tissue infections	1	1
Oral soft tissue signs and symptoms	391	545
Oral soft tissue swelling and oedema	125	166
Peritoneal and retroperitoneal fibrosis and adhesions	1	1
Rectal inflammations NEC	1	1
Salivary gland disorders NEC	2	2
Salivary gland enlargements	4	4
Stomatitis and ulceration	40	47
Tongue disorders	24	31
Tongue signs and symptoms	154	199
	4,381	5,520

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		52	81	29	36
		14	22	7	9
				1	1
		1	1		
		270	393	121	152
		68	91	57	75
				1	1
				1	1
		1	1	1	1
		4	4		
		29	36	11	11
		16	23	8	8
		71	100	83	99
4	4	2879	3808	1502	1712

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site reactions NEC	3	5			2	4	1	1
Adverse effect absent	10	10			10	10		
Asthenic conditions	3,921	4,829	8	8	2774	3570	1147	1259
Body temperature altered	16	16			5	5	11	11
Complications associated with device NEC		1				1		
Death and sudden death	207	210					207	210
Febrile disorders	2,774	3,282	5	5	1933	2366	841	916
Feelings and sensations NEC	2,988	3,680	4	4	2206	2817	782	863
Gait disturbances	88	104			59	72	29	32
General signs and symptoms NEC	1,199	1,435			770	967	429	468
Inflamations	31	38			17	23	14	15
Injection site reactions	47	59			40	51	7	8
Interactions	12	13			10	10	2	3
Mass conditions NEC	12	14			11	13	1	1
Mucosal findings abnormal	3	5			3	4		1
Oedema NEC	44	49			27	31	17	18
Pain and discomfort NEC	2,109	2,608			1548	1981	561	627
Therapeutic and nontherapeutic responses	1,063	1,251	1	1	22	23	1041	1228
Ulcers NEC	1	1			1	1		
Vaccination site reactions	3,578	4,456	5	5	2928	3735	650	721
	18,106	22,066	23	23	12366	15684	5740	6382

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis	1	1			1	1
Cholestasis and jaundice	4	4	3	3	1	1
Gal bladder disorders NEC	1	2		1	1	1
Hepatic vascular disorders	1	1			1	1
Hepatobiliary signs and symptoms	1	2		1	1	1
Hepatocellular damage and hepatitis NEC	4	4			4	4
Obstructive bile duct disorders (excl neoplasms)	1	1			1	1
	13	15	3	5	10	10

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	169	222	93	122	76	100
Allergies to foods, food additives, drugs and other chemicals	64	93	38	59	26	34
Anaphylactic and anaphylactoid responses	199	245	1	1	198	244
Atopic disorders	4	4	4	4		
Autoimmune disorders NEC	1	4			1	4
Immune and associated conditions NEC	3	6	2	3	1	3
Immunodeficiency disorders NEC	1	2			1	2
	441	576	138	189	303	387

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System Organ Class

Infections and infestations

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

		Non Interventional Study		Spontaneous				
		Serious		Nonserious		Serious		
		I	C	I	C	I	C	
Abdominal and gastrointestinal infections	7	10			1	2	6	8
Bacterial infections NEC	31	37			3	4	28	33
Bordetella infections		1						1
Breast infections	4	5					4	5
Candida infections	6	7			4	5	2	2
Central nervous system and spinal infections	1	2					1	2
Clostridia infections	1	1					1	1
Coronavirus infections	824	944	1	1	10	13	814	931
Coxiella infections	2	2					2	2
Dental and oral soft tissue infections	6	7			4	5	2	2
Ear infections	10	13			6	7	4	6
Ectoparasitic infestations	1	1			1	1		
Escherichia infections	2	2					2	2
Eye and eyelid infections	11	17			6	12	5	5
Female reproductive tract infections	1	2			1	2		
Fungal infections NEC	4	4			4	4		
Hepatobiliary and spleen infections	2	2					2	2
Herpes viral infections	100	123			80	100	20	23
Infections NEC	37	39			12	14	25	25
Influenza viral infections	68	83			38	52	30	31
Lower respiratory tract and lung infections	49	55			4	5	45	50
Male reproductive tract infections		1				1		
Rhinoviral infections	1	1			1	1		
Sepsis, bacteraemia, viraemia and fungaemia NEC	21	21					21	21
Skin structures and soft tissue infections	6	9			3	5	3	4
Staphylococcal infections	4	5			2	2	2	3
Streptococcal infections	3	5				1	3	4
Trypanosomal infections	1	1					1	1
Tuberculous infections	2	2					2	2
Upper respiratory tract infections	131	167			100	134	31	33
Urinary tract infections	20	22			9	11	11	11

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Vascular infections	1	1					1	1
Viral infections NEC	29	34			9	11	20	23
	1,386	1,626	1	1	298	392	1088	1234

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abdominal and gastrointestinal injuries NEC	3	3			2	2	1	1
Accidental exposures to product	10	15			9	14	1	1
Bone and joint injuries NEC	1	1			1	1		
Chest and respiratory tract injuries NEC		1						1
Conditions caused by cold	3	3			2	2	1	1
Exposures associated with pregnancy, delivery and lactation	186	247			182	243	4	4
Exposures to agents or circumstances NEC	37	44	1	1	25	32	12	12
Eye injuries NEC	9	9			5	5	4	4
Fractures and dislocations NEC	2	4					2	4
Gastrointestinal and hepatobiliary procedural complications	4	4			2	2	2	2
Heat injuries (excl thermal burns)	3	3			2	2	1	1
Intentional product misuses	1	1			1	1		
Limb fractures and dislocations	4	4					4	4
Medication errors, product use errors and issues NEC	391	503			384	496	7	7
Muscle, tendon and ligament injuries	10	12			6	8	4	4
Nerve injuries NEC		1				1		
Neurological and psychiatric procedural complications	1	1					1	1
Non-site specific injuries NEC	62	68			27	31	35	37
Non-site specific procedural complications	7	9			2	3	5	6
Occupational exposures	10	12			9	11	1	1
Off label uses	288	355			283	350	5	5
Overdoses NEC	62	83			62	83		
Pathways and sources of exposure	12	16			11	15	1	1
Pelvic fractures and dislocations	1	1					1	1
Peripheral nerve injuries	1	1					1	1
Poisoning and toxicity	1	1					1	1
Product administration errors and issues	646	864			636	851	10	13
Product confusion errors and issues	4	6			4	6		
Product preparation errors and issues	167	215			167	213		2

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System Organ Class

**Injury, poisoning and procedural complications**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>
Product prescribing errors and issues	2	5
Radiation injuries	2	2
Site specific injuries NEC	28	32
Skin injuries NEC	41	51
Stoma complications	1	4
Thermal burns	1	1
Thoracic cage fractures and dislocations	1	1
Underdoses NEC	113	156
Vaccination related complications	9	10
	2,124	2,749

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		2	5		
		2	2		
		18	21	10	11
		26	35	15	16
			1	1	3
				1	1
				1	1
		113	156		
		6	7	3	3
1	1	1989	2599	135	150

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adrenal cortex tests	1	1					1	1
Adrenal medulla tests		1				1		
Bacteria identification and serology (excl mycobacteria)		1				1		
Blood counts NEC		1				1		
Blood gas and acid base analyses	53	59			16	18	37	41
Carbohydrate tolerance analyses (incl diabetes)	35	38			20	23	15	15
Cardiac function diagnostic procedures		1				1		
Chemistry analyses NEC	2	3			1	1	1	2
Coagulation and bleeding analyses	14	15			4	5	10	10
ECG investigations	5	6			3	3	2	3
Gastrointestinal function diagnostic procedures	1	1			1	1		
Haematological analyses NEC	4	4			3	3	1	1
Heart rate and pulse investigations	271	386			175	267	96	119
Immunology analyses NEC	2	2			2	2		
Investigations NEC	1	2					1	2
Lipoprotein and lipid tests NEC		1				1		
Liver function analyses	17	17			7	7	10	10
Metabolism tests NEC	2	2			1	1	1	1
Microbiology and serology tests NEC	1	1					1	1
Mineral and electrolyte analyses	9	9			6	6	3	3
Neurologic diagnostic procedures	3	4					3	4
Ophthalmic function diagnostic procedures	3	3			1	1	2	2
Physical examination procedures and organ system status	210	252	1	1	134	170	76	82
Pituitary analyses anterior	2	2			2	2		
Platelet analyses	8	9			4	5	4	4
Protein analyses NEC	13	13			8	8	5	5
Red blood cell analyses	13	13			10	10	3	3
Renal function analyses	3	3			2	2	1	1
Reproductive hormone analyses	1	1			1	1		

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Respiratory and pulmonary function diagnostic procedures	1	1
Skeletal and cardiac muscle analyses	7	8
Therapeutic drug monitoring analyses	1	1
Thyroid analyses	2	2
Tissue enzyme analyses NEC	2	2
Urinalysis NEC	11	12
Urinary tract function analyses NEC	2	2
Vascular tests NEC (incl blood pressure)	174	243
Virus identification and serology	284	361
Water and electrolyte analyses NEC	1	1
White blood cell analyses	12	13
	1,171	1,497

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		1	1		
		1	1	6	7
				1	1
		1	1	1	1
		1	1	1	1
		9	10	2	2
		1	1	1	1
		95	139	79	104
		37	41	247	320
		1	1		
		4	4	8	9
1	1	552	741	619	756

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	207	239	114	137	93	102
Calcium metabolism disorders	4	5			4	5
Diabetes mellitus (incl subtypes)	5	8			5	8
Diabetic complications NEC	3	4			3	4
Disorders of purine metabolism	7	7	5	5	2	2
Electrolyte imbalance NEC	1	1			1	1
Fluid intake decreased	5	5	2	2	3	3
Fluid intake increased	3	3	3	3		
General nutritional disorders NEC	16	20	13	17	3	3
Hyperglycaemic conditions NEC	12	14	3	4	9	10
Hypoglycaemic conditions NEC	12	15	6	8	6	7
Magnesium metabolism disorders	1	1			1	1
Metabolic acidoses (excl diabetic acidoses)	1	1			1	1
Mixed acid-base disorders	2	2	1	1	1	1
Potassium imbalance	3	3			3	3
Sodium imbalance	2	2			2	2
Total fluid volume decreased	33	41	20	27	13	14
Total fluid volume increased		2		2		
	317	373	167	206	150	167

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	33	39			21	26	12	13
Bone disorders NEC	3	3			3	3		
Bone related signs and symptoms	129	159			97	126	32	33
Cartilage disorders	4	4			1	1	3	3
Connective tissue disorders NEC	3	6					3	6
Intervertebral disc disorders NEC	1	1			1	1		
Joint related disorders NEC	12	13			6	6	6	7
Joint related signs and symptoms	1,273	1,511	1	1	848	1054	425	457
Ligament disorders	2	2			1	1	1	1
Lupus erythematosus (incl subtypes)	2	2					2	2
Muscle infections and inflammations	2	2					2	2
Muscle pains	1,630	1,952	4	4	1099	1378	531	574
Muscle related signs and symptoms NEC	188	228			144	176	44	52
Muscle tone abnormalities	14	15			6	7	8	8
Muscle weakness conditions	118	141			68	87	50	54
Musculoskeletal and connective tissue conditions NEC	207	243			133	160	74	83
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	2			1	2		
Musculoskeletal and connective tissue pain and discomfort	2,210	2,719	3	3	1669	2121	541	598
Myopathies	4	4			1	1	3	3
Osteoarthropathies	1	1			1	1		
Psoriatic arthropathies	2	2					2	2
Rheumatoid arthropathies	5	6					5	6
Soft tissue disorders NEC	33	40			24	30	9	10
Spondyloarthropathies	3	4					3	4
Synovial disorders	2	2			1	1	1	1
Tendon disorders	6	8			4	6	2	2
	5,888	7,109	8	8	4129	5188	1759	1921

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aural neoplasms malignant and unspecified	1	1	1	1		
Leukaemias NEC	1	1			1	1
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	1	1			1	1
Skin neoplasms malignant and unspecified (excl melanoma)	2	2	1	1	1	1
	5	5	2	2	3	3

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Abnormal reflexes	2	2
Abnormal sleep-related events	1	1
Absence seizures	3	3
Acute polyneuropathies	3	4
Alzheimer's disease (incl subtypes)	1	1
Auditory nerve disorders		1
Autonomic nervous system disorders	4	4
Central nervous system haemorrhages and cerebrovascular accidents	78	88
Cerebrovascular venous and sinus thrombosis	1	1
Chronic polyneuropathies	1	1
Coma states	3	3
Coordination and balance disturbances	74	90
Cortical dysfunction NEC	9	13
Cranial nerve disorders NEC	3	3
Dementia (excl Alzheimer's type)	3	3
Demyelinating disorders NEC	3	3
Disturbances in consciousness NEC	610	720
Disturbances in sleep phase rhythm		1
Dyskinesias and movement disorders NEC	62	70
Dystonias	3	3
Encephalitis NEC	1	2
Encephalopathies NEC	2	2
Eye movement disorders	1	1
Facial cranial nerve disorders	123	149
Generalised tonic-clonic seizures	5	7
Headaches NEC	3,564	4,326
Increased intracranial pressure disorders	3	3
Lumbar spinal cord and nerve root disorders	5	5
Memory loss (excl dementia)	24	29
Mental impairment (excl dementia and memory loss)	60	81

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
				2	2
		1	1		
				3	3
				3	4
				1	1
					1
				4	4
				78	88
				1	1
				1	1
				3	3
1	1	42	50	32	40
		2	6	7	7
		2	2	1	1
				3	3
				3	3
		230	287	380	433
			1		
		43	50	19	20
				3	3
				1	2
				2	2
				1	1
		9	13	114	136
				5	7
7	7	2513	3178	1051	1148
				3	3
		2	2	3	3
		14	18	10	11
		29	39	31	42

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE
Migraine headaches	231	259
Mononeuropathies	12	13
Multiple sclerosis acute and progressive	9	9
Muscle tone abnormal	11	12
Myelitis (incl infective)	1	2
Narcolepsy and hypersomnia	36	48
Nervous system disorders NEC	4	5
Neurological signs and symptoms NEC	1,330	1,733
Neurologic visual problems NEC	7	9
Neuromuscular disorders NEC	10	10
Olfactory nerve disorders	92	129
Optic nerve disorders NEC	2	2
Paraesthesias and dysaesthesias	904	1,186
Paralysis and paresis (excl cranial nerve)	40	46
Parkinson's disease and parkinsonism	1	3
Peripheral neuropathies NEC	27	28
Seizures and seizure disorders NEC	50	57
Sensory abnormalities NEC	360	475
Sleep disturbances NEC	30	39
Speech and language abnormalities	42	52
Spinal cord and nerve root disorders NEC	3	3
Structural brain disorders NEC	2	2
Transient cerebrovascular events	9	11
Tremor (excl congenital)	234	285
Trigeminal disorders	5	6
	8,104	10,044

Non Interventional Study		Spontaneous			
Serious		Nonserious		Serious	
I	C	I	C	I	C
		136	160	95	99
		6	7	6	6
		1	1	8	8
		3	4	8	8
				1	2
		24	35	12	13
		1	2	3	3
1	1	880	1199	450	534
		3	3	4	6
		6	6	4	4
		72	104	20	25
				2	2
		644	883	260	303
		4	5	36	41
			2	1	1
		5	5	22	23
		1	1	49	56
		283	386	77	89
		21	30	9	9
		19	29	23	23
				3	3
				2	2
				9	11
		136	171	98	114
		3	4	2	2
		5135	6684	2969	3360

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System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions spontaneous	8	8			8	8
Labour onset and length abnormalities	1	1			1	1
Maternal complications of pregnancy NEC	1	1			1	1
Normal pregnancy, labour and delivery	1	1	1	1		
	11	11	1	1	10	10

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Counterfeit, falsified and substandard products		1		1		
Device physical property and chemical issues	7	11	6	10	1	1
Product distribution and storage issues	25	115	25	115		
Product packaging issues	1	20	1	20		
Product physical issues	50	71	50	71		
Product quality issues NEC	1	5	1	4		1
	84	223	83	221	1	2

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System Organ Class

**Psychiatric disorders**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1	1	2	3
1	1		
111	158	44	53
4	5	4	4
5	5	4	4
	1	2	2
43	53	53	58
		19	20
		1	1
5	5	5	6
4	5	2	2
156	185	50	53
5	8	2	3
26	30	9	9
14	17	2	4
		32	34
1	1		
24	29	8	12
2	4	2	2
10	13	7	7
		1	1
1	2	5	5
		2	2
		1	1
8	12	5	7
23	31	9	9
3	3	2	2
1	1	2	2
2	2	1	1
		1	1

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sleep disorders NEC	61	72	42	52	19	20
Somatic symptom disorders	3	4	2	2	1	2
Speech and language usage disturbances	1	1	1	1		
Speech articulation and rhythm disturbances	1	2		1	1	1
Stereotypies and automatisms	1	1	1	1		
Stress disorders	1	2	1	2		
Substance related and addictive disorders	1	1			1	1
Suicidal and self-injurious behaviour	1	1			1	1
Thinking disturbances	12	14	9	11	3	3
Tic disorders	1	1	1	1		
	810	979	507	643	303	336

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	43	49	25	30	18	19
Genital and urinary tract disorders NEC	1	1			1	1
Glomerulonephritis and nephrotic syndrome	1	1			1	1
Myoneurogenic bladder disorders		1		1		
Renal disorders NEC	3	3	2	2	1	1
Renal failure and impairment	21	21			21	21
Renal lithiasis	1	1			1	1
Urinary abnormalities	9	12	6	8	3	4
Urinary tract signs and symptoms NEC	29	30	23	24	6	6
	108	119	56	65	52	54

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	2	2	1	1	1	1
Breast signs and symptoms	40	48	29	36	11	12
Cervix disorders NEC	1	1	1	1		
Erection and ejaculation conditions and disorders	2	2			2	2
Lactation disorders	5	5	4	4	1	1
Menopausal effects NEC	2	2	2	2		
Menstruation and uterine bleeding NEC	26	32	24	30	2	2
Menstruation with increased bleeding	6	8	2	4	4	4
Pelvis and broad ligament disorders NEC	1	1	1	1		
Penile disorders NEC (excl erection and ejaculation)	2	2			2	2
Prostatic signs, symptoms and disorders NEC	1	1	1	1		
Reproductive tract disorders NEC (excl neoplasms)	1	1	1	1		
Reproductive tract signs and symptoms NEC	6	6	5	5	1	1
Scrotal disorders NEC	1	5	1	1		4
Sexual function and fertility disorders NEC	1	1			1	1
Uterine disorders NEC	1	1			1	1
Vulvovaginal disorders NEC	12	13	3	4	9	9
Vulvovaginal signs and symptoms	6	6	3	3	3	3
	116	137	78	94	38	43

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	590	722	1	1	246	321	344	401
Bronchial conditions NEC	1	1			1	1		
Bronchospasm and obstruction	97	123			35	51	62	72
Conditions associated with abnormal gas exchange	7	9					7	9
Coughing and associated symptoms	385	484			247	326	138	158
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1	1					1	1
Laryngeal spasm, oedema and obstruction	31	34				1	31	33
Lower respiratory tract inflammatory and immunologic conditions	11	11			1	1	10	10
Lower respiratory tract signs and symptoms	19	27			5	11	14	16
Nasal congestion and inflammations	104	152			91	137	13	15
Nasal disorders NEC	56	70			41	51	15	19
Paranasal sinus disorders (excl infections and neoplasms)	28	35			23	30	5	5
Parenchymal lung disorders NEC	2	4					2	4
Pharyngeal disorders (excl infections and neoplasms)	145	191			68	99	77	92
Pleural infections and inflammations	3	3					3	3
Pneumothorax and pleural effusions NEC	4	4			1	1	3	3
Pulmonary oedemas	11	13					11	13
Pulmonary thrombotic and embolic conditions	11	12					11	12
Respiratory failures (excl neonatal)	17	17					17	17
Respiratory signs and symptoms NEC	9	14			6	9	3	5
Respiratory tract disorders NEC	24	27			13	16	11	11
Tracheal disorders (excl infections and neoplasms)		1						1
Upper respiratory tract signs and symptoms	848	1,124			585	801	263	323
	2,404	3,079	1	1	1363	1856	1041	1223

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	4	5	4	5		
Alopecias	5	5	5	5		
Angioedemas	42	54	2	2	40	52
Apocrine and eccrine gland disorders	439	547	287	373	152	174
Bullous conditions	29	35	20	26	9	9
Dermal and epidermal conditions NEC	171	202	117	139	54	63
Dermatitis and eczema	53	67	36	47	17	20
Dermatitis ascribed to specific agent	6	7	1	2	5	5
Erythemas	300	376	214	276	86	100
Exfoliative conditions	13	13	4	4	9	9
Nail and nail bed conditions (excl infections and infestations)	2	2			2	2
Panniculitides	1	1	1	1		
Papulosquamous conditions	1	1	1	1		
Photosensitivity and photodermatosis conditions	5	9	5	8		1
Pilar disorders NEC	6	9	4	6	2	3
Pruritus NEC	462	609	330	453	132	156
Psoriatic conditions	2	3	1	2	1	1
Purpura and related conditions	20	21	14	15	6	6
Rashes, eruptions and exanthems NEC	778	992	549	711	229	281
Rosaceas	2	2	1	1	1	1
Skin and subcutaneous conditions NEC	3	4	2	3	1	1
Skin and subcutaneous tissue ulcerations	4	4	1	1	3	3
Skin haemorrhages	1	1			1	1
Skin preneoplastic conditions NEC	1	1	1	1		
Skin vasculitides	1	1			1	1
Skin vasomotor conditions	4	6	2	3	2	3
Urticarias	316	409	220	302	96	107
	2,671	3,386	1822	2387	849	999

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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	53	62	37	44	16	18
Social issues NEC	4	4	4	4		
	57	66	41	48	16	18

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	14	16	14	16
	14	16	14	16

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dietary and nutritional therapies	1	1			1	1
Limb therapeutic procedures	1	1	1	1		
Respiratory tract therapeutic procedures NEC	1	1			1	1
Spine and spinal cord therapeutic procedures	1	1			1	1
	4	4	1	1	3	3

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	16	19			16	19
Aneurysms and dissections non-site specific	1	1			1	1
Aortic aneurysms and dissections	4	4			4	4
Arterial infections and inflammations	1	1	1	1		
Blood pressure disorders NEC	7	8	4	5	3	3
Circulatory collapse and shock	35	38			35	38
Haemorrhages NEC	11	13	5	5	6	8
Lymphoedemas	12	14	7	9	5	5
Non-site specific embolism and thrombosis	13	13			13	13
Non-site specific necrosis and vascular insufficiency NEC	2	2			2	2
Non-site specific vascular disorders NEC	8	10	4	6	4	4
Peripheral embolism and thrombosis	13	13	1	1	12	12
Peripheral vascular disorders NEC	255	386	162	262	93	124
Peripheral vasoconstriction, necrosis and vascular insufficiency	57	79	37	55	20	24
Phlebitis NEC	2	2	1	1	1	1
Site specific vascular disorders NEC	54	71	31	39	23	32
Varicose veins NEC	2	2	2	2		
Vascular hypertensive disorders NEC	145	188	63	89	82	99
Vascular hypotensive disorders	87	97	31	36	56	61
Vasculitides NEC	2	2	1	1	1	1
Vena caval embolism and thrombosis	1	1			1	1
	728	964	350	512	378	452

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**APPENDIX 2.6.1: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions From Post-Marketing Data Sources Organized per MedDRA System Organ Class by High Level Term per Country**

Cumulative Reporting Period: Through 31-JAN-2021

Interval Reporting Period: 01-JAN-2021 Through 31-JAN-2021

Total Number of Cases: 14,525 (Interval) / 18,061 (Cumulative)

Total Number of Adverse Events (PT): 51,740 (Interval) / 63,975 (Cumulative)

MedDRA Version: v.23.1J

Country Where Event Occurred

**AFGHANISTAN**

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Feelings and sensations NEC		2		2
General signs and symptoms NEC		1		1
		3		3

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle related signs and symptoms NEC		1		1
		1		1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial cranial nerve disorders		1				1
Paraesthesias and dysaesthesias		1		1		
		2		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Erythemas		1		1
Pruritus NEC		1		1
Rashes, eruptions and exanthems NEC		1		1
		3		3

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Country Where Event Occurred

**ANDORRA**

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**AUSTRIA**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	1	1	1		
Ischaemic coronary artery disorders	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	2	2	2	2
Nausea and vomiting symptoms	7	7	7	7
	9	9	9	9

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	8	8	5	5	3	3
Death and sudden death	3	3			3	3
Feelings and sensations NEC	2	2	2	2		
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	6	6	6	6		
	20	20	13	13	7	7

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	1	1	1	1
	1	1	1	1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Influenza viral infections	1	1	1	1
	1	1	1	1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC	1	1	1	1
Product administration errors and issues	2	2	2	2
Product preparation errors and issues	1	1	1	1
	4	4	4	4

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Virus identification and serology	1	1	1	1
	1	1	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC	2	2	2	2		
Migraine headaches	2	2	2	2		
Paraesthesias and dysaesthesias	1	1	1	1		
	6	6	5	5	1	1

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vulvovaginal signs and symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	1	1	1
Lower respiratory tract signs and symptoms	1	1	1	1
Pulmonary thrombotic and embolic conditions	1	1	1	1
	3	3	3	3

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus NEC	2	2	2	2
Urticarias	1	1	1	1
	3	3	3	3

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Country Where Event Occurred

**BAHRAIN**

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**BELGIUM**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukocytoses NEC	1	1	1	1
Neutropenias	1	1	1	1
	2	2	2	2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	4	4			4	4
Cardiac signs and symptoms NEC	1	1	1	1		
Rate and rhythm disorders NEC	2	2			2	2
	7	7	1	1	6	6

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ocular nerve and muscle disorders	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	1			1	1
Gastrointestinal atonic and hypomotility disorders NEC	1	1			1	1
Gastrointestinal vascular occlusion and infarction	2	2			2	2
Nausea and vomiting symptoms	1	1	1	1		
Tongue signs and symptoms	1	1	1	1		
	6	6	2	2	4	4

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	10	10	7	7	3	3
Death and sudden death	3	3			3	3
Febrile disorders	1	1			1	1
General signs and symptoms NEC	2	2	1	1	1	1
Therapeutic and nontherapeutic responses	5	5			5	5
Vaccination site reactions	7	7	7	7		
	28	28	15	15	13	13

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	5	5	5	5
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	2	2	2
	7	7	7	7

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Occupational exposures	1	1	1	1
Pathways and sources of exposure	1	1	1	1
	2	2	2	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Blood gas and acid base analyses	2	2	2	2
Liver function analyses	1	1	1	1
	3	3	3	3

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hypoglycaemic conditions NEC	1	1	1	1
Metabolic acidoses (excl diabetic acidoses)	1	1	1	1
	2	2	2	2

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Musculoskeletal and connective tissue conditions NEC	2	2	2	2
Musculoskeletal and connective tissue pain and discomfort	2	2	2	2
	4	4	4	4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC	1	1	1	1		
Memory loss (excl dementia)	2	2	1	1	1	1
Nervous system disorders NEC	1	1			1	1
Neurological signs and symptoms NEC	4	4	1	1	3	3
Sensory abnormalities NEC	1	1	1	1		
Sleep disturbances NEC	1	1	1	1		
	12	12	5	5	7	7

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abnormal behaviour NEC	1	1	1	1
Anxiety symptoms	2	2	2	2
Confusion and disorientation	3	3	3	3
	6	6	6	6

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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal disorders NEC	1	1	1	1
Renal failure and impairment	1	1	1	1
	2	2	2	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	2	2	2	2
Lower respiratory tract inflammatory and immunologic conditions	1	1	1	1
Parenchymal lung disorders NEC	1	1	1	1
Pulmonary thrombotic and embolic conditions	1	1	1	1
Respiratory failures (excl neonatal)	1	1	1	1
Respiratory tract disorders NEC	2	2	2	2
	8	8	8	8

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Circulatory collapse and shock	1	1	1	1
Vascular hypotensive disorders	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**BERMUDA**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**BULGARIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	4	4	4	4
	4	4	4	4

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	2	2	2	2		
Nausea and vomiting symptoms	4	4	3	3	1	1
Oral soft tissue signs and symptoms	1	1	1	1		
	7	7	6	6	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	4	4	4	4		
Febrile disorders	2	2	2	2		
Feelings and sensations NEC	2	3	1	2	1	1
General signs and symptoms NEC	2	2	2	2		
Pain and discomfort NEC	1	1	1	1		
Therapeutic and nontherapeutic responses	3	4			3	4
Vaccination site reactions	12	12	12	12		
	26	28	22	23	4	5

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	3	4	3	4
	3	4	3	4

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Physical examination procedures and organ system status	3	3	3	3
Vascular tests NEC (incl blood pressure)	1	1	1	1
	4	4	4	4

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	3	3	3	3
Muscle pains	5	5	5	5
Musculoskeletal and connective tissue pain and discomfort	2	3	2	3
	10	11	10	11

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	5	5	4	4	1	1
Neurological signs and symptoms NEC	5	5	3	3	2	2
Olfactory nerve disorders		1		1		
Paraesthesias and dysaesthesias	1	1	1	1		
Sensory abnormalities NEC		1		1		
	11	13	8	10	3	3

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	1	1	1
	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	2		1	1	1
Erythemas	1	1	1	1		
Rashes, eruptions and exanthems NEC	3	3	3	3		
	5	6	4	5	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1	1	1
Site specific vascular disorders NEC	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**CANADA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	6	7	6	7
	6	7	6	7

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	1	1	1	1		
Rate and rhythm disorders NEC	5	5	3	3	2	2
	6	6	4	4	2	2

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	1	1	1	1		
Hearing losses	1	1			1	1
	2	2	1	1	1	1

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	2	2	2	2
Ocular infections, inflammations and associated manifestations	1	1	1	1
Visual disorders NEC	1	1	1	1
Visual impairment and blindness (excl colour blindness)	1	1	1	1
	5	5	5	5

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	8	10	8	10		
Gastrointestinal and abdominal pains (excl oral and throat)	4	4	4	4		
Gastrointestinal atonic and hypomotility disorders NEC	1	1	1	1		
Gastrointestinal signs and symptoms NEC	2	3	2	3		
Nausea and vomiting symptoms	15	17	15	17		
Oral soft tissue signs and symptoms	3	7	3	6		1
Oral soft tissue swelling and oedema	2	2	2	2		
Stomatitis and ulceration	1	1	1	1		
Tongue disorders	1	1			1	1
Tongue signs and symptoms	2	4	1	3	1	1
	39	50	37	47	2	3

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	1	1	1		
Asthenic conditions	27	30	26	29	1	1
Febrile disorders	16	18	16	18		
Feelings and sensations NEC	14	18	13	17	1	1
General signs and symptoms NEC	6	7	5	6	1	1
Oedema NEC	1	1			1	1
Pain and discomfort NEC	9	11	7	9	2	2
Therapeutic and nontherapeutic responses	8	8	1	1	7	7
Vaccination site reactions	19	20	18	19	1	1
	101	114	87	100	14	14

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	5	5	4	4	1	1
Allergies to foods, food additives, drugs and other chemicals		1		1		
Anaphylactic and anaphylactoid responses	2	2	1	1	1	1
	7	8	5	6	2	2

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	1	1	1	1		
Bacterial infections NEC	1	1			1	1
Coronavirus infections	4	4			4	4
Herpes viral infections	4	4	4	4		
Infections NEC	1	1	1	1		
Skin structures and soft tissue infections	1	1	1	1		
Upper respiratory tract infections	1	1	1	1		
	13	13	8	8	5	5

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	23	23	23	23
Medication errors, product use errors and issues NEC	15	15	15	15
Off label uses	17	17	17	17
Overdoses NEC	6	6	6	6
Product administration errors and issues	4	4	4	4
Product preparation errors and issues	10	10	10	10
Site specific injuries NEC	1	1	1	1
Underdoses NEC	4	4	4	4
	80	80	80	80

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	1	2	1	2		
Physical examination procedures and organ system status	2	2	1	1	1	1
Virus identification and serology	3	3			3	3
	6	7	2	3	4	4

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	3	3	3	3
Total fluid volume increased		1		1
	3	4	3	4

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	13	13	11	11	2	2
Muscle pains	17	17	16	16	1	1
Muscle related signs and symptoms NEC	2	2	2	2		
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	3	3	3	3		
Musculoskeletal and connective tissue pain and discomfort	18	21	18	21		
Rheumatoid arthropathies	1	1			1	1
	55	58	51	54	4	4

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	4	5	3	3	1	2
Facial cranial nerve disorders		1				1
Headaches NEC	28	31	28	31		
Mental impairment (excl dementia and memory loss)	1	1	1	1		
Migraine headaches	1	1	1	1		
Narcolepsy and hypersomnia		1		1		
Neurological signs and symptoms NEC	7	8	6	7	1	1
Paraesthesias and dysaesthesias	10	12	8	9	2	3
Sensory abnormalities NEC	1	2	1	2		
Tremor (excl congenital)	2	2	2	2		
	54	64	50	57	4	7

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Affect alterations NEC	1	1	1	1
Anxiety symptoms	4	4	4	4
Cognitive and attention disorders and disturbances NEC	1	1	1	1
Depressive disorders	1	1	1	1
Disturbances in initiating and maintaining sleep	1	1	1	1
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1
	9	9	9	9

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Menstruation and uterine bleeding NEC	1	1	1	1		
Reproductive tract disorders NEC (excl neoplasms)	1	1	1	1		
Vulvovaginal disorders NEC	1	1			1	1
	3	3	2	2	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	2	2	2		
Lower respiratory tract signs and symptoms	1	1			1	1
Nasal congestion and inflammations	1	1	1	1		
Pharyngeal disorders (excl infections and neoplasms)	3	3	2	2	1	1
Respiratory tract disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	5	6	5	6		
	13	14	10	11	3	3

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Apocrine and eccrine gland disorders	2	2	2	2		
Dermal and epidermal conditions NEC	4	4	4	4		
Dermatitis and eczema	1	1	1	1		
Erythemas	2	2	1	1	1	1
Pruritus NEC	6	6	5	5	1	1
Purpura and related conditions	1	1	1	1		
Rashes, eruptions and exanthems NEC	6	6	5	5	1	1
Skin preneoplastic conditions NEC	1	1	1	1		
Urticarias	3	4	3	4		
	27	28	23	24	4	4

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disability issues	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC	1	1	1	1		
Peripheral vascular disorders NEC	2	2	1	1	1	1
Vascular hypertensive disorders NEC	2	3	1	2	1	1
Vascular hypotensive disorders	1	1			1	1
	6	7	3	4	3	3

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Country Where Event Occurred

**CHILE**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	5	6	4	5	1	1
	5	6	4	5	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC	1	1	1	1		
Ocular infections, inflammations and associated manifestations	2	2			2	2
Ocular sensation disorders	1	1			1	1
	4	4	1	1	3	3

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Diarrhoea (excl infective)	4	4	4	4		
Gastrointestinal and abdominal pains (excl oral and throat)	1	1			1	1
Nausea and vomiting symptoms	1	2		1	1	1
Oral dryness and saliva altered		1				1
	7	9	4	5	3	4

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	3	5	3	5		
Febrile disorders	3	4	2	3	1	1
Feelings and sensations NEC	3	3	2	2	1	1
General signs and symptoms NEC	3	4	3	3		1
Pain and discomfort NEC		1		1		
Vaccination site reactions	2	3	1	2	1	1
	14	20	11	16	3	4

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
Medication errors, product use errors and issues NEC	2	2	2	2
Off label uses	2	2	2	2
Product administration errors and issues	1	1	1	1
	6	6	6	6

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Urinalysis NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Fluid intake increased	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	1			1	1
Joint related signs and symptoms	4	4	2	2	2	2
Muscle pains	2	3	1	2	1	1
Muscle related signs and symptoms NEC	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	3	3	3	3		
	11	12	7	8	4	4

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	6	7	5	6	1	1
Neurological signs and symptoms NEC		1		1		
Paraesthesias and dysaesthesias	2	3	2	2		1
Sensory abnormalities NEC	1	1	1	1		
	9	12	8	10	1	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	1			1	1
Nasal congestion and inflammations	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Apocrine and eccrine gland disorders	1	1	1	1		
Dermatitis and eczema		4		4		
Erythemas	1	1	1	1		
	3	7	2	6	1	1

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Country Where Event Occurred

**COLOMBIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Leukocytoses NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Oral soft tissue swelling and oedema	1	1	1	1
Stomatitis and ulceration	1	1	1	1
	2	2	2	2

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Candida infections	1	1	1	1
Dental and oral soft tissue infections	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**COSTA RICA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	1	1	1	1		
Spleen disorders	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rate and rhythm disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular infections, inflammations and associated manifestations	2	2	2	2
	2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	4	4	3	3	1	1
Febrile disorders	3	3	2	2	1	1
Feelings and sensations NEC	4	4	4	4		
General signs and symptoms NEC	1	1	1	1		
Pain and discomfort NEC	1	1	1	1		
Vaccination site reactions	3	3	3	3		
	16	16	14	14	2	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haematological analyses NEC	1	1	1	1		
Heart rate and pulse investigations	1	1	1	1		
Liver function analyses	1	1			1	1
	3	3	2	2	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	1	1			1	1
Muscle pains	2	2	1	1	1	1
Musculoskeletal and connective tissue conditions NEC	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort	3	3	3	3		
	7	7	4	4	3	3

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	6	6	6	6
	6	6	6	6

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in initiating and maintaining sleep	1	1	1	1
Emotional and mood disturbances NEC	1	1	1	1
Sleep disorders NEC	1	1	1	1
	3	3	3	3

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pruritus NEC	1	1	1	1
Rashes, eruptions and exanthems NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vasculitides NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**CROATIA**

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders	1	1			1	1
Ocular disorders NEC	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1		
Oral soft tissue disorders NEC	1	1			1	1
Oral soft tissue signs and symptoms	1	1			1	1
Tongue signs and symptoms	2	2			2	2
	5	5	1	1	4	4

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	3	5	3	5		
Febrile disorders	6	8	6	8		
Feelings and sensations NEC	4	4	4	4		
General signs and symptoms NEC	3	3	1	1	2	2
Pain and discomfort NEC	1	1	1	1		
Vaccination site reactions	10	12	8	10	2	2
	27	33	23	29	4	4

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	1			1	1
Allergies to foods, food additives, drugs and other chemicals	1	1	1	1		
Anaphylactic and anaphylactoid responses	2	2			2	2
	4	4	1	1	3	3

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Physical examination procedures and organ system status	2	3	2	3
	2	3	2	3

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains		2		2
Musculoskeletal and connective tissue pain and discomfort	1	2	1	2
	1	4	1	4

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	7	8	6	7	1	1
Neurological signs and symptoms NEC	1	1	1	1		
Paraesthesias and dysaesthesias	2	2			2	2
Sensory abnormalities NEC	1	1			1	1
Tremor (excl congenital)	1	1			1	1
	13	14	7	8	6	6

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	2	2	2	2
Bronchospasm and obstruction	2	2	2	2
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1
Respiratory tract disorders NEC	1	1	1	1
	6	6	6	6

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Erythemas	2	2	1	1	1	1
Pruritus NEC	1	1			1	1
Rashes, eruptions and exanthems NEC	3	3	1	1	2	2
	7	7	2	2	5	5

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Country Where Event Occurred

**CYPRUS**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ischaemic coronary artery disorders		1		1
Rate and rhythm disorders NEC	2	2	2	2
	2	3	2	3

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders	1	1	1	1		
Ocular sensation disorders	1	1			1	1
	2	2	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Oral soft tissue signs and symptoms	1	1			1	1
Tongue signs and symptoms	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Febrile disorders	1	1	1	1
Vaccination site reactions	2	2	2	2
	3	3	3	3

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular tests NEC (incl blood pressure)	1	1	1	1
	1	1	1	1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Facial cranial nerve disorders	2	2	1	1	1	1
Headaches NEC	2	2	2	2		
Migraine headaches	1	1	1	1		
Neurological signs and symptoms NEC	1	1	1	1		
Paraesthesias and dysaesthesias	1	1			1	1
Sensory abnormalities NEC	1	1	1	1		
	8	8	6	6	2	2

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cervix disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breathing abnormalities	1	1	1	1
	1	1	1	1

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rashes, eruptions and exanthems NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular hypertensive disorders NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**CZECH REPUBLIC**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular sensation disorders	1	1	1	1
Visual disorders NEC	1	1	1	1
	2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	1	1	1		
Nausea and vomiting symptoms	5	5	3	3	2	2
Oral soft tissue swelling and oedema	1	1			1	1
Tongue signs and symptoms	2	2			2	2
	9	9	4	4	5	5

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	12	12	12	12		
Febrile disorders	4	4	4	4		
Feelings and sensations NEC	2	2	1	1	1	1
General signs and symptoms NEC	3	3			3	3
Pain and discomfort NEC	1	1	1	1		
Therapeutic and nontherapeutic responses	3	3			3	3
Vaccination site reactions	3	3	3	3		
	28	28	21	21	7	7

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	2	1	1	1	1
Allergies to foods, food additives, drugs and other chemicals	2	2			2	2
Anaphylactic and anaphylactoid responses	2	2			2	2
	6	6	1	1	5	5

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	2	2			2	2
Upper respiratory tract infections	1	1	1	1		
	3	3	1	1	2	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	1	1	1	1		
Vascular tests NEC (incl blood pressure)	1	1			1	1
Virus identification and serology	1	1			1	1
	3	3	1	1	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	3	3	3	3
Muscle pains	2	2	2	2
Musculoskeletal and connective tissue conditions NEC	2	2	2	2
Musculoskeletal and connective tissue pain and discomfort	5	5	5	5
	12	12	12	12

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	2	2	2	2		
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	5	5	5	5		
Neurological signs and symptoms NEC	2	2	1	1	1	1
Paraesthesias and dysaesthesias	3	3	2	2	1	1
	13	13	10	10	3	3

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	5	5	2	2	3	3
Bronchospasm and obstruction	1	1			1	1
Coughing and associated symptoms	1	1	1	1		
Pharyngeal disorders (excl infections and neoplasms)	1	1			1	1
Upper respiratory tract signs and symptoms	2	2	1	1	1	1
	10	10	4	4	6	6

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Erythemas	2	2	2	2		
Pruritus NEC	1	1	1	1		
Rashes, eruptions and exanthems NEC	1	1	1	1		
	5	5	4	4	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock	1	1			1	1
Vascular hypertensive disorders NEC	1	1	1	1		
	2	2	1	1	1	1

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Country Where Event Occurred

**DENMARK**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	4	4	4	4
	4	4	4	4

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	9	9	5	5	4	4
Rate and rhythm disorders NEC	3	3	1	1	2	2
Supraventricular arrhythmias	1	1	1	1		
Ventricular arrhythmias and cardiac arrest	1	1			1	1
	14	14	7	7	7	7

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders	1	1	1	1		
Ocular disorders NEC	3	3	3	3		
Ocular infections, inflammations and associated manifestations	1	1	1	1		
Visual disorders NEC	1	1			1	1
Visual impairment and blindness (excl colour blindness)	1	1	1	1		
	7	7	6	6	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	5	5	5	5		
Gastrointestinal and abdominal pains (excl oral and throat)	2	2	2	2		
Gastrointestinal atonic and hypomotility disorders NEC	1	1	1	1		
Gastrointestinal signs and symptoms NEC	1	1			1	1
Nausea and vomiting symptoms	26	26	14	14	12	12
Oral soft tissue signs and symptoms	2	2	1	1	1	1
Tongue signs and symptoms	4	4	1	1	3	3
	41	41	24	24	17	17

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	43	43	27	27	16	16
Death and sudden death	2	2			2	2
Febrile disorders	31	31	26	26	5	5
Feelings and sensations NEC	20	20	13	13	7	7
General signs and symptoms NEC	13	13	5	5	8	8
Interactions	1	1			1	1
Pain and discomfort NEC	13	13	6	6	7	7
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	62	62	56	56	6	6
	186	186	133	133	53	53

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC	5	5	5	5
Anaphylactic and anaphylactoid responses	7	7	7	7
	12	12	12	12

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	2	2			2	2
Lower respiratory tract and lung infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	2			2	2
Upper respiratory tract infections	1	1	1	1		
	6	6	1	1	5	5

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious			
			I	C		
Product administration errors and issues	3	3	3	3		
Underdoses NEC	1	1	1	1		
	4	4	4	4		

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	1	1			1	1
Heart rate and pulse investigations	3	3	2	2	1	1
Physical examination procedures and organ system status	2	2	2	2		
Vascular tests NEC (incl blood pressure)	4	4	1	1	3	3
	10	10	5	5	5	5

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	1	1	1	1
Fluid intake decreased	1	1	1	1
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	9	9	9	9		
Muscle pains	19	19	18	18	1	1
Muscle related signs and symptoms NEC	2	2	2	2		
Musculoskeletal and connective tissue conditions NEC	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort	8	8	8	8		
	39	39	37	37	2	2

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coma states	1	1			1	1
Disturbances in consciousness NEC	5	5			5	5
Headaches NEC	37	37	31	31	6	6
Mental impairment (excl dementia and memory loss)	2	2	1	1	1	1
Migraine headaches	1	1	1	1		
Neurological signs and symptoms NEC	33	33	14	14	19	19
Paraesthesias and dysaesthesias	8	8	4	4	4	4
Paralysis and paresis (excl cranial nerve)	1	1			1	1
Sensory abnormalities NEC	2	2	2	2		
Tremor (excl congenital)	2	2			2	2
	92	92	53	53	39	39

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	1			1	1
Behaviour and socialisation disturbances	1	1			1	1
Confusion and disorientation	1	1			1	1
Disturbances in initiating and maintaining sleep	1	1	1	1		
Increased physical activity levels	3	3	3	3		
Perception disturbances NEC	1	1	1	1		
Thinking disturbances	1	1			1	1
	9	9	5	5	4	4

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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Bladder and urethral symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	14	14	1	1	13	13
Bronchospasm and obstruction	3	3			3	3
Coughing and associated symptoms	2	2			2	2
Laryngeal spasm, oedema and obstruction	1	1			1	1
Lower respiratory tract inflammatory and immunologic conditions	1	1			1	1
Lower respiratory tract signs and symptoms	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)	4	4			4	4
Pulmonary oedemas	1	1			1	1
Respiratory failures (excl neonatal)	2	2			2	2
Respiratory tract disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	10	10	7	7	3	3
	40	40	8	8	32	32

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	3	3			3	3
Apocrine and eccrine gland disorders	3	3	2	2	1	1
Dermal and epidermal conditions NEC	1	1	1	1		
Dermatitis and eczema	1	1			1	1
Erythemas	2	2			2	2
Pruritus NEC	4	4	3	3	1	1
Rashes, eruptions and exanthems NEC	12	12	4	4	8	8
Urticarias	4	4	1	1	3	3
	30	30	11	11	19	19

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC	6	6	3	3	3	3
Site specific vascular disorders NEC	6	6	3	3	3	3
Vascular hypertensive disorders NEC	2	2	1	1	1	1
Vascular hypotensive disorders	2	2			2	2
	16	16	7	7	9	9

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Country Where Event Occurred

**ESTONIA**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC	1	1	1	1
Rate and rhythm disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	2	2	2	2		
Feelings and sensations NEC	1	1	1	1		
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	1	1	1	1		
	5	5	4	4	1	1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	4	4	4	4		
Fractures and dislocations NEC	1	1			1	1
Medication errors, product use errors and issues NEC	1	1	1	1		
Off label uses	1	1	1	1		
Underdoses NEC	1	1	1	1		
	8	8	7	7	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	1	1	1	1
	1	1	1	1

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Facial cranial nerve disorders	1	1	1	1
Headaches NEC	1	1	1	1
Paraesthesias and dysaesthesias	5	5	5	5
	7	7	7	7

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System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	1	1	1	1
	1	1	1	1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms	2	2	2	2
Increased physical activity levels	1	1	1	1
	3	3	3	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular hypertensive disorders NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**FINLAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	3	3	3	3
	3	3	3	3

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rate and rhythm disorders NEC	2	2	2	2
	2	2	2	2

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms	3	3	1	1	2	2
Oral soft tissue signs and symptoms	2	2	2	2		
	5	5	3	3	2	2

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	6	6	4	4	2	2
Death and sudden death	1	1			1	1
Febrile disorders	2	2	2	2		
Feelings and sensations NEC	2	2	2	2		
Gait disturbances	1	1	1	1		
General signs and symptoms NEC	1	1	1	1		
Mass conditions NEC	1	1	1	1		
Pain and discomfort NEC	4	4	2	2	2	2
Vaccination site reactions	10	10	10	10		
	28	28	23	23	5	5

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	1	1	1		
Anaphylactic and anaphylactoid responses	3	3			3	3
	4	4	1	1	3	3

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	2	2			2	2
Protein analyses NEC	1	1	1	1		
	3	3	1	1	2	2

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Potassium imbalance	2	2	2	2
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Muscle pains	2	2	2	2
Muscle tone abnormalities	1	1	1	1
Musculoskeletal and connective tissue conditions NEC	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	2	2	2	2
	7	7	7	7

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	1	1			1	1
Disturbances in consciousness NEC	2	2	1	1	1	1
Headaches NEC	2	2			2	2
Migraine headaches	1	1			1	1
Neurological signs and symptoms NEC	2	2	2	2		
Paraesthesias and dysaesthesias	2	2	1	1	1	1
Seizures and seizure disorders NEC	1	1			1	1
Tremor (excl congenital)	1	1			1	1
	12	12	4	4	8	8

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Perception disturbances NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	3	1	1	2	2
Coughing and associated symptoms	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)	2	2			2	2
Upper respiratory tract signs and symptoms	1	1			1	1
	7	7	1	1	6	6

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythemas	3	3	1	1	2	2
Rashes, eruptions and exanthems NEC	2	2	1	1	1	1
Urticarias	1	1			1	1
	6	6	2	2	4	4

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Aneurysms and dissections non-site specific	1	1	1	1
Vascular hypotensive disorders	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**FRANCE**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukocytoses NEC	1	1			1	1
Leukopenias NEC	1	1	1	1		
Lymphatic system disorders NEC	1	1	1	1		
Thrombocytopenias	1	1			1	1
	4	4	2	2	2	2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	1	1	1	1		
Heart failures NEC	2	2			2	2
Rate and rhythm disorders NEC	4	4	2	2	2	2
Supraventricular arrhythmias	3	3			3	3
Ventricular arrhythmias and cardiac arrest	3	3			3	3
	13	13	3	3	10	10

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lid, lash and lacrimal infections, irritations and inflammations	1	1	1	1
Ocular disorders NEC	1	1	1	1
	2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	2	2			2	2
Gastrointestinal and abdominal pains (excl oral and throat)	1	1			1	1
Gastrointestinal atonic and hypomotility disorders NEC	1	1	1	1		
Gastrointestinal signs and symptoms NEC	2	2			2	2
Nausea and vomiting symptoms	8	8	4	4	4	4
Oral soft tissue signs and symptoms	1	1	1	1		
Oral soft tissue swelling and oedema	1	1			1	1
Stomatitis and ulceration	1	1	1	1		
Tongue disorders	2	2	2	2		
	19	19	9	9	10	10

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	13	13	8	8	5	5
Death and sudden death	16	16			16	16
Febrile disorders	6	6	5	5	1	1
Feelings and sensations NEC	2	2	2	2		
General signs and symptoms NEC	1	1			1	1
Injection site reactions	2	2	2	2		
Oedema NEC	1	1			1	1
Pain and discomfort NEC	2	2	1	1	1	1
Therapeutic and nontherapeutic responses	10	10	1	1	9	9
Vaccination site reactions	9	9	9	9		
	62	62	28	28	34	34

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC	1	1	1	1
Anaphylactic and anaphylactoid responses	1	1	1	1
	2	2	2	2

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	9	9			9	9
Ear infections	1	1	1	1		
Herpes viral infections	1	1	1	1		
Lower respiratory tract and lung infections	1	1			1	1
	12	12	2	2	10	10

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	2	2	2	2		
Medication errors, product use errors and issues NEC	3	3	3	3		
Non-site specific injuries NEC	1	1			1	1
Occupational exposures	1	1	1	1		
Off label uses	1	1	1	1		
Overdoses NEC	6	6	6	6		
Product administration errors and issues	8	8	8	8		
Product preparation errors and issues	19	19	19	19		
Underdoses NEC	13	13	13	13		
Vaccination related complications	1	1	1	1		
	55	55	54	54	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	1	1			1	1
Carbohydrate tolerance analyses (incl diabetes)	1	1	1	1		
Coagulation and bleeding analyses	1	1			1	1
Metabolism tests NEC	1	1	1	1		
Protein analyses NEC	2	2	1	1	1	1
Vascular tests NEC (incl blood pressure)	1	1			1	1
Virus identification and serology	1	1	1	1		
	8	8	4	4	4	4

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	2	2	2	2
Muscle pains	2	2	2	2
Musculoskeletal and connective tissue conditions NEC	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	3	3	3	3
	8	8	8	8

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Absence seizures	1	1			1	1
Central nervous system haemorrhages and cerebrovascular accidents	4	4			4	4
Disturbances in consciousness NEC	3	3			3	3
Headaches NEC	4	4	4	4		
Mental impairment (excl dementia and memory loss)	1	1			1	1
Muscle tone abnormal	1	1			1	1
Neurological signs and symptoms NEC	2	2	1	1	1	1
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	2	2	1	1	1	1
Sensory abnormalities NEC	1	1	1	1		
Speech and language abnormalities	1	1			1	1
	21	21	8	8	13	13

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System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	1	1	1	1
Product distribution and storage issues	1	1	1	1
	2	2	2	2

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	2			2	2
Confusion and disorientation	1	1			1	1
Disturbances in initiating and maintaining sleep	2	2	2	2		
Fear symptoms and phobic disorders (incl social phobia)	1	1			1	1
	6	6	2	2	4	4

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	3	3			3	3
Bronchospasm and obstruction	1	1			1	1
Coughing and associated symptoms	3	3	1	1	2	2
Lower respiratory tract signs and symptoms	2	2			2	2
Nasal congestion and inflammations	1	1	1	1		
Pulmonary oedemas	1	1			1	1
Respiratory failures (excl neonatal)	1	1			1	1
Upper respiratory tract signs and symptoms	1	1			1	1
	13	13	2	2	11	11

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Apocrine and eccrine gland disorders	1	1	1	1		
Dermal and epidermal conditions NEC	1	1	1	1		
Erythemas	2	2	2	2		
Pruritus NEC	3	3	3	3		
Rashes, eruptions and exanthems NEC	2	2	2	2		
Urticarias	2	2			2	2
	12	12	9	9	3	3

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Aortic aneurysms and dissections	2	2			2	2
Peripheral vascular disorders NEC	1	1	1	1		
Vascular hypertensive disorders NEC	2	2	2	2		
Vascular hypotensive disorders	1	1			1	1
	7	7	3	3	4	4

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Country Where Event Occurred

**GERMANY**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenias NEC		1				1
Lymphatic system disorders NEC	16	16	16	16		
	16	17	16	16		1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	6	6	5	5	1	1
Cardiac signs and symptoms NEC	15	17	13	15	2	2
Heart failures NEC	8	8			8	8
Ischaemic coronary artery disorders	9	9			9	9
Rate and rhythm disorders NEC	26	27	9	9	17	18
Supraventricular arrhythmias	2	2			2	2
Ventricular arrhythmias and cardiac arrest	3	3			3	3
	69	72	27	29	42	43

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological disorders congenital NEC	3	3	3	3
	3	3	3	3

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	3	3	3	3		
Hearing losses	2	2			2	2
Inner ear signs and symptoms	4	4	4	4		
	9	9	7	7	2	2

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders	2	2	2	2		
Ocular bleeding and vascular disorders NEC	1	1			1	1
Ocular disorders NEC	3	3	2	2	1	1
Ocular infections, inflammations and associated manifestations	4	4	3	3	1	1
Ocular sensation disorders	1	1	1	1		
Scleral infections, irritations and inflammations	1	1	1	1		
Visual disorders NEC	3	3	1	1	2	2
Visual impairment and blindness (excl colour blindness)	2	2	1	1	1	1
	17	17	11	11	6	6

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	22	22	21	21	1	1
Dyspeptic signs and symptoms	1	1	1	1		
Faecal abnormalities NEC	5	5	5	5		
Flatulence, bloating and distension	2	2	2	2		
Gastrointestinal and abdominal pains (excl oral and throat)	12	12	12	12		
Gastrointestinal atonic and hypomotility disorders NEC	1	1	1	1		
Gastrointestinal signs and symptoms NEC	4	4			4	4
Gastrointestinal vascular occlusion and infarction	1	1			1	1
Nausea and vomiting symptoms	50	52	41	43	9	9
Oral dryness and saliva altered	1	1	1	1		
Oral soft tissue signs and symptoms	5	5	5	5		
Oral soft tissue swelling and oedema	3	3	2	2	1	1
Stomatitis and ulceration	1	1	1	1		
Tongue disorders	1	1	1	1		
Tongue signs and symptoms	4	4	2	2	2	2
	113	115	95	97	18	18

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Asthenic conditions	159	172	2	2	150	159	9	13
Death and sudden death	40	40					40	40
Febrile disorders	52	54	1	1	44	45	8	9
Feelings and sensations NEC	56	57			51	52	5	5
Gait disturbances	2	2			2	2		
General signs and symptoms NEC	55	57			36	38	19	19
Injection site reactions	2	2			2	2		
Interactions	1	1			1	1		
Oedema NEC	2	2					2	2
Pain and discomfort NEC	19	21			17	18	2	3
Therapeutic and nontherapeutic responses	113	113					113	113
Vaccination site reactions	234	243			233	242	1	1
	735	764	3	3	536	559	199	205

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	15	15	6	6	9	9
Allergies to foods, food additives, drugs and other chemicals	2	2	1	1	1	1
Anaphylactic and anaphylactoid responses	13	14			13	14
	30	31	7	7	23	24

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	88	88	1	1	87	87
Ear infections	1	1	1	1		
Eye and eyelid infections	1	1	1	1		
Herpes viral infections	4	4	4	4		
Infections NEC	6	6			6	6
Lower respiratory tract and lung infections	7	7	1	1	6	6
Sepsis, bacteraemia, viraemia and fungaemia NEC	3	3			3	3
Staphylococcal infections	1	1			1	1
Upper respiratory tract infections	8	9	8	9		
	119	120	16	17	103	103

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	16	16	16	16		
Limb fractures and dislocations	1	1			1	1
Medication errors, product use errors and issues NEC	10	10	10	10		
Non-site specific injuries NEC	4	4			4	4
Occupational exposures	1	1	1	1		
Off label uses	8	8	8	8		
Product administration errors and issues	20	28	18	25	2	3
Product preparation errors and issues	3	3	3	3		
Site specific injuries NEC	1	1			1	1
Skin injuries NEC	1	1	1	1		
Underdoses NEC	9	9	9	9		
	74	82	66	73	8	9

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	4	4			4	4
Carbohydrate tolerance analyses (incl diabetes)	1	1	1	1		
Heart rate and pulse investigations	1	2		1	1	1
Physical examination procedures and organ system status	12	12	9	9	3	3
Urinalysis NEC	2	2	1	1	1	1
Vascular tests NEC (incl blood pressure)	6	6	3	3	3	3
Virus identification and serology	43	43	12	12	31	31
	69	70	26	27	43	43

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	6	6	1	1	5	5
Calcium metabolism disorders	1	1			1	1
Diabetes mellitus (incl subtypes)		1				1
	7	8	1	1	6	7

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Bone related signs and symptoms	1	1			1	1		
Joint related signs and symptoms	19	19			18	18	1	1
Muscle pains	55	55	1	1	55	55		
Muscle related signs and symptoms NEC	3	3			3	3		
Muscle weakness conditions	6	6			6	6		
Musculoskeletal and connective tissue conditions NEC	7	7			4	4	3	3
Musculoskeletal and connective tissue pain and discomfort	82	84			81	83	1	1
	173	175	1	1	168	170	5	5

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Alzheimer's disease (incl subtypes)	1	1					1	1
Autonomic nervous system disorders	1	1					1	1
Central nervous system haemorrhages and cerebrovascular accidents	5	5					5	5
Coordination and balance disturbances	1	1			1	1		
Cranial nerve disorders NEC	1	1			1	1		
Dementia (excl Alzheimer's type)	1	1					1	1
Disturbances in consciousness NEC	12	12			5	5	7	7
Dyskinesias and movement disorders NEC	4	5			2	3	2	2
Facial cranial nerve disorders	1	2					1	2
Headaches NEC	111	119	1	1	106	113	5	6
Mental impairment (excl dementia and memory loss)	5	5			4	4	1	1
Migraine headaches		1				1		
Muscle tone abnormal	2	2			1	1	1	1
Narcolepsy and hypersomnia	1	1			1	1		
Neurological signs and symptoms NEC	53	57			45	48	8	9
Olfactory nerve disorders	1	1			1	1		
Paraesthesias and dysaesthesias	23	23			20	20	3	3
Paralysis and paresis (excl cranial nerve)	1	2				1	1	1
Peripheral neuropathies NEC	1	1					1	1
Seizures and seizure disorders NEC	7	9			1	1	6	8
Sensory abnormalities NEC	10	10			9	9	1	1
Sleep disturbances NEC	2	2			1	1	1	1
Speech and language abnormalities	2	2					2	2
Transient cerebrovascular events	1	1					1	1
Tremor (excl congenital)	7	7			5	5	2	2
	254	272	1	1	203	216	51	56

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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product physical issues	1	1	1	1
	1	1	1	1

System Organ Class

Psychiatric disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms		2		2		
Behaviour and socialisation disturbances	1	1			1	1
Confusion and disorientation	2	2	2	2		
Disturbances in initiating and maintaining sleep	2	2	2	2		
Increased physical activity levels	2	2	2	2		
Mental disorders NEC	1	1			1	1
Mood disorders NEC	2	2			2	2
Sleep disorders NEC	2	2	2	2		
	12	14	8	10	4	4

System Organ Class

Renal and urinary disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	3	3	3	3		
Renal failure and impairment	7	7			7	7
Urinary abnormalities	1	1	1	1		
Urinary tract signs and symptoms NEC	1	1	1	1		
	12	12	5	5	7	7

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	29	31	10	11	19	20
Bronchial conditions NEC	1	1	1	1		
Bronchospasm and obstruction	3	3	2	2	1	1
Coughing and associated symptoms	8	10	8	9		1
Laryngeal spasm, oedema and obstruction	3	3			3	3
Lower respiratory tract inflammatory and immunologic conditions	3	3			3	3
Lower respiratory tract signs and symptoms	2	2			2	2
Nasal congestion and inflammations	1	1	1	1		
Nasal disorders NEC	3	3	3	3		
Pharyngeal disorders (excl infections and neoplasms)	5	5	2	2	3	3
Pulmonary thrombotic and embolic conditions	3	3			3	3
Respiratory failures (excl neonatal)	3	3			3	3
Respiratory signs and symptoms NEC	1	1	1	1		
Upper respiratory tract signs and symptoms	32	32	29	29	3	3
	97	101	57	59	40	42

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	1	1	1	1		
Angioedemas	2	2			2	2
Apocrine and eccrine gland disorders	8	9	7	8	1	1
Bullous conditions	1	1	1	1		
Dermal and epidermal conditions NEC	2	2	2	2		
Dermatitis and eczema	3	3	3	3		
Erythemas	10	10	10	10		
Photosensitivity and photodermatosis conditions	1	1	1	1		
Pruritus NEC	12	12	8	8	4	4
Psoriatic conditions	1	1	1	1		
Rashes, eruptions and exanthems NEC	23	23	14	14	9	9
Rosaceas	1	1			1	1
Skin vasomotor conditions	1	1	1	1		
Urticarias	4	4	2	2	2	2
	70	71	51	52	19	19

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC	1	1	1	1		
Circulatory collapse and shock	4	4			4	4
Haemorrhages NEC	1	1	1	1		
Peripheral embolism and thrombosis	1	1	1	1		
Peripheral vascular disorders NEC	13	14	5	5	8	9
Vascular hypertensive disorders NEC	12	14	4	5	8	9
Vascular hypotensive disorders	7	7	1	1	6	6
	39	42	13	14	26	28

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Country Where Event Occurred

**GREECE**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukocytoses NEC	1	1			1	1
Lymphatic system disorders NEC	2	2	2	2		
	3	3	2	2	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	1			1	1
Cardiac signs and symptoms NEC	2	2	2	2		
Cardiac valve disorders NEC	1	1			1	1
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	9	10	6	6	3	4
Supraventricular arrhythmias	1	1			1	1
Ventricular arrhythmias and cardiac arrest	3	3			3	3
	18	19	8	8	10	11

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Hearing losses	1	1			1	1
Inner ear signs and symptoms	2	2	2	2		
	3	3	2	2	1	1

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Eyelid movement disorders	1	1	1	1
Ocular disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	3	3	2	2	1	1
Flatulence, bloating and distension		1				1
Gastrointestinal and abdominal pains (excl oral and throat)	2	2	2	2		
Gastrointestinal disorders NEC	2	2	2	2		
Gastrointestinal signs and symptoms NEC	4	4	2	2	2	2
Gastrointestinal spastic and hypermotility disorders		2				2
Nausea and vomiting symptoms	10	10	8	8	2	2
Oral dryness and saliva altered	2	2	2	2		
Oral soft tissue signs and symptoms	7	7	4	4	3	3
Tongue disorders	1	1	1	1		
	31	34	23	23	8	11

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	1	1	1	1		
Asthenic conditions	13	13	11	11	2	2
Death and sudden death	2	2			2	2
Febrile disorders	12	12	10	10	2	2
Feelings and sensations NEC	6	6	4	4	2	2
Gait disturbances	2	2	2	2		
General signs and symptoms NEC	2	2	1	1	1	1
Injection site reactions	1	1	1	1		
Interactions	1	1			1	1
Mucosal findings abnormal		1				1
Pain and discomfort NEC	5	5	3	3	2	2
Therapeutic and nontherapeutic responses	2	2	1	1	1	1
Vaccination site reactions	16	17	16	17		
	63	65	50	51	13	14

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	9	9	6	6	3	3
Anaphylactic and anaphylactoid responses	5	6			5	6
	14	15	6	6	8	9

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	1	1			1	1
Herpes viral infections	1	1	1	1		
Infections NEC	1	1			1	1
Lower respiratory tract and lung infections	1	1			1	1
	4	4	1	1	3	3

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Non-site specific injuries NEC	2	2	1	1	1	1
Off label uses	1	1	1	1		
Product administration errors and issues	4	4	4	4		
	8	8	7	7	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	1	1	1	1		
Vascular tests NEC (incl blood pressure)	5	5	4	4	1	1
	6	6	5	5	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	2	2	2	2		
Muscle pains	3	3	2	2	1	1
Muscle related signs and symptoms NEC	1	1	1	1		
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	7	7	7	7		
Rheumatoid arthropathies	1	1			1	1
	15	15	13	13	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	2	2	1	1	1	1
Headaches NEC	12	12	11	11	1	1
Migraine headaches	1	1	1	1		
Neurological signs and symptoms NEC	13	13	8	8	5	5
Paraesthesias and dysaesthesias	8	8	7	7	1	1
Seizures and seizure disorders NEC	1	1			1	1
Sensory abnormalities NEC	5	5	3	3	2	2
Sleep disturbances NEC	1	1	1	1		
Tremor (excl congenital)	1	2			1	2
	44	45	32	32	12	13

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System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product physical issues	3	3	3	3
Product quality issues NEC	1	1	1	1
	4	4	4	4

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	1	1	1		
Emotional and mood disturbances NEC	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	7	7	3	3	4	4
Bronchospasm and obstruction	2	2			2	2
Coughing and associated symptoms	3	3			3	3
Laryngeal spasm, oedema and obstruction	1	1			1	1
Nasal congestion and inflammations	2	2	2	2		
Pulmonary oedemas	1	1			1	1
Pulmonary thrombotic and embolic conditions	1	1			1	1
Respiratory failures (excl neonatal)	1	1			1	1
Upper respiratory tract signs and symptoms	7	7	4	4	3	3
	25	25	9	9	16	16

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	2	2			2	2
Apocrine and eccrine gland disorders	3	3	2	2	1	1
Bullous conditions	1	1	1	1		
Dermal and epidermal conditions NEC	1	1	1	1		
Erythemas	1	2	1	1		1
Pruritus NEC	3	3	2	2	1	1
Rashes, eruptions and exanthems NEC	9	9	8	8	1	1
	20	21	15	15	5	6

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	2	2			2	2
Blood pressure disorders NEC	1	1	1	1		
Peripheral vascular disorders NEC	3	4	2	2	1	2
Vascular hypertensive disorders NEC	5	5	3	3	2	2
Vascular hypotensive disorders	2	2	2	2		
	13	14	8	8	5	6

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Country Where Event Occurred

**HUNGARY**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	6	6	5	5	1	1
	6	6	5	5	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC	4	4	4	4
Inner ear signs and symptoms	1	1	1	1
	5	5	5	5

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lacrimation disorders	1	1	1	1
Visual disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Nausea and vomiting symptoms	10	10	10	10		
Oral dryness and saliva altered		1				1
Oral soft tissue signs and symptoms	2	2	2	2		
	12	13	12	12		1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	1	1	1	1		
Asthenic conditions	22	24	20	22	2	2
Febrile disorders	12	12	10	10	2	2
Feelings and sensations NEC	12	15	10	11	2	4
Gait disturbances	2	2	2	2		
General signs and symptoms NEC	3	3	3	3		
Oedema NEC	1	1			1	1
Pain and discomfort NEC	6	6	6	6		
Therapeutic and nontherapeutic responses	3	3			3	3
Vaccination site reactions	31	31	31	31		
	93	98	83	86	10	12

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC		1		1		
Anaphylactic and anaphylactoid responses	1	1			1	1
	1	2		1	1	1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	2	2			2	2
Herpes viral infections	1	1	1	1		
Upper respiratory tract infections	1	1	1	1		
	4	4	2	2	2	2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
Off label uses	1	1	1	1
Product administration errors and issues	1	1	1	1
	3	3	3	3

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Carbohydrate tolerance analyses (incl diabetes)		1		1		
Heart rate and pulse investigations	1	2	1	2		
Physical examination procedures and organ system status	2	2	2	2		
Vascular tests NEC (incl blood pressure)	1	2	1	1		1
Virus identification and serology	1	1			1	1
	5	8	4	6	1	2

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hypoglycaemic conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	1	1			1	1
Muscle pains	7	7	6	6	1	1
Muscle related signs and symptoms NEC	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	15	15	15	15		
	25	25	23	23	2	2

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1	1	1		
Headaches NEC	17	17	15	15	2	2
Neurological signs and symptoms NEC	8	8	8	8		
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	8	10	8	9		1
Sensory abnormalities NEC	3	3	3	3		
Tremor (excl congenital)	1	2	1	1		1
	39	42	37	38	2	4

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation	1	1	1	1
Depressive disorders	1	1	1	1
Panic attacks and disorders	1	1	1	1
	3	3	3	3

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms		1		1
		1		1

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Sexual function and fertility disorders NEC	1	1			1	1
Vulvovaginal signs and symptoms	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	1			1	1
Laryngeal spasm, oedema and obstruction	1	1			1	1
Upper respiratory tract signs and symptoms	2	2	2	2		
	4	4	2	2	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	2	2	2	2		
Bullous conditions	1	1	1	1		
Dermal and epidermal conditions NEC	1	2	1	2		
Dermatitis and eczema	1	1	1	1		
Erythemas	2	2	2	2		
Pruritus NEC	3	3	3	3		
Rashes, eruptions and exanthems NEC	5	5	4	4	1	1
Urticarias	1	2	1	2		
	16	18	15	17	1	1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC	1	1			1	1
Site specific vascular disorders NEC	1	1	1	1		
	2	2	1	1	1	1

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Country Where Event Occurred

**ICELAND**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart failures NEC	2	2			2	2
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	2	2	1	1	1	1
	5	5	1	1	4	4

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea and vomiting symptoms	6	6	6	6
Oral dryness and saliva altered	1	1	1	1
	7	7	7	7

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	18	18	16	16	2	2
Death and sudden death	3	3			3	3
Febrile disorders	15	15	13	13	2	2
Feelings and sensations NEC	5	5	5	5		
General signs and symptoms NEC	2	2	1	1	1	1
Pain and discomfort NEC	3	3	3	3		
Vaccination site reactions	10	10	10	10		
	56	56	48	48	8	8

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lower respiratory tract and lung infections	2	2			2	2
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1			1	1
Upper respiratory tract infections	5	5	5	5		
	8	8	5	5	3	3

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System Organ Class

Investigations	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
High Level Term				
Heart rate and pulse investigations	1	1	1	1
Vascular tests NEC (incl blood pressure)	1	1	1	1
	2	2	2	2

System Organ Class

Musculoskeletal and connective tissue disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
High Level Term				
Bone related signs and symptoms	2	2	2	2
Joint related signs and symptoms	1	1	1	1
Muscle pains	3	3	3	3
Musculoskeletal and connective tissue pain and discomfort	2	2	2	2
	8	8	8	8

System Organ Class

Nervous system disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
High Level Term				
Headaches NEC	13	13	13	13
Migraine headaches	1	1	1	1
Neurological signs and symptoms NEC	5	5	5	5
Paraesthesias and dysaesthesias	4	4	4	4
Sensory abnormalities NEC	1	1	1	1
Tremor (excl congenital)	1	1	1	1
	25	25	25	25

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	2	1	1	1	1
Coughing and associated symptoms	3	3	2	2	1	1
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1		
Upper respiratory tract signs and symptoms	6	6	6	6		
	12	12	10	10	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Apocrine and eccrine gland disorders	1	1	1	1
Erythemas	1	1	1	1
Pruritus NEC	1	1	1	1
	3	3	3	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aortic aneurysms and dissections	1	1			1	1
Peripheral vascular disorders NEC	1	1	1	1		
Site specific vascular disorders NEC	1	1	1	1		
	3	3	2	2	1	1

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Country Where Event Occurred

**INDIA**

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Counterfeit, falsified and substandard products		1		1
		1		1

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Country Where Event Occurred

**IRELAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hearing losses	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Visual impairment and blindness (excl colour blindness)	2	2	2	2
	2	2	2	2

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adverse effect absent	1	1	1	1		
Asthenic conditions	3	3	3	3		
Death and sudden death	2	2			2	2
Febrile disorders	1	1	1	1		
Injection site reactions	1	1			1	1
Pain and discomfort NEC	1	1			1	1
	9	9	5	5	4	4

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Heart rate and pulse investigations	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Joint related disorders NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	2	2			2	2
Eye movement disorders	1	1			1	1
Headaches NEC	2	2	2	2		
Neurological signs and symptoms NEC	1	1			1	1
	6	6	2	2	4	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	1	1	1
	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Apocrine and eccrine gland disorders	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**ISRAEL**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC	1	1			1	1
Leukocytoses NEC	2	2	1	1	1	1
Leukopenias NEC	1	1			1	1
Lymphatic system disorders NEC	4	5	4	5		
	8	9	5	6	3	3

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	2	2			2	2
Cardiac signs and symptoms NEC	8	8	8	8		
Heart failures NEC		1				1
Ischaemic coronary artery disorders	4	4			4	4
Noninfectious pericarditis	1	2			1	2
Rate and rhythm disorders NEC	6	6	3	3	3	3
Supraventricular arrhythmias	2	3	1	1	1	2
Ventricular arrhythmias and cardiac arrest	5	6			5	6
	28	32	12	12	16	20

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC	4	4	4	4
Inner ear signs and symptoms	1	1	1	1
	5	5	5	5

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Colour blindness (incl acquired)	1	1			1	1
Lacrimation disorders	2	2	1	1	1	1
Ocular bleeding and vascular disorders NEC	1	1			1	1
Ocular disorders NEC	2	2			2	2
Ocular infections, inflammations and associated manifestations	2	2	1	1	1	1
Visual disorders NEC	3	3	3	3		
	11	11	5	5	6	6

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Dental pain and sensation disorders	2	2	2	2		
Diarrhoea (excl infective)	7	7	6	6	1	1
Dyspeptic signs and symptoms	5	5	5	5		
Gastrointestinal and abdominal pains (excl oral and throat)	2	4	2	4		
Gastrointestinal signs and symptoms NEC	5	5	4	4	1	1
Gingival disorders, signs and symptoms NEC	1	1	1	1		
Nausea and vomiting symptoms	29	33	28	32	1	1
Oesophagitis (excl infective)	1	1	1	1		
Oral dryness and saliva altered	1	1	1	1		
Oral soft tissue signs and symptoms	18	24	16	22	2	2
Oral soft tissue swelling and oedema	2	2	1	1	1	1
Tongue signs and symptoms	4	5	1	1	3	4
	78	91	68	80	10	11

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Asthenic conditions	89	104			84	99	5	5
Death and sudden death	5	7					5	7
Febrile disorders	37	39			34	36	3	3
Feelings and sensations NEC	41	49			38	45	3	4
Gait disturbances	2	2					2	2
General signs and symptoms NEC	15	16			14	14	1	2
Inflamations	1	1					1	1
Pain and discomfort NEC	14	16			13	15	1	1
Therapeutic and nontherapeutic responses	18	20	1	1	6	6	12	14
Vaccination site reactions	58	78			58	78		
	280	332	1	1	247	293	33	39

System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholestasis and jaundice	1	1	1	1		
Hepatocellular damage and hepatitis NEC	1	1			1	1
	2	2	1	1	1	1

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	4		1	2	3
Allergies to foods, food additives, drugs and other chemicals	3	3	1	1	2	2
Anaphylactic and anaphylactoid responses	4	4			4	4
	9	11	1	2	8	9

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Coronavirus infections	8	9	1	1	2	2	6	7
Ear infections	1	1			1	1		
Eye and eyelid infections		1				1		
Herpes viral infections	4	4			3	3	1	1
Infections NEC	1	1			1	1		
Influenza viral infections	1	2			1	2		
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1					1	1
Upper respiratory tract infections	2	2			2	2		
Viral infections NEC	1	1			1	1		
	19	22	1	1	11	13	8	9

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Exposures associated with pregnancy, delivery and lactation	2	5			2	5		
Exposures to agents or circumstances NEC			1	1				
Limb fractures and dislocations	1	1					1	1
Medication errors, product use errors and issues NEC	4	5			4	5		
Non-site specific injuries NEC	3	3			1	1	2	2
Off label uses	1	2			1	2		
Overdoses NEC	2	4			2	4		
Pelvic fractures and dislocations	1	1					1	1
Product administration errors and issues	9	36			9	36		
Product preparation errors and issues	3	5			3	5		
Site specific injuries NEC	1	1					1	1
Skin injuries NEC	1	1					1	1
Thoracic cage fractures and dislocations	1	1					1	1
Underdoses NEC	2	3			2	3		
	31	68	1	1	24	61	7	7

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System Organ Class

Investigations	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
High Level Term							
Blood gas and acid base analyses	2	2	1	1	1	1	
Carbohydrate tolerance analyses (incl diabetes)	3	3	1	1	2	2	
Chemistry analyses NEC		1				1	
Coagulation and bleeding analyses	1	1			1	1	
Heart rate and pulse investigations	7	8	6	7	1	1	
Mineral and electrolyte analyses	2	2	1	1	1	1	
Physical examination procedures and organ system status	3	3	1	1	2	2	
Platelet analyses	1	1	1	1			
Protein analyses NEC	1	1	1	1			
Red blood cell analyses	6	6	5	5	1	1	
Renal function analyses	1	1			1	1	
Vascular tests NEC (incl blood pressure)	10	11	5	6	5	5	
Virus identification and serology	7	8	1	1	6	7	
White blood cell analyses	2	2	1	1	1	1	
	46	50	24	26	22	24	

System Organ Class

Metabolism and nutrition disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
High Level Term						
Appetite disorders	5	5	4	4	1	1
	5	5	4	4	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	1	1	1		
Bone related signs and symptoms	3	4	3	4		
Joint related signs and symptoms	11	12	9	10	2	2
Muscle pains	27	29	25	27	2	2
Muscle related signs and symptoms NEC	1	1	1	1		
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC		1				1
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	39	43	39	43		
	84	93	80	88	4	5

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	4	4			4	4
Coordination and balance disturbances	1	2		1	1	1
Disturbances in consciousness NEC	10	12	1	1	9	11
Dyskinesias and movement disorders NEC	2	2	1	1	1	1
Facial cranial nerve disorders	10	11			10	11
Headaches NEC	43	45	40	42	3	3
Migraine headaches	1	1	1	1		
Multiple sclerosis acute and progressive	4	4			4	4
Neurological signs and symptoms NEC	25	31	22	28	3	3
Neuromuscular disorders NEC	2	2	2	2		
Olfactory nerve disorders	2	3	2	3		
Paraesthesias and dysaesthesias	37	45	36	44	1	1
Paralysis and paresis (excl cranial nerve)	1	2			1	2
Peripheral neuropathies NEC	3	3	3	3		
Seizures and seizure disorders NEC	1	1			1	1
Sensory abnormalities NEC	11	13	11	13		
Sleep disturbances NEC		1		1		
Speech and language abnormalities	1	1	1	1		
Tremor (excl congenital)	3	4	3	4		
	161	187	123	145	38	42

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product packaging issues	1	12	1	12
Product physical issues		15		15
Product quality issues NEC		1		1
	1	28	1	28

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms	2	2	2	2
Behaviour and socialisation disturbances	1	1	1	1
Confusion and disorientation	1	1	1	1
Depressive disorders	1	1	1	1
Disturbances in initiating and maintaining sleep	1	3	1	3
Emotional and mood disturbances NEC	1	1	1	1
Mood alterations with depressive symptoms	1	1	1	1
Sleep disorders NEC		1		1
	8	11	8	11

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Reproductive tract signs and symptoms NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	17	19	7	9	10	10
Bronchospasm and obstruction	2	2	1	1	1	1
Coughing and associated symptoms	6	6	6	6		
Lower respiratory tract signs and symptoms		1				1
Pharyngeal disorders (excl infections and neoplasms)	1	3	1	3		
Pneumothorax and pleural effusions NEC	1	1			1	1
Respiratory signs and symptoms NEC	1	1	1	1		
Respiratory tract disorders NEC	1	1	1	1		
Upper respiratory tract signs and symptoms	18	20	14	16	4	4
	47	54	31	37	16	17

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	1	1	1	1		
Apocrine and eccrine gland disorders	5	5	5	5		
Dermal and epidermal conditions NEC	2	3	2	3		
Erythemas	6	7	6	7		
Pruritus NEC	3	3	2	2	1	1
Rashes, eruptions and exanthems NEC	10	12	8	9	2	3
Urticarias	5	6	2	3	3	3
	32	37	26	30	6	7

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System Organ Class

Social circumstances

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Social issues NEC	1	1	1	1
	1	1	1	1

System Organ Class

Vascular disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Circulatory collapse and shock	1	1			1	1
Non-site specific embolism and thrombosis	3	3			3	3
Peripheral vascular disorders NEC	1	1	1	1		
Vascular hypertensive disorders NEC	4	5	1	2	3	3
Vascular hypotensive disorders	1	1	1	1		
	10	11	3	4	7	7

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Country Where Event Occurred

**ITALY**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	39	39	36	36	3	3
	39	39	36	36	3	3

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	1			1	1
Cardiac signs and symptoms NEC	3	3	3	3		
Heart failures NEC	1	1			1	1
Ischaemic coronary artery disorders	6	6			6	6
Rate and rhythm disorders NEC	31	31	23	23	8	8
Supraventricular arrhythmias	2	2	1	1	1	1
	44	44	27	27	17	17

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	2	2	2		
Hearing losses	1	1			1	1
Inner ear signs and symptoms	23	23	21	21	2	2
	26	26	23	23	3	3

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	1	1			1	1
Lacrimation disorders	2	2	2	2		
Lid, lash and lacrimal infections, irritations and inflammations	2	2	1	1	1	1
Ocular disorders NEC	5	5	4	4	1	1
Ocular infections, inflammations and associated manifestations	5	5	5	5		
Ocular sensation disorders	2	2	2	2		
Visual disorders NEC	5	5	5	5		
Visual impairment and blindness (excl colour blindness)	1	1	1	1		
	23	23	20	20	3	3

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal	1	1	1	1		
Diarrhoea (excl infective)	25	25	25	25		
Dyspeptic signs and symptoms	1	1	1	1		
Flatulence, bloating and distension	2	2	2	2		
Gastritis (excl infective)	1	1	1	1		
Gastrointestinal and abdominal pains (excl oral and throat)	19	20	19	20		
Gastrointestinal atonic and hypomotility disorders NEC	1	1	1	1		
Gastrointestinal disorders NEC	1	1	1	1		
Gastrointestinal signs and symptoms NEC	12	12	8	8	4	4
Gingival disorders, signs and symptoms NEC	1	1	1	1		
Nausea and vomiting symptoms	63	63	59	59	4	4
Oral dryness and saliva altered	13	13	11	11	2	2
Oral soft tissue signs and symptoms	33	33	29	29	4	4
Oral soft tissue swelling and oedema	14	14	10	10	4	4
Salivary gland enlargements	1	1	1	1		
Tongue disorders	1	1	1	1		
Tongue signs and symptoms	11	11	6	6	5	5
	200	201	177	178	23	23

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Administration site reactions NEC	1	1					1	1
Asthenic conditions	84	86	1	1	78	80	6	6
Body temperature altered	2	2			1	1	1	1
Death and sudden death	4	4					4	4
Febrile disorders	108	108	1	1	101	101	7	7
Feelings and sensations NEC	63	64	2	2	58	59	5	5
General signs and symptoms NEC	16	18			12	14	4	4
Inflamations	1	1					1	1
Injection site reactions	5	5			4	4	1	1
Mucosal findings abnormal	1	1			1	1		
Oedema NEC	5	5			4	4	1	1
Pain and discomfort NEC	27	27			23	23	4	4
Therapeutic and nontherapeutic responses	11	11					11	11
Vaccination site reactions	225	228			217	220	8	8
	553	561	4	4	499	507	54	54

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	3	3	1	1	2	2
Allergies to foods, food additives, drugs and other chemicals	1	1			1	1
Anaphylactic and anaphylactoid responses	13	13			13	13
	17	17	1	1	16	16

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast infections	1	1			1	1
Coronavirus infections	5	5			5	5
Coxiella infections	1	1			1	1
Herpes viral infections	4	4	3	3	1	1
Upper respiratory tract infections	4	4	3	3	1	1
Vascular infections	1	1			1	1
	16	16	6	6	10	10

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Medication errors, product use errors and issues NEC	4	5	4	5		
Non-site specific injuries NEC	1	1			1	1
Off label uses	3	3	3	3		
Overdoses NEC	4	4	4	4		
Product administration errors and issues	9	9	9	9		
Product confusion errors and issues		1		1		
Product preparation errors and issues	1	1	1	1		
Underdoses NEC	7	7	7	7		
	30	32	29	31	1	1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	2	1	1	1	1
Carbohydrate tolerance analyses (incl diabetes)	1	1	1	1		
Heart rate and pulse investigations	1	1	1	1		
Neurologic diagnostic procedures	1	1			1	1
Physical examination procedures and organ system status	5	6	3	4	2	2
Respiratory and pulmonary function diagnostic procedures	1	1	1	1		
Vascular tests NEC (incl blood pressure)	9	9	6	6	3	3
Virus identification and serology	8	8	2	2	6	6
	28	29	15	16	13	13

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	2	2	2		
Hypoglycaemic conditions NEC	1	1	1	1		
Total fluid volume decreased	1	1			1	1
	4	4	3	3	1	1

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	8	8	8	8		
Joint related signs and symptoms	41	42	39	40	2	2
Muscle pains	46	46	44	44	2	2
Muscle related signs and symptoms NEC	1	1	1	1		
Muscle tone abnormalities	3	3	1	1	2	2
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	2	2	2	2		
Musculoskeletal and connective tissue pain and discomfort	58	58	54	54	4	4
	160	161	150	151	10	10

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	2	2					2	2
Coordination and balance disturbances	2	2			2	2		
Cranial nerve disorders NEC	2	2			1	1	1	1
Disturbances in consciousness NEC	23	23			18	18	5	5
Facial cranial nerve disorders	2	2					2	2
Headaches NEC	119	120	1	1	116	117	3	3
Lumbar spinal cord and nerve root disorders	1	1			1	1		
Migraine headaches	8	8			8	8		
Multiple sclerosis acute and progressive	1	1			1	1		
Neurological signs and symptoms NEC	30	30			29	29	1	1
Neuromuscular disorders NEC	1	1					1	1
Olfactory nerve disorders	2	2			2	2		
Paraesthesias and dysaesthesias	44	44			39	39	5	5
Paralysis and paresis (excl cranial nerve)	3	3			2	2	1	1
Parkinson's disease and parkinsonism	1	1					1	1
Peripheral neuropathies NEC	1	1			1	1		
Seizures and seizure disorders NEC	1	1					1	1
Sensory abnormalities NEC	20	20			18	18	2	2
Speech and language abnormalities	1	1			1	1		
Tremor (excl congenital)	10	10			9	9	1	1
	274	275	1	1	248	249	26	26

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	5	5	5	5		
Confusion and disorientation	8	8	7	7	1	1
Disturbances in initiating and maintaining sleep	4	4	4	4		
Emotional and mood disturbances NEC	1	1	1	1		
Increased physical activity levels	1	1			1	1
	19	19	17	17	2	2

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	1	1			1	1
Renal failure and impairment	1	1			1	1
Urinary tract signs and symptoms NEC	2	2	2	2		
	4	4	2	2	2	2

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breast signs and symptoms	3	3	3	3
	3	3	3	3

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Breathing abnormalities	21	21	1	1	10	10	11	11
Bronchospasm and obstruction	2	2					2	2
Conditions associated with abnormal gas exchange	1	1					1	1
Coughing and associated symptoms	9	9			8	8	1	1
Laryngeal spasm, oedema and obstruction	10	10					10	10
Nasal congestion and inflammations	3	3			3	3		
Nasal disorders NEC	2	2			2	2		
Pharyngeal disorders (excl infections and neoplasms)	7	7			6	6	1	1
Pulmonary thrombotic and embolic conditions	1	1					1	1
Respiratory failures (excl neonatal)	1	1					1	1
Respiratory signs and symptoms NEC	1	1					1	1
Upper respiratory tract signs and symptoms	29	29			24	24	5	5
	87	87	1	1	53	53	34	34

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	2	2			2	2
Apocrine and eccrine gland disorders	13	13	12	12	1	1
Dermal and epidermal conditions NEC	2	2	2	2		
Dermatitis and eczema	2	2			2	2
Erythemas	31	31	26	26	5	5
Exfoliative conditions	1	1			1	1
Papulosquamous conditions	1	1	1	1		
Pruritus NEC	27	27	24	24	3	3
Rashes, eruptions and exanthems NEC	29	29	28	28	1	1
Urticarias	34	34	31	31	3	3
	142	142	124	124	18	18

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	6	6			6	6
Circulatory collapse and shock	1	1			1	1
Haemorrhages NEC	1	1	1	1		
Lymphoedemas	1	1	1	1		
Non-site specific necrosis and vascular insufficiency NEC	1	1			1	1
Peripheral embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC	17	17	17	17		
Peripheral vasoconstriction, necrosis and vascular insufficiency	6	6	6	6		
Site specific vascular disorders NEC	3	3	3	3		
Vascular hypertensive disorders NEC	8	8	3	3	5	5
Vascular hypotensive disorders	11	11	8	8	3	3
	56	56	39	39	17	17

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Country Where Event Occurred

**KUWAIT**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	1	1	1	1
Febrile disorders	1	1	1	1
General signs and symptoms NEC	1	1	1	1
Pain and discomfort NEC	1	1	1	1
Vaccination site reactions	2	2	2	2
	6	6	6	6

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	2	2	2	2

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Country Where Event Occurred

**LATVIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	1	1	1		
Nausea and vomiting symptoms	2	2	2	2		
Oral dryness and saliva altered	1	1			1	1
Oral soft tissue swelling and oedema	1	1	1	1		
	5	5	4	4	1	1

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	8	8	7	7	1	1
Febrile disorders	3	3	2	2	1	1
Feelings and sensations NEC	2	2	2	2		
General signs and symptoms NEC	1	1	1	1		
Pain and discomfort NEC	1	1	1	1		
Therapeutic and nontherapeutic responses	5	5			5	5
Vaccination site reactions	11	11	10	10	1	1
	31	31	23	23	8	8

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	4	4	4	4
	4	4	4	4

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	6	6	5	5	1	1
Vascular tests NEC (incl blood pressure)	3	3	2	2	1	1
Virus identification and serology	1	1			1	1
	10	10	7	7	3	3

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	5	5	4	4	1	1
Muscle pains	4	4	4	4		
Musculoskeletal and connective tissue pain and discomfort	4	4	3	3	1	1
	13	13	11	11	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC	5	5	3	3	2	2
Neurological signs and symptoms NEC	1	1	1	1		
Paraesthesias and dysaesthesias	2	2			2	2
Sensory abnormalities NEC	2	2			2	2
	11	11	4	4	7	7

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anxiety symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breathing abnormalities	1	1	1	1
Bronchospasm and obstruction	1	1	1	1
Coughing and associated symptoms	1	1	1	1
Upper respiratory tract signs and symptoms	1	1	1	1
	4	4	4	4

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	2	2	1	1	1	1
Erythemas	1	1			1	1
Pruritus NEC	1	1			1	1
	4	4	1	1	3	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency	2	2	1	1	1	1
	2	2	1	1	1	1

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Country Where Event Occurred

**LITHUANIA**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Rate and rhythm disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Febrile disorders	6	6	6	6
Feelings and sensations NEC	2	2	2	2
General signs and symptoms NEC	1	1	1	1
Vaccination site reactions	3	3	3	3
	12	12	12	12

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Overdoses NEC	1	1	1	1
Underdoses NEC	1	1	1	1
Vaccination related complications	1	1	1	1
	3	3	3	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	2	2	2	2
Muscle pains	5	5	5	5
Musculoskeletal and connective tissue pain and discomfort	4	4	4	4
	11	11	11	11

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	4	4	4	4
Neurological signs and symptoms NEC	2	2	2	2
Paraesthesias and dysaesthesias	1	1	1	1
Tremor (excl congenital)	1	1	1	1
	8	8	8	8

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dermal and epidermal conditions NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**LUXEMBOURG**

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Herpes viral infections	2	2	2	2
	2	2	2	2

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Country Where Event Occurred

**MALTA**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		1		1		
Rate and rhythm disorders NEC		1				1
		2		1		1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		1		1
Nausea and vomiting symptoms	1	3	1	3
	1	4	1	4

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	2	3	2	3		
Pain and discomfort NEC	1	1	1	1		
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	1	2	1	2		
	5	7	4	6	1	1

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC		1		1
		1		1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	2	2	2	2
	2	2	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Disturbances in consciousness NEC	2	3	2	3
Facial cranial nerve disorders	1	1	1	1
Neurological signs and symptoms NEC		1		1
Paraesthesias and dysaesthesias	2	3	2	3
	5	8	5	8

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	1	1	1
Bronchospasm and obstruction	1	1	1	1
	2	2	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Erythemas		1		1		
Rashes, eruptions and exanthems NEC	1	2		1	1	1
	1	3		2	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vascular disorders NEC		1		1		
Vascular hypertensive disorders NEC		1				1
		2		1		1

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Country Where Event Occurred

**MEXICO**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Leukopenias NEC	1	1			1	1
Lymphatic system disorders NEC	3	3	3	3		
	4	4	3	3	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	1	1	1	1		
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	11	11	10	10	1	1
	13	13	11	11	2	2

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC	1	1	1	1
Inner ear signs and symptoms	1	1	1	1
	2	2	2	2

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ocular disorders NEC	2	3	1	2	1	1
Ocular infections, inflammations and associated manifestations	1	1	1	1		
	3	4	2	3	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	6	6	5	5	1	1
Dyspeptic signs and symptoms	1	1	1	1		
Gastrointestinal and abdominal pains (excl oral and throat)	6	6	6	6		
Gastrointestinal disorders NEC	1	1			1	1
Gastrointestinal dyskinetic disorders	1	1	1	1		
Nausea and vomiting symptoms	20	20	17	17	3	3
Oral soft tissue signs and symptoms	2	2	1	1	1	1
Oral soft tissue swelling and oedema	1	1	1	1		
Salivary gland enlargements	1	1	1	1		
	39	39	33	33	6	6

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	28	29	26	27	2	2
Febrile disorders	31	31	30	30	1	1
Feelings and sensations NEC	18	18	18	18		
General signs and symptoms NEC	3	3	3	3		
Inflamations	2	2	1	1	1	1
Mass conditions NEC	1	1	1	1		
Oedema NEC	8	8	8	8		
Pain and discomfort NEC	23	23	22	22	1	1
Therapeutic and nontherapeutic responses	11	11			11	11
Vaccination site reactions	54	55	53	54	1	1
	179	181	162	164	17	17

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	3	2	3		
Allergies to foods, food additives, drugs and other chemicals	3	3	3	3		
Anaphylactic and anaphylactoid responses	1	2			1	2
	6	8	5	6	1	2

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	10	10			10	10
Dental and oral soft tissue infections	1	1	1	1		
Lower respiratory tract and lung infections	3	3			3	3
	14	14	1	1	13	13

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1		
Medication errors, product use errors and issues NEC	2	2	2	2		
Off label uses	2	2	2	2		
Peripheral nerve injuries	1	1			1	1
Product administration errors and issues	1	1	1	1		
	7	7	6	6	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	1	1			1	1
Coagulation and bleeding analyses	1	1			1	1
Physical examination procedures and organ system status	4	4	4	4		
Vascular tests NEC (incl blood pressure)	1	1			1	1
Virus identification and serology	1	1			1	1
	8	8	4	4	4	4

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders	2	2	2	2
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	1	1			1	1
Joint related signs and symptoms	36	36	35	35	1	1
Muscle pains	33	33	32	32	1	1
Muscle related signs and symptoms NEC	2	3	2	2		1
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	4	4	4	4		
Musculoskeletal and connective tissue pain and discomfort	5	6	5	6		
	82	84	79	80	3	4

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Demyelinating disorders NEC	2	2			2	2
Disturbances in consciousness NEC	3	4	1	1	2	3
Dyskinesias and movement disorders NEC	1	1	1	1		
Encephalitis NEC		1				1
Headaches NEC	54	55	51	52	3	3
Lumbar spinal cord and nerve root disorders	1	1			1	1
Mononeuropathies	2	2			2	2
Myelitis (incl infective)		1				1
Nervous system disorders NEC	1	1			1	1
Neurological signs and symptoms NEC	19	19	18	18	1	1
Neuromuscular disorders NEC	2	2	1	1	1	1
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	13	14	8	8	5	6
Paralysis and paresis (excl cranial nerve)		1				1
Peripheral neuropathies NEC	4	4			4	4
Seizures and seizure disorders NEC	6	7			6	7
Sensory abnormalities NEC	5	5	4	4	1	1
Spinal cord and nerve root disorders NEC	2	2			2	2
	116	123	85	86	31	37

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Reproductive tract signs and symptoms NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	8	10	4	5	4	5
Bronchospasm and obstruction	1	1	1	1		
Coughing and associated symptoms	9	9	9	9		
Laryngeal spasm, oedema and obstruction		1		1		
Nasal congestion and inflammations		1		1		
Upper respiratory tract signs and symptoms	10	12	10	12		
	28	34	24	29	4	5

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	2			1	2
Apocrine and eccrine gland disorders	1	1	1	1		
Erythemas	2	2	2	2		
Pruritus NEC	4	5	3	4	1	1
Rashes, eruptions and exanthems NEC	14	15	12	12	2	3
Urticarias	1	1	1	1		
	23	26	19	20	4	6

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Disability issues	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	2	2			2	2
Peripheral vascular disorders NEC	1	2	1	2		
Vascular hypertensive disorders NEC	2	2	1	1	1	1
	5	6	2	3	3	3

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Country Where Event Occurred

**NETHERLANDS**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac signs and symptoms NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	1	1	1		
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1		
Gastrointestinal signs and symptoms NEC	1	1			1	1
Nausea and vomiting symptoms	3	3	3	3		
Oral soft tissue signs and symptoms	1	1	1	1		
Tongue signs and symptoms	1	1			1	1
	8	8	6	6	2	2

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	1			1	1
Feelings and sensations NEC	2	2	1	1	1	1
General signs and symptoms NEC	1	1	1	1		
Pain and discomfort NEC	2	2	1	1	1	1
Vaccination site reactions	1	1	1	1		
	7	7	4	4	3	3

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergies to foods, food additives, drugs and other chemicals	1	1	1	1
Anaphylactic and anaphylactoid responses	2	2	2	2
	3	3	3	3

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
Medication errors, product use errors and issues NEC	1	1	1	1
Product administration errors and issues	1	1	1	1
Product confusion errors and issues	1	1	1	1
Product preparation errors and issues	1	1	1	1
	5	5	5	5

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	2	2	2	2
	2	2	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Headaches NEC	4	4	4	4		
Neurological signs and symptoms NEC	3	3	1	1	2	2
Paraesthesias and dysaesthesias	1	1			1	1
	8	8	5	5	3	3

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anxiety symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	1			1	1
Coughing and associated symptoms	1	1	1	1		
Pharyngeal disorders (excl infections and neoplasms)	1	1			1	1
Upper respiratory tract signs and symptoms	2	2	2	2		
	5	5	3	3	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Erythemas	2	2	1	1	1	1
Pruritus NEC	1	1			1	1
Rashes, eruptions and exanthems NEC	2	2	1	1	1	1
Urticarias	2	2	1	1	1	1
	8	8	3	3	5	5

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1	1	1
	1	1	1	1

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Country Where Event Occurred  
**NORTHERN MARIANA ISLANDS**

*System Organ Class*

**General disorders and administration site conditions**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	1	1	1	1
Feelings and sensations NEC	1	1	1	1
Pain and discomfort NEC	1	1	1	1
	3	3	3	3

*System Organ Class*

**Musculoskeletal and connective tissue disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	2	2	2	2

*System Organ Class*

**Nervous system disorders**

<i>High Level Term</i>	<i>Interval Total # Spontaneous AE</i>	<i>Cumulative Total # Spontaneous AE</i>	Spontaneous	
			Nonserious	
			I	C
Headaches NEC	1	1	1	1
Neurological signs and symptoms NEC	1	1	1	1
Sleep disturbances NEC	1	1	1	1
	3	3	3	3

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Confusion and disorientation	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**NORWAY**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cardiac disorders NEC	2	2	2	2
Heart failures NEC	1	1	1	1
Ischaemic coronary artery disorders	2	2	2	2
	5	5	5	5

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eyelid movement disorders	1	1	1	1		
Pupil disorders	2	2			2	2
	3	3	1	1	2	2

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	2	2			2	2
Gastrointestinal signs and symptoms NEC	1	1			1	1
Nausea and vomiting symptoms	9	9	3	3	6	6
Non-site specific gastrointestinal haemorrhages	1	1			1	1
	13	13	3	3	10	10

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	9	9	4	4	5	5
Death and sudden death	11	11			11	11
Febrile disorders	6	6	2	2	4	4
Feelings and sensations NEC	3	3	2	2	1	1
General signs and symptoms NEC	13	13			13	13
Injection site reactions	1	1	1	1		
Pain and discomfort NEC	1	1			1	1
Vaccination site reactions	6	6	3	3	3	3
	50	50	12	12	38	38

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Allergic conditions NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Infections NEC	1	1			1	1
Lower respiratory tract and lung infections	3	3			3	3
Urinary tract infections	1	1	1	1		
	5	5	1	1	4	4

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC	1	1	1	1
Product administration errors and issues	8	8	8	8
Product preparation errors and issues	2	2	2	2
	11	11	11	11

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	3	3			3	3
Heart rate and pulse investigations	3	3	1	1	2	2
Physical examination procedures and organ system status	5	5	2	2	3	3
Vascular tests NEC (incl blood pressure)	3	3	1	1	2	2
	14	14	4	4	10	10

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Appetite disorders	3	3	3	3
	3	3	3	3

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	2	2	2	2

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	3	3			3	3
Coordination and balance disturbances	1	1			1	1
Disturbances in consciousness NEC	7	7			7	7
Headaches NEC	2	2	2	2		
Neurological signs and symptoms NEC	2	2	1	1	1	1
Paraesthesias and dysaesthesias	1	1			1	1
Tremor (excl congenital)	1	1			1	1
	17	17	3	3	14	14

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	6	6	6	6
	6	6	6	6

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	1	1	1	1		
Confusion and disorientation	3	3			3	3
Deliria	1	1			1	1
Hallucinations (excl sleep-related)	1	1			1	1
Increased physical activity levels	1	1	1	1		
Mood disorders NEC	1	1			1	1
	8	8	2	2	6	6

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	6	6	1	1	5	5
Coughing and associated symptoms	1	1			1	1
Lower respiratory tract signs and symptoms	1	1			1	1
	8	8	1	1	7	7

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Apocrine and eccrine gland disorders	3	3	3	3
	3	3	3	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Peripheral vascular disorders NEC	1	1	1	1		
Site specific vascular disorders NEC	2	2			2	2
Vascular hypotensive disorders	2	2			2	2
	6	6	1	1	5	5

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Country Where Event Occurred

**OMAN**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)		1		1
Gastritis (excl infective)		1		1
		2		2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions		1		1
Febrile disorders		1		1
Pain and discomfort NEC		1		1
		3		3

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Headaches NEC		1		1
		1		1

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Country Where Event Occurred

**POLAND**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	7	7	7	7
	7	7	7	7

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Rate and rhythm disorders NEC	3	3	3	3
	3	3	3	3

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ear disorders NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Conjunctival infections, irritations and inflammations	1	1	1	1
Iris and uveal tract infections, irritations and inflammations	1	1	1	1
Ocular disorders NEC	1	1	1	1
Visual disorders NEC	1	1	1	1
	4	4	4	4

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic pancreatitis	1	1			1	1
Dental pain and sensation disorders	1	2	1	2		
Diarrhoea (excl infective)	5	5	5	5		
Gastrointestinal and abdominal pains (excl oral and throat)	4	4	3	3	1	1
Nausea and vomiting symptoms	15	15	15	15		
Oral dryness and saliva altered	1	1	1	1		
Oral soft tissue signs and symptoms	2	2	1	1	1	1
	29	30	26	27	3	3

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	41	42	40	41	1	1
Febrile disorders	33	34	29	30	4	4
Feelings and sensations NEC	21	21	19	19	2	2
Gait disturbances	1	1	1	1		
General signs and symptoms NEC	10	10	8	8	2	2
Inflamations	2	2	2	2		
Oedema NEC	1	1	1	1		
Pain and discomfort NEC	8	8	7	7	1	1
Therapeutic and nontherapeutic responses	14	14	1	1	13	13
Vaccination site reactions	68	69	67	68	1	1
	199	202	175	178	24	24

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Allergic conditions NEC	2	2	2	2
	2	2	2	2

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	12	12			12	12
Dental and oral soft tissue infections		1		1		
Herpes viral infections	4	4	4	4		
Infections NEC	1	1	1	1		
Lower respiratory tract and lung infections	1	1			1	1
Upper respiratory tract infections	1	1	1	1		
Urinary tract infections	1	1	1	1		
	20	21	7	8	13	13

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	9	9	9	9		
Medication errors, product use errors and issues NEC	9	9	8	8	1	1
Off label uses	8	8	7	7	1	1
Product administration errors and issues	4	4	4	4		
Product confusion errors and issues	2	2	2	2		
	32	32	30	30	2	2

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System Organ Class

Investigations	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous				
			Nonserious		Serious		
			I	C	I	C	
High Level Term							
Blood gas and acid base analyses	1	1			1	1	
Heart rate and pulse investigations	2	2	1	1	1	1	
Physical examination procedures and organ system status	2	2	2	2			
Urinalysis NEC	1	1	1	1			
Vascular tests NEC (incl blood pressure)	3	3	2	2	1	1	
Virus identification and serology	1	1			1	1	
	10	10	6	6	4	4	

System Organ Class

Metabolism and nutrition disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
High Level Term				
Appetite disorders	2	2	2	2
	2	2	2	2

System Organ Class

Musculoskeletal and connective tissue disorders	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
High Level Term						
Arthropathies NEC		1		1		
Bone related signs and symptoms	5	5	4	4	1	1
Joint related signs and symptoms	20	21	19	20	1	1
Muscle pains	20	20	19	19	1	1
Musculoskeletal and connective tissue conditions NEC	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	22	23	19	20	3	3
	68	71	62	65	6	6

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coordination and balance disturbances	1	1	1	1		
Disturbances in consciousness NEC	3	3	3	3		
Headaches NEC	25	26	24	25	1	1
Migraine headaches	1	1	1	1		
Neurological signs and symptoms NEC	6	6	6	6		
Neurologic visual problems NEC	1	1	1	1		
Olfactory nerve disorders	3	3	3	3		
Paraesthesias and dysaesthesias	6	6	4	4	2	2
Paralysis and paresis (excl cranial nerve)	4	4	1	1	3	3
Sensory abnormalities NEC	6	6	6	6		
Sleep disturbances NEC	1	1	1	1		
Tremor (excl congenital)	2	2	2	2		
	59	60	53	54	6	6

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Device physical property and chemical issues	1	1	1	1
	1	1	1	1

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	2	2	2		
Disturbances in initiating and maintaining sleep	3	3	3	3		
Psychiatric symptoms NEC	1	1			1	1
	6	6	5	5	1	1

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast signs and symptoms	1	1	1	1		
Lactation disorders	2	2	1	1	1	1
	3	3	2	2	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breathing abnormalities	2	2	2	2
Coughing and associated symptoms	3	3	3	3
Nasal disorders NEC	2	2	2	2
Pharyngeal disorders (excl infections and neoplasms)	1	1	1	1
Respiratory signs and symptoms NEC	1	1	1	1
Upper respiratory tract signs and symptoms	6	6	6	6
	15	15	15	15

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1	1	1		
Dermal and epidermal conditions NEC	1	1	1	1		
Erythemas	1	1			1	1
Pruritus NEC	1	1	1	1		
Rashes, eruptions and exanthems NEC	3	3	3	3		
Urticarias	2	2	2	2		
	9	9	8	8	1	1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Haemorrhages NEC	1	1	1	1		
Peripheral vascular disorders NEC	3	3	2	2	1	1
Site specific vascular disorders NEC	2	2	1	1	1	1
	6	6	4	4	2	2

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Country Where Event Occurred

**PORTUGAL**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	8	8	5	5	3	3
	8	8	5	5	3	3

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	1	1	1	1		
Rate and rhythm disorders NEC	5	5	3	3	2	2
Supraventricular arrhythmias		1				1
Ventricular arrhythmias and cardiac arrest	1	1			1	1
	7	8	4	4	3	4

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Thyroid hypofunction disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lacrimation disorders	1	1	1	1		
Lid, lash and lacrimal infections, irritations and inflammations	1	1			1	1
Ocular disorders NEC	2	2	2	2		
Ocular infections, inflammations and associated manifestations	1	1	1	1		
Ocular nerve and muscle disorders	1	1			1	1
Ocular sensation disorders	1	1			1	1
Structural change, deposit and degeneration of eye NEC	1	1	1	1		
	8	8	5	5	3	3

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	2	2	2	2		
Dyspeptic signs and symptoms	2	2	2	2		
Gastrointestinal and abdominal pains (excl oral and throat)	2	2	1	1	1	1
Gastrointestinal disorders NEC	1	1			1	1
Gastrointestinal signs and symptoms NEC	4	4	2	2	2	2
Nausea and vomiting symptoms	14	15	8	8	6	7
Oral soft tissue disorders NEC	1	1			1	1
Oral soft tissue signs and symptoms	14	15	2	3	12	12
Oral soft tissue swelling and oedema	4	4			4	4
Stomatitis and ulceration	2	2	2	2		
Tongue disorders	1	1	1	1		
Tongue signs and symptoms	6	6			6	6
	53	55	20	21	33	34

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	14	15	11	11	3	4
Death and sudden death	2	2			2	2
Febrile disorders	12	12	8	8	4	4
Feelings and sensations NEC	8	8	4	4	4	4
Oedema NEC	5	5	2	2	3	3
Pain and discomfort NEC	5	5	2	2	3	3
Therapeutic and nontherapeutic responses	18	18			18	18
Vaccination site reactions	47	48	38	38	9	10
	111	113	65	65	46	48

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	6	7	4	4	2	3
Allergies to foods, food additives, drugs and other chemicals	2	2			2	2
Anaphylactic and anaphylactoid responses	1	1			1	1
	9	10	4	4	5	6

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	15	15	15	15
	15	15	15	15

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	4	5	4	5
Medication errors, product use errors and issues NEC	2	2	2	2
Off label uses	3	3	3	3
Overdoses NEC	4	4	4	4
Product administration errors and issues	3	3	3	3
Skin injuries NEC	1	1	1	1
	17	18	17	18

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	2	2	2	2		
Thyroid analyses	1	1	1	1		
Vascular tests NEC (incl blood pressure)	1	1			1	1
Virus identification and serology	4	4			4	4
	8	8	3	3	5	5

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	2	2	2	2		
Hyperglycaemic conditions NEC	1	1			1	1
	3	3	2	2	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	1			1	1
Joint related signs and symptoms	1	1	1	1		
Muscle pains	20	20	14	14	6	6
Muscle weakness conditions	1	1			1	1
Musculoskeletal and connective tissue pain and discomfort	2	2	1	1	1	1
Spondyloarthropathies	1	1			1	1
Tendon disorders	1	1	1	1		
	27	27	17	17	10	10

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coordination and balance disturbances	1	2			1	2
Disturbances in consciousness NEC	6	6	3	3	3	3
Facial cranial nerve disorders	1	1	1	1		
Generalised tonic-clonic seizures	1	1			1	1
Headaches NEC	19	20	14	15	5	5
Memory loss (excl dementia)	1	1	1	1		
Migraine headaches	4	4	1	1	3	3
Neurological signs and symptoms NEC	6	7	5	5	1	2
Paraesthesias and dysaesthesias	8	8	5	5	3	3
Sensory abnormalities NEC	6	6	4	4	2	2
Speech and language abnormalities	1	1	1	1		
Tremor (excl congenital)	2	2	2	2		
	56	59	37	38	19	21

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	1	1			1	1
Coughing and associated symptoms	4	4			4	4
Laryngeal spasm, oedema and obstruction	4	4			4	4
Pharyngeal disorders (excl infections and neoplasms)	4	4	1	1	3	3
Respiratory tract disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	11	11	3	3	8	8
	25	25	4	4	21	21

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	1	1			1	1
Apocrine and eccrine gland disorders	1	1			1	1
Dermatitis and eczema	1	1			1	1
Dermatitis ascribed to specific agent	1	1			1	1
Erythemas	7	8	3	3	4	5
Pruritus NEC	6	7	2	2	4	5
Rashes, eruptions and exanthems NEC	15	16	11	11	4	5
Urticarias	4	4	2	2	2	2
	36	39	18	18	18	21

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Non-site specific embolism and thrombosis	1	1			1	1
Peripheral vascular disorders NEC	2	2			2	2
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1			1	1
Site specific vascular disorders NEC	3	3	2	2	1	1
	7	7	2	2	5	5

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Country Where Event Occurred

**PUERTO RICO**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC		1		1		
Rate and rhythm disorders NEC		1		1		
Supraventricular arrhythmias	1	1			1	1
	1	3		2	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	2	1	2
Gastrointestinal and abdominal pains (excl oral and throat)		1		1
Gastrointestinal signs and symptoms NEC	1	1	1	1
Gingival haemorrhages	1	1	1	1
Nausea and vomiting symptoms		3		3
	3	8	3	8

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	5	8	5	8
Febrile disorders	5	7	5	7
Feelings and sensations NEC	4	4	4	4
Gait disturbances		1		1
General signs and symptoms NEC		1		1
Inflamations		1		1
Mass conditions NEC		1		1
Pain and discomfort NEC	2	4	2	4
Vaccination site reactions	4	10	4	10
	20	37	20	37

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
Off label uses	1	1	1	1
Product administration errors and issues	1	1	1	1
	3	3	3	3

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	1	1			1	1
Physical examination procedures and organ system status	1	1	1	1		
	2	2	1	1	1	1

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Appetite disorders		1		1
		1		1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone disorders NEC	1	1	1	1
Bone related signs and symptoms	1	1	1	1
Joint related signs and symptoms	1	4	1	4
Muscle pains	1	1	1	1
Muscle related signs and symptoms NEC	1	1	1	1
Musculoskeletal and connective tissue conditions NEC		1		1
Musculoskeletal and connective tissue pain and discomfort	3	7	3	7
	8	16	8	16

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dyskinesias and movement disorders NEC	2	2	1	1	1	1
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	5	9	5	9		
Migraine headaches	1	1			1	1
Neurological signs and symptoms NEC	1	1	1	1		
Paraesthesias and dysaesthesias	4	8	4	8		
Sensory abnormalities NEC		2		2		
Speech and language abnormalities		1		1		
	14	25	11	22	3	3

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Depressive disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Upper respiratory tract signs and symptoms		1		1
		1		1

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1			1	1
Erythemas	1	1	1	1		
Pruritus NEC	1	1	1	1		
Rashes, eruptions and exanthems NEC	1	1	1	1		
	4	4	3	3	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Haemorrhages NEC	1	1	1	1
Vascular hypertensive disorders NEC		1		1
	1	2	1	2

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Country Where Event Occurred

**QATAR**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea and vomiting symptoms		1		1
		1		1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Overdoses NEC	1	1	1	1
Product preparation errors and issues	1	1	1	1
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains		1		1
		1		1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological signs and symptoms NEC		1		1
		1		1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erythemas		1		1
		1		1

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Country Where Event Occurred

**ROMANIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	9	9	9	9
	9	9	9	9

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	2	2			2	2
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	5	5	2	2	3	3
Ventricular arrhythmias and cardiac arrest	1	1	1	1		
	9	9	3	3	6	6

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	2	2	2	2		
Inner ear disorders NEC	1	1	1	1		
Inner ear signs and symptoms	3	3	2	2	1	1
	6	6	5	5	1	1

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System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Glaucomas (excl congenital)	1	1			1	1
Lid, lash and lacrimal infections, irritations and inflammations	1	1	1	1		
	2	2	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	1	1	1		
Gastrointestinal signs and symptoms NEC	1	1			1	1
Nausea and vomiting symptoms	16	16	13	13	3	3
Oral dryness and saliva altered	1	1			1	1
Oral soft tissue signs and symptoms	2	2	2	2		
Oral soft tissue swelling and oedema	4	4	2	2	2	2
Tongue signs and symptoms	1	1			1	1
	26	26	18	18	8	8

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	33	33	30	30	3	3
Body temperature altered	1	1	1	1		
Febrile disorders	32	32	32	32		
Feelings and sensations NEC	26	27	21	22	5	5
General signs and symptoms NEC	1	2	1	2		
Inflamations	1	1	1	1		
Injection site reactions	3	3	3	3		
Oedema NEC	2	2	1	1	1	1
Pain and discomfort NEC	12	12	11	11	1	1
Therapeutic and nontherapeutic responses	19	19			19	19
Vaccination site reactions	80	82	80	82		
	210	214	181	185	29	29

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	2	2	2		
Allergies to foods, food additives, drugs and other chemicals	1	1	1	1		
Anaphylactic and anaphylactoid responses	3	3			3	3
	6	6	3	3	3	3

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	12	12	12	12
	12	12	12	12

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	2	2	2	2		
Medication errors, product use errors and issues NEC	21	22	21	22		
Off label uses	3	3	3	3		
Product administration errors and issues	3	3	3	3		
Product preparation errors and issues	12	17	12	17		
Site specific injuries NEC	1	1			1	1
Underdoses NEC	1	1	1	1		
	43	49	42	48	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Heart rate and pulse investigations	1	1	1	1		
Liver function analyses	1	1	1	1		
Physical examination procedures and organ system status	2	2	2	2		
Vascular tests NEC (incl blood pressure)	1	2	1	2		
Virus identification and serology	8	8	1	1	7	7
	13	14	6	7	7	7

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	1	1	1	1		
Calcium metabolism disorders	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone related signs and symptoms	1	1	1	1		
Joint related disorders NEC	1	1			1	1
Joint related signs and symptoms	14	14	12	12	2	2
Muscle pains	25	26	23	24	2	2
Muscle related signs and symptoms NEC	1	1	1	1		
Muscle weakness conditions	2	2	2	2		
Musculoskeletal and connective tissue pain and discomfort	23	29	22	28	1	1
	67	74	61	68	6	6

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Autonomic nervous system disorders	1	1			1	1
Coordination and balance disturbances	2	2	1	1	1	1
Disturbances in consciousness NEC	5	5	4	4	1	1
Facial cranial nerve disorders	3	3			3	3
Headaches NEC	31	32	28	29	3	3
Mental impairment (excl dementia and memory loss)	1	1	1	1		
Migraine headaches	2	2	1	1	1	1
Neurological signs and symptoms NEC	10	10	10	10		
Neuromuscular disorders NEC	1	1	1	1		
Olfactory nerve disorders	2	2	1	1	1	1
Paraesthesias and dysaesthesias	10	10	8	8	2	2
Seizures and seizure disorders NEC	1	1			1	1
Sensory abnormalities NEC	3	3	1	1	2	2
Tremor (excl congenital)	2	2	1	1	1	1
	74	75	57	58	17	17

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product quality issues NEC		1		1
		1		1

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	6	6	4	4	2	2
Disturbances in initiating and maintaining sleep	1	1	1	1		
Emotional and mood disturbances NEC	1	1	1	1		
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1		
Panic attacks and disorders	1	2	1	2		
	10	11	8	9	2	2

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breast signs and symptoms	1	1	1	1
Lactation disorders	1	1	1	1
	2	2	2	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	2	2			2	2
Coughing and associated symptoms	3	3	1	1	2	2
Laryngeal spasm, oedema and obstruction	2	2			2	2
Nasal disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	3	3	2	2	1	1
	11	11	3	3	8	8

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	4	4	3	3	1	1
Dermal and epidermal conditions NEC	2	2	2	2		
Erythemas	9	10	8	9	1	1
Panniculitides	1	1	1	1		
Pruritus NEC	5	5	4	4	1	1
Rashes, eruptions and exanthems NEC	10	10	8	8	2	2
Urticarias	3	4	3	4		
	34	36	29	31	5	5

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Peripheral vascular disorders NEC	1	1	1	1		
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1	1	1		
Vascular hypertensive disorders NEC	6	6			6	6
	9	9	2	2	7	7

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Country Where Event Occurred

**SAUDI ARABIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Gastrointestinal and abdominal pains (excl oral and throat)	1	1	1	1
Stomatitis and ulceration	1	1	1	1
	2	2	2	2

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Asthenic conditions	5	5	5	5
Febrile disorders	2	2	2	2
Feelings and sensations NEC	1	1	1	1
Pain and discomfort NEC	1	1	1	1
Vaccination site reactions	2	2	2	2
	11	11	11	11

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Female reproductive tract infections	1	1	1	1
Herpes viral infections	1	1	1	1
Upper respiratory tract infections	1	1	1	1
	3	3	3	3

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
Muscle pains	2	2	2	2
Musculoskeletal and connective tissue conditions NEC	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	1	1	1	1
	5	5	5	5

System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1			1	1
Dyskinesias and movement disorders NEC	1	1	1	1		
Headaches NEC	2	2	2	2		
Neurological signs and symptoms NEC	1	1	1	1		
	5	5	4	4	1	1

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System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Upper respiratory tract signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Apocrine and eccrine gland disorders	2	2	2	2
Dermal and epidermal conditions NEC	1	1	1	1
	3	3	3	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1	1	1		
Vascular hypotensive disorders	1	1			1	1
	2	2	1	1	1	1

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Country Where Event Occurred

**SERBIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Lymphatic system disorders NEC	2	2	1	1	1	1
	2	2	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	1	1	1	1		
Rate and rhythm disorders NEC	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Neurological disorders congenital NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lid, lash and lacrimal infections, irritations and inflammations	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Diarrhoea (excl infective)	1	1	1	1
Nausea and vomiting symptoms	8	8	8	8
Oral dryness and saliva altered	1	1	1	1
	10	10	10	10

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	11	11	11	11		
Febrile disorders	17	17	16	16	1	1
Feelings and sensations NEC	3	3	2	2	1	1
General signs and symptoms NEC	2	2	1	1	1	1
Pain and discomfort NEC	3	3	3	3		
Vaccination site reactions	16	16	15	15	1	1
	52	52	48	48	4	4

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	2	2	1	1	1	1
Anaphylactic and anaphylactoid responses	1	1			1	1
	3	3	1	1	2	2

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Infections NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Non-site specific injuries NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Chemistry analyses NEC	1	1	1	1		
Ophthalmic function diagnostic procedures	1	1			1	1
Physical examination procedures and organ system status	3	3	2	2	1	1
Vascular tests NEC (incl blood pressure)	1	1	1	1		
White blood cell analyses	1	1	1	1		
	7	7	5	5	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bone related signs and symptoms	3	3	3	3
Joint related signs and symptoms	3	3	3	3
Muscle pains	5	5	5	5
Muscle weakness conditions	2	2	2	2
Musculoskeletal and connective tissue pain and discomfort	4	4	4	4
	17	17	17	17

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC	4	4	4	4		
Neurological signs and symptoms NEC	1	1	1	1		
Olfactory nerve disorders	1	1	1	1		
Paraesthesias and dysaesthesias	1	1	1	1		
Sensory abnormalities NEC	1	1	1	1		
	9	9	8	8	1	1

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Anxiety symptoms	1	1	1	1
Confusion and disorientation	1	1	1	1
Fear symptoms and phobic disorders (incl social phobia)	1	1	1	1
Sleep disorders NEC	1	1	1	1
	4	4	4	4

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conditions associated with abnormal gas exchange	1	1			1	1
Coughing and associated symptoms	1	1			1	1
Upper respiratory tract signs and symptoms	1	1	1	1		
	3	3	1	1	2	2

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	2	2	2	2		
Dermal and epidermal conditions NEC	1	1			1	1
Erythemas	3	3	3	3		
Rashes, eruptions and exanthems NEC	3	3	1	1	2	2
Urticarias	1	1	1	1		
	10	10	7	7	3	3

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Phlebitis NEC	1	1			1	1
Vascular hypertensive disorders NEC	2	2	1	1	1	1
	3	3	1	1	2	2

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Country Where Event Occurred

**SINGAPORE**

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Febrile disorders	1	1	1	1
Feelings and sensations NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	5	5	5	5
	5	5	5	5

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Urticarias	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**SLOVAKIA**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Cardiac signs and symptoms NEC	1	1	1	1
Rate and rhythm disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Visual disorders NEC	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Nausea and vomiting symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	2	2	2	2		
Febrile disorders	4	4	4	4		
Feelings and sensations NEC	7	7	6	6	1	1
Therapeutic and nontherapeutic responses	6	6			6	6
Vaccination site reactions	9	9	7	7	2	2
	28	28	19	19	9	9

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	3	3			3	3
Upper respiratory tract infections	1	1	1	1		
	4	4	1	1	3	3

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Exposures associated with pregnancy, delivery and lactation	1	1	1	1
Product administration errors and issues	1	1	1	1
	2	2	2	2

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	2	2	1	1	1	1
Vascular tests NEC (incl blood pressure)	1	1	1	1		
Virus identification and serology	4	4			4	4
	7	7	2	2	5	5

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	5	5	5	5
	6	6	6	6

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1			1	1
Headaches NEC	5	5	4	4	1	1
Neurological signs and symptoms NEC	2	2	2	2		
Paraesthesias and dysaesthesias	3	3	2	2	1	1
	11	11	8	8	3	3

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Breathing abnormalities	1	1	1	1
Coughing and associated symptoms	2	2	2	2
Upper respiratory tract signs and symptoms	3	3	3	3
	6	6	6	6

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Apocrine and eccrine gland disorders	1	1	1	1		
Erythemas	1	1			1	1
Pruritus NEC	1	1			1	1
Rashes, eruptions and exanthems NEC	2	2	2	2		
	5	5	3	3	2	2

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Vascular hypertensive disorders NEC	2	2	2	2
	2	2	2	2

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Country Where Event Occurred

**SLOVENIA**

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Ischaemic coronary artery disorders	1	1	1	1
	1	1	1	1

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Nausea and vomiting symptoms	2	2	2	2
	2	2	2	2

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC	1	1	1	1		
Asthenic conditions	3	3	3	3		
Death and sudden death	1	1			1	1
General signs and symptoms NEC	1	1			1	1
Vaccination site reactions	2	2	2	2		
	8	8	6	6	2	2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
White blood cell analyses	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Vascular hypertensive disorders NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**SPAIN**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	2	2	2	2
	2	2	2	2

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac signs and symptoms NEC	4	4	2	2	2	2
Heart failures NEC	1	1			1	1
Rate and rhythm disorders NEC	2	2	1	1	1	1
	7	7	3	3	4	4

System Organ Class

**Eye disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Ocular disorders NEC	1	1	1	1
Ocular infections, inflammations and associated manifestations	1	1	1	1
	2	2	2	2

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	15	16	14	15	1	1
Flatulence, bloating and distension	1	1			1	1
Gastrointestinal and abdominal pains (excl oral and throat)	4	4	3	3	1	1
Gastrointestinal signs and symptoms NEC	2	2	1	1	1	1
Gastrointestinal vascular occlusion and infarction	1	1			1	1
Intestinal haemorrhages	1	1			1	1
Nausea and vomiting symptoms	19	20	16	17	3	3
Oral dryness and saliva altered	2	2	1	1	1	1
Oral soft tissue infections	1	1	1	1		
Oral soft tissue signs and symptoms	4	4	4	4		
Oral soft tissue swelling and oedema	2	2	1	1	1	1
Stomatitis and ulceration	4	4	3	3	1	1
Tongue disorders	2	2	1	1	1	1
Tongue signs and symptoms	5	5	4	4	1	1
	63	65	49	51	14	14

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System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	25	25	20	20	5	5
Body temperature altered	2	2	2	2		
Death and sudden death	4	4			4	4
Febrile disorders	45	45	42	42	3	3
Feelings and sensations NEC	12	12	11	11	1	1
General signs and symptoms NEC	4	4	2	2	2	2
Interactions	1	1	1	1		
Oedema NEC	1	1			1	1
Pain and discomfort NEC	11	11	8	8	3	3
Therapeutic and nontherapeutic responses	7	7			7	7
Vaccination site reactions	41	41	39	39	2	2
	153	153	125	125	28	28

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	1	1			1	1
Anaphylactic and anaphylactoid responses	4	5			4	5
Immune and associated conditions NEC	1	1	1	1		
	6	7	1	1	5	6

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coronavirus infections	6	6			6	6
Lower respiratory tract and lung infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	1			1	1
Upper respiratory tract infections	2	2	2	2		
Urinary tract infections	1	1	1	1		
	11	11	3	3	8	8

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Exposures associated with pregnancy, delivery and lactation	2	2	2	2		
Medication errors, product use errors and issues NEC	3	3	3	3		
Off label uses	2	2	2	2		
Overdoses NEC	1	1	1	1		
Product administration errors and issues	3	3	3	3		
Underdoses NEC	1	1	1	1		
Vaccination related complications	2	2	1	1	1	1
	14	14	13	13	1	1

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Physical examination procedures and organ system status	1	1	1	1		
Skeletal and cardiac muscle analyses	1	1			1	1
Vascular tests NEC (incl blood pressure)	1	1			1	1
Virus identification and serology	2	2	1	1	1	1
	5	5	2	2	3	3

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Hyperglycaemic conditions NEC	2	2	2	2
	2	2	2	2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone disorders NEC	1	1	1	1		
Joint related disorders NEC	1	1	1	1		
Joint related signs and symptoms	7	7	5	5	2	2
Muscle pains	14	14	14	14		
Muscle related signs and symptoms NEC	2	2	1	1	1	1
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue conditions NEC	4	4	2	2	2	2
Musculoskeletal and connective tissue pain and discomfort	10	10	7	7	3	3
	40	40	32	32	8	8

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coordination and balance disturbances	1	1	1	1		
Disturbances in consciousness NEC	5	5	4	4	1	1
Dyskinesias and movement disorders NEC	2	2	2	2		
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	35	35	30	30	5	5
Migraine headaches	2	2	1	1	1	1
Neurological signs and symptoms NEC	13	13	9	9	4	4
Neuromuscular disorders NEC	1	1	1	1		
Paraesthesias and dysaesthesias	11	11	11	11		
Sensory abnormalities NEC	4	4	3	3	1	1
Speech and language abnormalities	2	2	1	1	1	1
	77	77	63	63	14	14

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anxiety symptoms	2	2	2	2		
Confusion and disorientation	1	1			1	1
Emotional and mood disturbances NEC	1	1	1	1		
Mood alterations with depressive symptoms	2	2	2	2		
Stereotypies and automatisms	1	1	1	1		
	7	7	6	6	1	1

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Reproductive tract signs and symptoms NEC	1	1	1	1
Vulvovaginal disorders NEC	1	1	1	1
	2	2	2	2

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	9	9			9	9
Conditions associated with abnormal gas exchange	1	1			1	1
Coughing and associated symptoms	2	2	2	2		
Laryngeal spasm, oedema and obstruction	2	2			2	2
Nasal congestion and inflammations	2	2	2	2		
Respiratory failures (excl neonatal)	4	4			4	4
Respiratory tract disorders NEC	1	1			1	1
Upper respiratory tract signs and symptoms	7	7	7	7		
	28	28	11	11	17	17

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Angioedemas	2	2	1	1	1	1
Apocrine and eccrine gland disorders	1	1	1	1		
Dermal and epidermal conditions NEC	1	1	1	1		
Erythemas	3	3	3	3		
Pruritus NEC	6	6	4	4	2	2
Purpura and related conditions	1	1	1	1		
Rashes, eruptions and exanthems NEC	8	8	7	7	1	1
Urticarias	2	2	1	1	1	1
	24	24	19	19	5	5

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1			1	1
Vascular hypotensive disorders	4	4	2	2	2	2
	5	5	2	2	3	3

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Country Where Event Occurred

**SWEDEN**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	1	1			1	1
Cardiac signs and symptoms NEC	3	3	3	3		
Heart failures NEC	1	1			1	1
Ischaemic coronary artery disorders	1	1			1	1
Rate and rhythm disorders NEC	1	1			1	1
Ventricular arrhythmias and cardiac arrest	3	4			3	4
	10	11	3	3	7	8

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Inner ear signs and symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	6	6	4	4	2	2
Gastrointestinal and abdominal pains (excl oral and throat)	3	3	3	3		
Gastrointestinal signs and symptoms NEC	1	1	1	1		
Nausea and vomiting symptoms	10	10	9	9	1	1
Oral soft tissue signs and symptoms	3	3	2	2	1	1
Oral soft tissue swelling and oedema	1	1			1	1
Tongue signs and symptoms	1	1			1	1
	25	25	19	19	6	6

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	13	13	10	10	3	3
Death and sudden death	13	13			13	13
Febrile disorders	17	17	11	11	6	6
Feelings and sensations NEC	13	13	11	11	2	2
General signs and symptoms NEC	9	9	5	5	4	4
Inflammations	1	1			1	1
Injection site reactions	1	1	1	1		
Pain and discomfort NEC	4	4	3	3	1	1
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	19	19	15	15	4	4
	91	91	56	56	35	35

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System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	2	2	2	2
	2	2	2	2

System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bacterial infections NEC	1	1			1	1
Coronavirus infections	1	1			1	1
Escherichia infections	1	1			1	1
Infections NEC	3	3			3	3
Lower respiratory tract and lung infections	1	1			1	1
Sepsis, bacteraemia, viraemia and fungaemia NEC	3	3			3	3
Streptococcal infections	1	1			1	1
Upper respiratory tract infections	2	2	1	1	1	1
Urinary tract infections	1	1			1	1
Viral infections NEC	1	1	1	1		
	15	15	2	2	13	13

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC	29	29	29	29
Product administration errors and issues	36	36	36	36
Underdoses NEC	2	2	2	2
	67	67	67	67

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System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	2	2	2	2		
Heart rate and pulse investigations	2	2			2	2
Physical examination procedures and organ system status	1	1			1	1
Protein analyses NEC	1	1			1	1
Vascular tests NEC (incl blood pressure)	3	3	2	2	1	1
	9	9	4	4	5	5

System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Total fluid volume decreased	1	1	1	1
	1	1	1	1

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Joint related signs and symptoms	5	5	4	4	1	1
Muscle pains	11	11	8	8	3	3
Muscle weakness conditions	1	1	1	1		
Musculoskeletal and connective tissue pain and discomfort	12	12	12	12		
	29	29	25	25	4	4

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Central nervous system haemorrhages and cerebrovascular accidents	3	3			3	3
Coordination and balance disturbances	1	1	1	1		
Disturbances in consciousness NEC	2	2			2	2
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	14	14	13	13	1	1
Memory loss (excl dementia)	1	1			1	1
Migraine headaches	2	2	2	2		
Neurological signs and symptoms NEC	3	3	2	2	1	1
Paraesthesias and dysaesthesias	6	6	4	4	2	2
	33	33	22	22	11	11

System Organ Class

**Product issues**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product physical issues	36	36	36	36
	36	36	36	36

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal behaviour NEC	1	1	1	1		
Anxiety symptoms	1	1			1	1
Confusion and disorientation	1	1			1	1
Disturbances in initiating and maintaining sleep	2	2	2	2		
Hallucinations (excl sleep-related)	1	1			1	1
Parasomnias	1	1			1	1
	7	7	3	3	4	4

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Renal failure and impairment	1	1	1	1
	1	1	1	1

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	10	10	1	1	9	9
Bronchospasm and obstruction	3	3	1	1	2	2
Coughing and associated symptoms	5	5	1	1	4	4
Nasal disorders NEC	1	1	1	1		
Pharyngeal disorders (excl infections and neoplasms)	2	2	1	1	1	1
Pulmonary oedemas	2	2			2	2
Upper respiratory tract signs and symptoms	6	6	3	3	3	3
	29	29	8	8	21	21

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dermatitis and eczema	1	1	1	1		
Erythemas	1	1	1	1		
Pruritus NEC	1	1			1	1
Skin and subcutaneous tissue ulcerations	1	1			1	1
Urticarias	1	1	1	1		
	5	5	3	3	2	2

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood pressure disorders NEC	1	1			1	1
Circulatory collapse and shock	1	1			1	1
Peripheral vasoconstriction, necrosis and vascular insufficiency	1	1	1	1		
Vascular hypertensive disorders NEC	1	1			1	1
Vascular hypotensive disorders	2	2			2	2
	6	6	1	1	5	5

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Country Where Event Occurred

**SWITZERLAND**

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Gastrointestinal and abdominal pains (excl oral and throat)	2	2	2	2
Gastrointestinal disorders NEC	1	1	1	1
Intestinal haemorrhages	1	1	1	1
Nausea and vomiting symptoms	1	1	1	1
	5	5	5	5

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	4	4	4	4		
Death and sudden death	3	3			3	3
Febrile disorders	1	1	1	1		
Feelings and sensations NEC	2	2	2	2		
General signs and symptoms NEC	2	2			2	2
Vaccination site reactions	3	3	3	3		
	15	15	10	10	5	5

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Anaphylactic and anaphylactoid responses	1	1	1	1
	1	1	1	1

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Lower respiratory tract and lung infections	1	1	1	1
	1	1	1	1

System Organ Class

**Investigations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Blood gas and acid base analyses	1	1			1	1
Heart rate and pulse investigations	2	2	1	1	1	1
Protein analyses NEC	1	1			1	1
Vascular tests NEC (incl blood pressure)	2	2	1	1	1	1
	6	6	2	2	4	4

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Muscle pains	1	1	1	1
Musculoskeletal and connective tissue pain and discomfort	2	2	2	2
	3	3	3	3

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Coma states	1	1			1	1
Disturbances in consciousness NEC	1	1			1	1
Neurological signs and symptoms NEC	1	1	1	1		
Sensory abnormalities NEC	1	1	1	1		
	4	4	2	2	2	2

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Increased physical activity levels	1	1	1	1
	1	1	1	1

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Bladder and urethral symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Breathing abnormalities	1	1	1	1
Respiratory failures (excl neonatal)	1	1	1	1
	2	2	2	2

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Dermal and epidermal conditions NEC	1	1	1	1
	1	1	1	1

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Country Where Event Occurred

**UNITED ARAB EMIRATES**

System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Hearing losses	1	1	1	1
	1	1	1	1

System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Diarrhoea (excl infective)	1	1	1	1		
Nausea and vomiting symptoms	1	1			1	1
	2	2	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Asthenic conditions	1	1	1	1		
Febrile disorders	2	2	2	2		
Pain and discomfort NEC	1	1			1	1
Therapeutic and nontherapeutic responses	1	1			1	1
Vaccination site reactions	2	2	2	2		
	7	7	5	5	2	2

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System Organ Class

**Infections and infestations**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coronavirus infections	1	1	1	1
	1	1	1	1

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Medication errors, product use errors and issues NEC		1		1
Off label uses		1		1
		2		2

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
	1	1	1	1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disturbances in consciousness NEC	1	1			1	1
Facial cranial nerve disorders	1	1			1	1
Headaches NEC	2	2	1	1	1	1
Neurological signs and symptoms NEC	1	1			1	1
Paraesthesias and dysaesthesias	1	1			1	1
	6	6	1	1	5	5

System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Mood alterations with depressive symptoms	1	1	1	1
	1	1	1	1

System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Erection and ejaculation conditions and disorders	1	1	1	1
	1	1	1	1

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Vascular hypertensive disorders NEC	2	2	1	1	1	1
	2	2	1	1	1	1

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Country Where Event Occurred

**UNITED KINGDOM**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Eosinophilic disorders	1	1	1	1		
Haematological disorders	1	1			1	1
Lymphatic system disorders NEC	340	399	156	192	184	207
Marrow depression and hypoplastic anaemias	1	1			1	1
Thrombocytopenias	6	6			6	6
Thrombocytoses	1	1			1	1
	350	409	157	193	193	216

System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac conduction disorders	1	1	1	1		
Cardiac disorders NEC	2	2			2	2
Cardiac signs and symptoms NEC	71	88	19	29	52	59
Coronary artery disorders NEC	2	2			2	2
Heart failures NEC	4	4			4	4
Ischaemic coronary artery disorders	20	23			20	23
Myocardial disorders NEC	1	1	1	1		
Noninfectious myocarditis	4	4			4	4
Noninfectious pericarditis	2	2			2	2
Rate and rhythm disorders NEC	98	125	19	35	79	90
Supraventricular arrhythmias	25	33	3	5	22	28
Ventricular arrhythmias and cardiac arrest	24	28	1	1	23	27
	254	313	44	72	210	241

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	40	45	20	21	20	24
External ear disorders NEC	1	1			1	1
Hearing losses	7	8	2	2	5	6
Hyperacusia	2	3		1	2	2
Inner ear signs and symptoms	66	81	19	27	47	54
Middle ear infections and inflammations	1	1			1	1
	117	139	41	51	76	88

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Amblyopic vision impairment	1	1	1	1		
Choroid and vitreous structural change, deposit and degeneration	1	2	1	2		
Conjunctival and corneal bleeding and vascular disorders	3	4			3	4
Eyelid movement disorders	3	4		1	3	3
Iris and uveal tract infections, irritations and inflammations	2	2			2	2
Lacrimation disorders	18	19	5	6	13	13
Lid, lash and lacrimal infections, irritations and inflammations	9	12	3	5	6	7
Lid, lash and lacrimal structural disorders	1	1			1	1
Ocular disorders NEC	86	98	24	32	62	66
Ocular infections, inflammations and associated manifestations	34	38	7	8	27	30
Ocular nerve and muscle disorders	3	3			3	3
Ocular sensation disorders	29	37	7	10	22	27
Pupil disorders	4	4			4	4
Retinal structural change, deposit and degeneration	1	2			1	2
Scleral infections, irritations and inflammations	1	1	1	1		
Visual disorders NEC	57	68	23	30	34	38
Visual impairment and blindness (excl colour blindness)	20	21	4	4	16	17
	273	317	76	100	197	217

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System Organ Class

**Gastrointestinal disorders**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

		Non Interventional Study		Spontaneous				
		Serious		Nonserious		Serious		
		I	C	I	C	I	C	
Benign oral cavity neoplasms	1	1			1	1		
Colitis (excl infective)	1	1					1	1
Dental pain and sensation disorders	5	5			2	2	3	3
Diarrhoea (excl infective)	203	252			59	87	144	165
Duodenal and small intestinal stenosis and obstruction	1	1					1	1
Dyspeptic signs and symptoms	13	13			5	5	8	8
Faecal abnormalities NEC	3	6			1	4	2	2
Flatulence, bloating and distension	9	11			3	4	6	7
Gastritis (excl infective)	2	3				1	2	2
Gastrointestinal and abdominal pains (excl oral and throat)	126	152			44	62	82	90
Gastrointestinal atonic and hypomotility disorders NEC	8	8			2	2	6	6
Gastrointestinal disorders NEC	3	3			2	2	1	1
Gastrointestinal inflammatory disorders NEC		1				1		
Gastrointestinal mucosal dystrophies and secretion disorders	1	1			1	1		
Gastrointestinal signs and symptoms NEC	39	43			10	13	29	30
Gastrointestinal spastic and hypermotility disorders	8	11			1	3	7	8
Gingival disorders, signs and symptoms NEC	8	9			3	4	5	5
Gingival haemorrhages	3	3			1	1	2	2
Intestinal haemorrhages	2	3					2	3
Nausea and vomiting symptoms	960	1,141	4	4	297	424	663	717
Non-site specific gastrointestinal haemorrhages	11	12					11	12
Oral dryness and saliva altered	32	47			11	22	21	25
Oral soft tissue disorders NEC	5	8			2	4	3	4
Oral soft tissue haemorrhages	1	1					1	1
Oral soft tissue signs and symptoms	129	177			61	92	68	85
Oral soft tissue swelling and oedema	38	54			9	18	29	36
Peritoneal and retroperitoneal fibrosis and adhesions	1	1					1	1

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Rectal inflammations NEC	1	1					1	1
Salivary gland disorders NEC	1	1					1	1
Salivary gland enlargements	2	2			2	2		
Stomatitis and ulceration	15	20			6	11	9	9
Tongue disorders	6	6			2	2	4	4
Tongue signs and symptoms	55	68			16	23	39	45
	1,693	2,066	4	4	541	791	1152	1275

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adverse effect absent	3	3			3	3		
Asthenic conditions	1,501	1,745	5	5	510	663	991	1082
Body temperature altered	9	9					9	9
Complications associated with device NEC		1				1		
Death and sudden death	62	62					62	62
Febrile disorders	1,024	1,157	3	3	294	374	730	783
Feelings and sensations NEC	1,016	1,169	2	2	354	462	662	707
Gait disturbances	28	31			9	11	19	20
General signs and symptoms NEC	486	542			163	198	323	344
Inflammations	15	15			5	5	10	10
Injection site reactions	9	11			6	7	3	4
Interactions		1						1
Mass conditions NEC	2	3			1	2	1	1
Oedema NEC	5	5			1	1	4	4
Pain and discomfort NEC	666	763			239	299	427	464
Therapeutic and nontherapeutic responses	231	251			2	2	229	249
Vaccination site reactions	1,039	1,285	5	5	468	650	571	635
	6,096	7,053	15	15	2055	2678	4041	4375

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Cholestasis and jaundice	1	1	1	1
Hepatic vascular disorders	1	1	1	1
Hepatobiliary signs and symptoms	1	1	1	1
Hepatocellular damage and hepatitis NEC	2	2	2	2
Obstructive bile duct disorders (excl neoplasms)	1	1	1	1
	6	6	6	6

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	43	59	10	17	33	42
Allergies to foods, food additives, drugs and other chemicals	16	23	5	11	11	12
Anaphylactic and anaphylactoid responses	66	75			66	75
Atopic disorders	1	1	1	1		
Immune and associated conditions NEC	1	2		1	1	1
	127	160	16	30	111	130

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	2	3		1	2	2
Bacterial infections NEC	23	27	1	2	22	25
Breast infections	3	3			3	3
Candida infections	4	4	2	2	2	2
Central nervous system and spinal infections	1	1			1	1
Clostridia infections	1	1			1	1
Coronavirus infections	224	238	1	1	223	237
Coxiella infections	1	1			1	1
Dental and oral soft tissue infections	3	3	1	1	2	2
Ear infections	6	7	2	2	4	5
Eye and eyelid infections	6	6	1	1	5	5
Hepatobiliary and spleen infections	2	2			2	2
Herpes viral infections	26	33	10	14	16	19
Infections NEC	12	13		1	12	12
Influenza viral infections	44	48	15	19	29	29
Lower respiratory tract and lung infections	16	19			16	19
Sepsis, bacteraemia, viraemia and fungaemia NEC	6	6			6	6
Skin structures and soft tissue infections	3	4		1	3	3
Staphylococcal infections	1	1	1	1		
Streptococcal infections	2	2			2	2
Trypanosomal infections	1	1			1	1
Upper respiratory tract infections	44	52	18	24	26	28
Urinary tract infections	7	7			7	7
Viral infections NEC	23	25	4	4	19	21
	461	507	56	74	405	433

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bone and joint injuries NEC	1	1	1	1		
Conditions caused by cold	1	1			1	1
Exposures associated with pregnancy, delivery and lactation	11	12	9	10	2	2
Exposures to agents or circumstances NEC	1	1			1	1
Eye injuries NEC	5	5	1	1	4	4
Gastrointestinal and hepatobiliary procedural complications	2	2			2	2
Heat injuries (excl thermal burns)	3	3	2	2	1	1
Limb fractures and dislocations	2	2			2	2
Medication errors, product use errors and issues NEC	41	54	38	51	3	3
Muscle, tendon and ligament injuries	4	4			4	4
Neurological and psychiatric procedural complications	1	1			1	1
Non-site specific injuries NEC	26	26	6	6	20	20
Non-site specific procedural complications	2	3	1	1	1	2
Occupational exposures	1	2	1	2		
Off label uses	46	57	43	54	3	3
Overdoses NEC	4	6	4	6		
Poisoning and toxicity	1	1			1	1
Product administration errors and issues	45	65	42	61	3	4
Product confusion errors and issues		1		1		
Product preparation errors and issues	2	5	2	5		
Site specific injuries NEC	10	10	5	5	5	5
Skin injuries NEC	16	18	4	5	12	13
Stoma complications	1	4		1	1	3
Underdoses NEC	1	5	1	5		
Vaccination related complications	3	4	1	2	2	2
	230	293	161	219	69	74

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Adrenal cortex tests	1	1					1	1
Blood gas and acid base analyses	17	22			2	3	15	19
Carbohydrate tolerance analyses (incl diabetes)	12	12			2	2	10	10
Chemistry analyses NEC	1	1					1	1
Coagulation and bleeding analyses	5	5					5	5
ECG investigations	2	2					2	2
Haematological analyses NEC	1	1					1	1
Heart rate and pulse investigations	69	79			22	28	47	51
Immunology analyses NEC	1	1			1	1		
Investigations NEC	1	2					1	2
Liver function analyses	9	9			3	3	6	6
Metabolism tests NEC	1	1					1	1
Microbiology and serology tests NEC	1	1					1	1
Mineral and electrolyte analyses	2	2			1	1	1	1
Neurologic diagnostic procedures	2	3					2	3
Ophthalmic function diagnostic procedures	1	1					1	1
Physical examination procedures and organ system status	79	90	1	1	23	31	56	59
Protein analyses NEC	2	2			1	1	1	1
Red blood cell analyses	2	2			1	1	1	1
Renal function analyses	1	1			1	1		
Skeletal and cardiac muscle analyses	3	3			1	1	2	2
Therapeutic drug monitoring analyses	1	1					1	1
Thyroid analyses	1	1					1	1
Tissue enzyme analyses NEC	2	2			1	1	1	1
Urinalysis NEC	2	2			2	2		
Urinary tract function analyses NEC	1	1					1	1
Vascular tests NEC (incl blood pressure)	41	58			19	28	22	30
Virus identification and serology	15	21			3	3	12	18
Water and electrolyte analyses NEC	1	1			1	1		
White blood cell analyses	1	1					1	1
	278	329	1	1	84	108	194	221

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	106	116	27	30	79	86
Diabetes mellitus (incl subtypes)	1	2			1	2
Diabetic complications NEC	3	4			3	4
Disorders of purine metabolism	2	2			2	2
Fluid intake decreased	2	2			2	2
General nutritional disorders NEC	7	7	5	5	2	2
Hyperglycaemic conditions NEC	6	8		1	6	7
Hypoglycaemic conditions NEC	6	8	1	2	5	6
Mixed acid-base disorders	2	2	1	1	1	1
Sodium imbalance	2	2			2	2
Total fluid volume decreased	15	16	7	8	8	8
Total fluid volume increased		1		1		
	152	170	41	48	111	122

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Arthropathies NEC	10	11			1	2	9	9
Bone disorders NEC	1	1			1	1		
Bone related signs and symptoms	43	49			19	24	24	25
Cartilage disorders	2	2					2	2
Connective tissue disorders NEC	1	2					1	2
Joint related disorders NEC	5	5			3	3	2	2
Joint related signs and symptoms	532	600	1	1	152	195	380	405
Ligament disorders	1	1					1	1
Lupus erythematosus (incl subtypes)	1	1					1	1
Muscle pains	694	805	3	3	210	285	484	520
Muscle related signs and symptoms NEC	52	64			19	25	33	39
Muscle tone abnormalities	6	6					6	6
Muscle weakness conditions	51	60			12	19	39	41
Musculoskeletal and connective tissue conditions NEC	93	106			34	41	59	65
Musculoskeletal and connective tissue pain and discomfort	808	961	3	3	314	425	494	536
Myopathies	3	3					3	3
Osteoarthropathies	1	1			1	1		
Psoriatic arthropathies	1	1					1	1
Rheumatoid arthropathies	2	2					2	2
Soft tissue disorders NEC	19	21			11	13	8	8
Spondyloarthropathies	2	3					2	3
Synovial disorders	2	2			1	1	1	1
Tendon disorders	1	1					1	1
	2,331	2,708	7	7	778	1035	1553	1673

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Leukaemias NEC	1	1	1	1
Skin neoplasms malignant and unspecified (excl melanoma)	1	1	1	1
	2	2	2	2

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Abnormal reflexes	2	2					2	2
Absence seizures	2	2					2	2
Acute polyneuropathies	1	1					1	1
Autonomic nervous system disorders	1	1					1	1
Central nervous system haemorrhages and cerebrovascular accidents	36	42					36	42
Cerebrovascular venous and sinus thrombosis	1	1					1	1
Coordination and balance disturbances	28	32	1	1	8	9	20	23
Cortical dysfunction NEC	4	4					4	4
Dementia (excl Alzheimer's type)	2	2					2	2
Disturbances in consciousness NEC	329	369			72	86	257	283
Dyskinesias and movement disorders NEC	15	15			4	4	11	11
Dystonias	2	2					2	2
Encephalopathies NEC	1	1					1	1
Facial cranial nerve disorders	40	45			2	5	38	40
Generalised tonic-clonic seizures	4	6					4	6
Headaches NEC	1,394	1,607	5	5	457	596	937	1011
Increased intracranial pressure disorders	1	1					1	1
Lumbar spinal cord and nerve root disorders	2	2					2	2
Memory loss (excl dementia)	5	6			2	3	3	3
Mental impairment (excl dementia and memory loss)	24	28			6	8	18	20
Migraine headaches	119	128			37	43	82	85
Mononeuropathies	2	2					2	2
Multiple sclerosis acute and progressive	4	4					4	4
Muscle tone abnormal	5	5					5	5
Narcolepsy and hypersomnia	13	16			3	5	10	11
Neurological signs and symptoms NEC	505	611	1	1	176	240	329	371
Neurologic visual problems NEC	3	3			1	1	2	2
Neuromuscular disorders NEC	2	2			1	1	1	1
Olfactory nerve disorders	25	27			12	14	13	13
Optic nerve disorders NEC	1	1					1	1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Non Interventional Study		Spontaneous			
			Serious		Nonserious		Serious	
			I	C	I	C	I	C
Paraesthesias and dysaesthesias	239	295			88	130	151	165
Paralysis and paresis (excl cranial nerve)	22	24			1	1	21	23
Peripheral neuropathies NEC	3	3					3	3
Seizures and seizure disorders NEC	25	26					25	26
Sensory abnormalities NEC	111	143			58	82	53	61
Sleep disturbances NEC	11	12			3	4	8	8
Speech and language abnormalities	14	14					14	14
Spinal cord and nerve root disorders NEC	1	1					1	1
Transient cerebrovascular events	5	6					5	6
Tremor (excl congenital)	99	115			26	33	73	82
Trigeminal disorders	2	2			1	1	1	1
	3,105	3,609	7	7	958	1266	2147	2343

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Abortions spontaneous	2	2	2	2
Maternal complications of pregnancy NEC	1	1	1	1
	3	3	3	3

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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product distribution and storage issues	3	3	3	3
Product packaging issues		4		4
Product physical issues		2		2
	3	9	3	9

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System Organ Class

**Psychiatric disorders**

High Level Term

Interval Total #  
Spontaneous AE      Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
17	24	30	36
		2	2
3	3	4	4
		1	1
8	12	39	43
		15	15
		1	1
		3	4
2	3	1	1
39	44	47	49
		1	1
5	5	6	6
3	3	1	2
		25	26
7	10	4	8
	1		
1	2	5	5
		2	2
		2	2
		1	1
		4	4
8	13	8	8
		1	1
1	1	2	2
		1	1
18	22	18	18
		1	2
1	1		
		1	1
		2	2

Anxiety symptoms	47	60
Behaviour and socialisation disturbances	2	2
Cognitive and attention disorders and disturbances NEC	7	7
Communications disorders	1	1
Confusion and disorientation	47	55
Deliria	15	15
Delusional symptoms	1	1
Depressive disorders	3	4
Dissociative states	3	4
Disturbances in initiating and maintaining sleep	86	93
Eating disorders NEC	1	1
Emotional and mood disturbances NEC	11	11
Fear symptoms and phobic disorders (incl social phobia)	4	5
Hallucinations (excl sleep-related)	25	26
Increased physical activity levels	11	18
Mental disorders NEC		1
Mood alterations with depressive symptoms	6	7
Mood disorders NEC	2	2
Narcolepsy and associated conditions	2	2
Obsessive-compulsive disorders and symptoms	1	1
Panic attacks and disorders	4	4
Parasomnias	16	21
Perception disturbances NEC	1	1
Psychiatric elimination disorders	3	3
Psychotic disorder NEC	1	1
Sleep disorders NEC	36	40
Somatic symptom disorders	1	2
Speech and language usage disturbances	1	1
Suicidal and self-injurious behaviour	1	1
Thinking disturbances	2	2

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
	341	392	113	144	228	248

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	18	18	4	4	14	14
Genital and urinary tract disorders NEC	1	1			1	1
Glomerulonephritis and nephrotic syndrome	1	1			1	1
Myoneurogenic bladder disorders		1		1		
Renal failure and impairment	7	7			7	7
Urinary abnormalities	3	4		1	3	3
Urinary tract signs and symptoms NEC	14	14	8	8	6	6
	44	46	12	14	32	32

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	1	1			1	1
Breast signs and symptoms	18	21	10	13	8	8
Erection and ejaculation conditions and disorders	1	1			1	1
Menopausal effects NEC	2	2	2	2		
Menstruation and uterine bleeding NEC	3	6	1	4	2	2
Menstruation with increased bleeding	5	7	1	3	4	4
Penile disorders NEC (excl erection and ejaculation)	1	1			1	1
Prostatic signs, symptoms and disorders NEC	1	1	1	1		
Scrotal disorders NEC	1	5	1	1		4
Vulvovaginal disorders NEC	4	4			4	4
Vulvovaginal signs and symptoms	1	1	1	1		
	38	50	17	25	21	25

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System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	196	233	44	61	152	172
Bronchospasm and obstruction	44	56	10	17	34	39
Conditions associated with abnormal gas exchange	4	4			4	4
Coughing and associated symptoms	134	151	43	53	91	98
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1	1			1	1
Laryngeal spasm, oedema and obstruction	1	1			1	1
Lower respiratory tract inflammatory and immunologic conditions	5	5			5	5
Lower respiratory tract signs and symptoms	6	8		1	6	7
Nasal congestion and inflammations	12	14	6	8	6	6
Nasal disorders NEC	21	26	9	11	12	15
Paranasal sinus disorders (excl infections and neoplasms)	6	6	2	2	4	4
Parenchymal lung disorders NEC	1	1			1	1
Pharyngeal disorders (excl infections and neoplasms)	40	46	11	13	29	33
Pleural infections and inflammations	2	2			2	2
Pneumothorax and pleural effusions NEC	1	1			1	1
Pulmonary oedemas	3	3			3	3
Pulmonary thrombotic and embolic conditions	2	2			2	2
Respiratory failures (excl neonatal)	2	2			2	2
Respiratory signs and symptoms NEC	3	5	1	2	2	3
Respiratory tract disorders NEC	5	6	1	2	4	4
Upper respiratory tract signs and symptoms	258	306	100	128	158	178
	747	879	227	298	520	581

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System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Alopecias	1	1	1	1		
Angioedemas	17	21			17	21
Apocrine and eccrine gland disorders	191	224	68	86	123	138
Bullous conditions	13	13	5	5	8	8
Dermal and epidermal conditions NEC	82	91	32	35	50	56
Dermatitis and eczema	23	30	11	15	12	15
Dermatitis ascribed to specific agent	5	5	1	1	4	4
Erythemas	97	121	45	63	52	58
Exfoliative conditions	7	7	1	1	6	6
Nail and nail bed conditions (excl infections and infestations)	2	2			2	2
Photosensitivity and photodermatosis conditions		1				1
Pilar disorders NEC	3	4	2	2	1	2
Pruritus NEC	154	195	69	95	85	100
Psoriatic conditions	1	1			1	1
Purpura and related conditions	7	8	2	3	5	5
Rashes, eruptions and exanthems NEC	283	355	127	173	156	182
Skin and subcutaneous conditions NEC	2	3	1	2	1	1
Skin and subcutaneous tissue ulcerations	3	3	1	1	2	2
Skin haemorrhages	1	1			1	1
Skin vasculitides	1	1			1	1
Skin vasomotor conditions	1	2		1	1	1
Urticarias	68	86	28	43	40	43
	962	1,175	394	527	568	648

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System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	14	15	3	3	11	12
	14	15	3	3	11	12

System Organ Class

**SOC Not Yet Coded**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
	14	16	14	16
	14	16	14	16

System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Dietary and nutritional therapies	1	1			1	1
Limb therapeutic procedures	1	1	1	1		
Respiratory tract therapeutic procedures NEC	1	1			1	1
	3	3	1	1	2	2

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System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	1	1			1	1
Aortic aneurysms and dissections	1	1			1	1
Blood pressure disorders NEC	1	1			1	1
Circulatory collapse and shock	22	24			22	24
Haemorrhages NEC	3	3	1	1	2	2
Lymphoedemas	5	5			5	5
Non-site specific embolism and thrombosis	4	4			4	4
Non-site specific necrosis and vascular insufficiency NEC	1	1			1	1
Non-site specific vascular disorders NEC	5	5	1	1	4	4
Peripheral embolism and thrombosis	5	5			5	5
Peripheral vascular disorders NEC	77	108	30	50	47	58
Peripheral vasoconstriction, necrosis and vascular insufficiency	26	31	10	12	16	19
Site specific vascular disorders NEC	22	33	8	12	14	21
Varicose veins NEC	1	1	1	1		
Vascular hypertensive disorders NEC	46	56	14	19	32	37
Vascular hypotensive disorders	35	42	8	11	27	31
Vasculitides NEC	1	1			1	1
Vena caval embolism and thrombosis	1	1			1	1
	257	323	73	107	184	216

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Country Where Event Occurred

**UNITED STATES**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Anaemias haemolytic NEC	1	1			1	1
Coagulopathies	1	1			1	1
Eosinophilic disorders	1	1	1	1		
Haematological disorders	1	1	1	1		
Leukocytoses NEC	3	3	2	2	1	1
Lymphatic system disorders NEC	404	495	381	466	23	29
Marrow depression and hypoplastic anaemias	1	1			1	1
Neutropenias	1	1			1	1
Thrombocytopenias	6	8			6	8
	419	512	385	470	34	42

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System Organ Class

**Cardiac disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cardiac disorders NEC	3	6	2	5	1	1
Cardiac signs and symptoms NEC	91	146	71	111	20	35
Cardiac valve disorders NEC	1	1			1	1
Ischaemic coronary artery disorders	10	13			10	13
Myocardial disorders NEC	2	2			2	2
Noninfectious myocarditis	1	1			1	1
Noninfectious pericarditis	4	5			4	5
Pericardial disorders NEC	1	1			1	1
Rate and rhythm disorders NEC	98	161	63	107	35	54
Supraventricular arrhythmias	17	19	6	6	11	13
Ventricular arrhythmias and cardiac arrest	12	18	1	4	11	14
	240	373	143	233	97	140

System Organ Class

**Congenital, familial and genetic disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Coagulation disorders congenital		1		1
		1		1

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System Organ Class

**Ear and labyrinth disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Ear disorders NEC	60	85	58	81	2	4
External ear disorders NEC	1	1	1	1		
Hearing losses	27	37	12	15	15	22
Hyperacusia	3	5	3	4		1
Inner ear signs and symptoms	95	131	85	114	10	17
	186	259	159	215	27	44

System Organ Class

**Endocrine disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acute and chronic thyroiditis	1	1			1	1
Thyroid disorders NEC	2	2	2	2		
Thyroid hypofunction disorders	2	2			2	2
	5	5	2	2	3	3

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System Organ Class

Eye disorders

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Conjunctival and corneal bleeding and vascular disorders	1	1			1	1
Conjunctival infections, irritations and inflammations	4	4	4	4		
Corneal infections, oedemas and inflammations	1	1	1	1		
Eyelid movement disorders	4	7	4	6		1
Glaucomas (excl congenital)	2	2			2	2
Lacrimation disorders	10	12	9	11	1	1
Lid, lash and lacrimal infections, irritations and inflammations	23	31	23	31		
Ocular bleeding and vascular disorders NEC	4	6			4	6
Ocular disorders NEC	100	143	84	124	16	19
Ocular infections, inflammations and associated manifestations	45	65	41	59	4	6
Ocular nerve and muscle disorders	1	2	1	1		1
Ocular sensation disorders	28	37	25	34	3	3
Pupil disorders	2	2	2	2		
Refractive and accommodative disorders	1	1	1	1		
Scleral infections, irritations and inflammations	3	3	2	2	1	1
Visual disorders NEC	52	66	43	53	9	13
Visual impairment and blindness (excl colour blindness)	16	24	12	17	4	7
	297	407	252	346	45	61

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal findings abnormal	2	2	2	2		
Acute and chronic pancreatitis	1	2			1	2
Colitis (excl infective)	1	1			1	1
Dental pain and sensation disorders	10	18	10	18		
Diarrhoea (excl infective)	245	329	237	317	8	12
Duodenal and small intestinal stenosis and obstruction		1				1
Dyspeptic signs and symptoms	16	21	16	21		
Faecal abnormalities NEC	3	4	3	4		
Flatulence, bloating and distension	14	20	13	19	1	1
Gastritis (excl infective)	2	3	2	3		
Gastrointestinal and abdominal pains (excl oral and throat)	121	158	115	146	6	12
Gastrointestinal atonic and hypomotility disorders NEC	8	9	7	8	1	1
Gastrointestinal disorders NEC	13	20	12	19	1	1
Gastrointestinal dyskinetic disorders	2	2	2	2		
Gastrointestinal signs and symptoms NEC	75	98	57	78	18	20
Gastrointestinal spastic and hypermotility disorders	4	5	4	5		
Gastrointestinal stenosis and obstruction NEC		1				1
Gingival disorders, signs and symptoms NEC	15	19	15	15		4
Gingival haemorrhages	2	4	2	4		
Haemorrhoids and gastrointestinal varices (excl oesophageal)	1	1	1	1		
Intestinal haemorrhages	1	1			1	1
Nausea and vomiting symptoms	939	1,288	889	1215	50	73
Non-site specific gastrointestinal haemorrhages	6	7			6	7
Oral dryness and saliva altered	25	44	22	40	3	4
Oral soft tissue disorders NEC	14	21	12	18	2	3
Oral soft tissue signs and symptoms	158	253	132	214	26	39
Oral soft tissue swelling and oedema	50	75	38	52	12	23
Salivary gland disorders NEC	1	1	1	1		

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System Organ Class

**Gastrointestinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Stomatitis and ulceration	14	16	13	15	1	1
Tongue disorders	9	16	7	14	2	2
Tongue signs and symptoms	54	83	38	58	16	25
	1,806	2,523	1650	2289	156	234

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Administration site reactions NEC		2		2		
Adverse effect absent	4	4	4	4		
Asthenic conditions	1,690	2,307	1615	2216	75	91
Body temperature altered	2	2	1	1	1	1
Death and sudden death	30	31			30	31
Febrile disorders	1,220	1,582	1166	1507	54	75
Feelings and sensations NEC	1,607	2,125	1533	2018	74	107
Gait disturbances	50	62	42	52	8	10
General signs and symptoms NEC	536	706	497	651	39	55
Inflammations	8	14	8	13		1
Injection site reactions	22	32	20	30	2	2
Interactions	8	8	8	8		
Mass conditions NEC	8	8	8	8		
Mucosal findings abnormal	2	3	2	3		
Oedema NEC	12	17	10	14	2	3
Pain and discomfort NEC	1,258	1,650	1159	1523	99	127
Therapeutic and nontherapeutic responses	570	735	10	11	560	724
Ulcers NEC	1	1	1	1		
Vaccination site reactions	1,448	2,030	1412	1988	36	42
	8,476	11,319	7496	10050	980	1269

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System Organ Class

**Hepatobiliary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Cholecystitis and cholelithiasis	1	1			1	1
Cholestasis and jaundice	2	2	2	2		
Gallbladder disorders NEC	1	2		1	1	1
Hepatobiliary signs and symptoms		1		1		
Hepatocellular damage and hepatitis NEC	1	1			1	1
	5	7	2	4	3	3

System Organ Class

**Immune system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Allergic conditions NEC	63	94	50	69	13	25
Allergies to foods, food additives, drugs and other chemicals	32	53	26	40	6	13
Anaphylactic and anaphylactoid responses	59	92			59	92
Atopic disorders	3	3	3	3		
Autoimmune disorders NEC	1	4			1	4
Immune and associated conditions NEC	1	3	1	1		2
Immunodeficiency disorders NEC	1	2			1	2
	160	251	80	113	80	138

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System Organ Class

Infections and infestations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal infections	4	6			4	6
Bacterial infections NEC	6	8	2	2	4	6
Bordetella infections		1				1
Breast infections		1				1
Candida infections	1	2	1	2		
Central nervous system and spinal infections		1				1
Coronavirus infections	405	509	6	9	399	500
Dental and oral soft tissue infections	1	1	1	1		
Ear infections	1	3	1	2		1
Ectoparasitic infestations	1	1	1	1		
Escherichia infections	1	1			1	1
Eye and eyelid infections	4	9	4	9		
Female reproductive tract infections		1		1		
Fungal infections NEC	4	4	4	4		
Herpes viral infections	48	64	46	62	2	2
Infections NEC	10	11	9	10	1	1
Influenza viral infections	22	32	21	30	1	2
Lower respiratory tract and lung infections	11	14	3	4	8	10
Male reproductive tract infections		1		1		
Rhinoviral infections	1	1	1	1		
Sepsis, bacteraemia, viraemia and fungaemia NEC	2	2			2	2
Skin structures and soft tissue infections	2	4	2	3		1
Staphylococcal infections	2	3	1	1	1	2
Streptococcal infections		2		1		1
Tuberculous infections	2	2			2	2
Upper respiratory tract infections	57	84	54	81	3	3
Urinary tract infections	9	11	6	8	3	3
Viral infections NEC	4	7	3	5	1	2
	598	786	166	238	432	548

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abdominal and gastrointestinal injuries NEC	3	3	2	2	1	1
Accidental exposures to product	10	15	9	14	1	1
Chest and respiratory tract injuries NEC		1				1
Conditions caused by cold	2	2	2	2		
Exposures associated with pregnancy, delivery and lactation	103	159	101	157	2	2
Exposures to agents or circumstances NEC	36	43	25	32	11	11
Eye injuries NEC	4	4	4	4		
Fractures and dislocations NEC	1	3			1	3
Gastrointestinal and hepatobiliary procedural complications	2	2	2	2		
Intentional product misuses	1	1	1	1		
Medication errors, product use errors and issues NEC	241	336	238	333	3	3
Muscle, tendon and ligament injuries	6	8	6	8		
Nerve injuries NEC		1		1		
Non-site specific injuries NEC	24	30	18	22	6	8
Non-site specific procedural complications	5	6	1	2	4	4
Occupational exposures	6	7	5	6	1	1
Off label uses	188	242	187	241	1	1
Overdoses NEC	33	50	33	50		
Pathways and sources of exposure	11	15	10	14	1	1
Product administration errors and issues	477	640	472	634	5	6
Product confusion errors and issues	1	1	1	1		
Product preparation errors and issues	112	150	112	148		2
Product prescribing errors and issues	2	5	2	5		
Radiation injuries	2	2	2	2		
Site specific injuries NEC	14	18	12	15	2	3
Skin injuries NEC	22	30	20	28	2	2
Thermal burns	1	1			1	1
Underdoses NEC	70	108	70	108		
Vaccination related complications	2	2	2	2		

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System Organ Class

**Injury, poisoning and procedural complications**

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
1337	1834	42	51

1,379

1,885

1337

1834

42

51

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System Organ Class

Investigations

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Adrenal medulla tests		1		1		
Bacteria identification and serology (excl mycobacteria)		1		1		
Blood counts NEC		1		1		
Blood gas and acid base analyses	16	17	10	11	6	6
Carbohydrate tolerance analyses (incl diabetes)	17	19	14	16	3	3
Cardiac function diagnostic procedures		1		1		
Coagulation and bleeding analyses	6	7	4	5	2	2
ECG investigations	3	4	3	3		1
Gastrointestinal function diagnostic procedures	1	1	1	1		
Haematological analyses NEC	2	2	2	2		
Heart rate and pulse investigations	172	273	136	218	36	55
Immunology analyses NEC	1	1	1	1		
Lipoprotein and lipid tests NEC		1		1		
Liver function analyses	5	5	3	3	2	2
Mineral and electrolyte analyses	5	5	4	4	1	1
Ophthalmic function diagnostic procedures	1	1	1	1		
Physical examination procedures and organ system status	69	98	64	90	5	8
Pituitary analyses anterior	2	2	2	2		
Platelet analyses	7	8	3	4	4	4
Protein analyses NEC	5	5	4	4	1	1
Red blood cell analyses	5	5	4	4	1	1
Renal function analyses	1	1	1	1		
Reproductive hormone analyses	1	1	1	1		
Skeletal and cardiac muscle analyses	3	4			3	4
Urinalysis NEC	5	6	5	6		
Urinary tract function analyses NEC	1	1	1	1		
Vascular tests NEC (incl blood pressure)	73	122	43	76	30	46
Virus identification and serology	183	253	16	20	167	233
White blood cell analyses	7	8	1	1	6	7
	591	854	324	480	267	374

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System Organ Class

**Metabolism and nutrition disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Appetite disorders	74	95	69	88	5	7
Calcium metabolism disorders	2	3			2	3
Diabetes mellitus (incl subtypes)	4	5			4	5
Disorders of purine metabolism	5	5	5	5		
Electrolyte imbalance NEC	1	1			1	1
Fluid intake decreased	2	2	1	1	1	1
Fluid intake increased	2	2	2	2		
General nutritional disorders NEC	9	13	8	12	1	1
Hyperglycaemic conditions NEC	3	3	1	1	2	2
Hypoglycaemic conditions NEC	3	4	3	4		
Magnesium metabolism disorders	1	1			1	1
Potassium imbalance	1	1			1	1
Total fluid volume decreased	16	23	13	19	3	4
	123	158	102	132	21	26

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System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Arthropathies NEC	20	24	19	22	1	2
Bone related signs and symptoms	61	84	55	78	6	6
Cartilage disorders	2	2	1	1	1	1
Connective tissue disorders NEC	2	4			2	4
Intervertebral disc disorders NEC	1	1	1	1		
Joint related disorders NEC	4	5	2	2	2	3
Joint related signs and symptoms	531	695	505	662	26	33
Ligament disorders	1	1	1	1		
Lupus erythematosus (incl subtypes)	1	1			1	1
Muscle infections and inflammations	2	2			2	2
Muscle pains	595	799	571	768	24	31
Muscle related signs and symptoms NEC	118	144	108	133	10	11
Muscle tone abnormalities	4	5	4	5		
Muscle weakness conditions	49	63	39	51	10	12
Musculoskeletal and connective tissue conditions NEC	83	104	75	94	8	10
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		1		1		
Musculoskeletal and connective tissue pain and discomfort	1,052	1,385	1019	1337	33	48
Myopathies	1	1	1	1		
Psoriatic arthropathies	1	1			1	1
Rheumatoid arthropathies	1	2			1	2
Soft tissue disorders NEC	14	19	13	17	1	2
Tendon disorders	4	6	3	5	1	1
	2,547	3,349	2417	3179	130	170

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System Organ Class

**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Aural neoplasms malignant and unspecified	1	1	1	1		
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	1	1			1	1
Skin neoplasms malignant and unspecified (excl melanoma)	1	1	1	1		
	3	3	2	2	1	1

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abnormal sleep-related events	1	1	1	1		
Acute polyneuropathies	2	3			2	3
Auditory nerve disorders		1				1
Autonomic nervous system disorders	1	1			1	1
Central nervous system haemorrhages and cerebrovascular accidents	19	23			19	23
Chronic polyneuropathies	1	1			1	1
Coma states	1	1			1	1
Coordination and balance disturbances	35	45	27	33	8	12
Cortical dysfunction NEC	5	9	2	6	3	3
Demyelinating disorders NEC	1	1			1	1
Disturbances in consciousness NEC	174	239	109	151	65	88
Disturbances in sleep phase rhythm		1		1		
Dyskinesias and movement disorders NEC	35	42	31	37	4	5
Dystonias	1	1			1	1
Encephalitis NEC	1	1			1	1
Encephalopathies NEC	1	1			1	1
Facial cranial nerve disorders	56	73	3	4	53	69
Headaches NEC	1,535	2,059	1468	1970	67	89
Increased intracranial pressure disorders	2	2			2	2
Lumbar spinal cord and nerve root disorders	1	1	1	1		
Memory loss (excl dementia)	15	19	10	13	5	6
Mental impairment (excl dementia and memory loss)	26	43	16	24	10	19
Migraine headaches	83	101	77	94	6	7
Mononeuropathies	8	9	6	7	2	2
Muscle tone abnormal	3	4	2	3	1	1
Myelitis (incl infective)	1	1			1	1
Narcolepsy and hypersomnia	22	30	20	28	2	2
Nervous system disorders NEC	2	3	1	2	1	1
Neurological signs and symptoms NEC	560	842	495	738	65	104
Neurologic visual problems NEC	3	5	1	1	2	4

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System Organ Class

**Nervous system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Neuromuscular disorders NEC	1	1			1	1
Olfactory nerve disorders	53	86	47	75	6	11
Optic nerve disorders NEC	1	1			1	1
Paraesthesias and dysaesthesias	434	640	367	548	67	92
Paralysis and paresis (excl cranial nerve)	8	9			8	9
Parkinson's disease and parkinsonism		2		2		
Peripheral neuropathies NEC	15	16	1	1	14	15
Seizures and seizure disorders NEC	7	10			7	10
Sensory abnormalities NEC	163	240	153	226	10	14
Sleep disturbances NEC	13	20	13	20		
Speech and language abnormalities	20	29	15	24	5	5
Structural brain disorders NEC	2	2			2	2
Transient cerebrovascular events	3	4			3	4
Tremor (excl congenital)	98	130	83	110	15	20
Trigeminal disorders	3	4	2	3	1	1
	3,416	4,757	2951	4123	465	634

System Organ Class

**Pregnancy, puerperium and perinatal conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Abortions spontaneous	6	6			6	6
Labour onset and length abnormalities	1	1			1	1
Normal pregnancy, labour and delivery	1	1	1	1		
	8	8	1	1	7	7

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System Organ Class

Product issues

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Device physical property and chemical issues	4	8	3	7	1	1
Product distribution and storage issues	15	105	15	105		
Product packaging issues		4		4		
Product physical issues	10	14	10	14		
Product quality issues NEC		2		1		1
	29	133	28	131	1	2

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System Organ Class

Psychiatric disorders

High Level Term

Interval Total #  
Spontaneous AE

Cumulative Total #  
Spontaneous AE

Spontaneous			
Nonserious		Serious	
I	C	I	C
		1	2
68	106	4	7
3	4		
1	1		
	1	1	1
22	28	3	4
		3	4
1	1	2	2
2	2	1	1
99	121	3	4
5	8	1	2
16	20	2	2
8	11		1
		5	6
1	1		
9	11	3	3
2	3	1	1
6	8	1	1
		1	1
1	2		
6	9	1	3
15	18		
1	1	1	1
2	2		
20	25	1	2
2	2		
	1	1	1
1	2		
		1	1
9	11		

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System Organ Class

**Psychiatric disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Tic disorders	1	1	1	1		
	338	450	301	400	37	50

System Organ Class

**Renal and urinary disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Bladder and urethral symptoms	16	21	15	19	1	2
Renal disorders NEC	2	2	2	2		
Renal failure and impairment	2	2			2	2
Renal lithiasis	1	1			1	1
Urinary abnormalities	5	7	5	6		1
Urinary tract signs and symptoms NEC	12	13	12	13		
	38	46	34	40	4	6

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System Organ Class

**Reproductive system and breast disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breast disorders NEC	1	1	1	1		
Breast signs and symptoms	17	22	17	21		1
Lactation disorders	2	2	2	2		
Menstruation and uterine bleeding NEC	22	25	22	25		
Menstruation with increased bleeding	1	1	1	1		
Pelvis and broad ligament disorders NEC	1	1	1	1		
Penile disorders NEC (excl erection and ejaculation)	1	1			1	1
Reproductive tract signs and symptoms NEC	3	3	2	2	1	1
Uterine disorders NEC	1	1			1	1
Vulvovaginal disorders NEC	6	7	2	3	4	4
Vulvovaginal signs and symptoms	3	3			3	3
	58	67	48	56	10	11

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\* I=Interval, C=Cumulative  
 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Respiratory, thoracic and mediastinal disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Breathing abnormalities	238	327	154	208	84	119
Bronchospasm and obstruction	31	45	19	28	12	17
Conditions associated with abnormal gas exchange		2				2
Coughing and associated symptoms	183	263	158	226	25	37
Laryngeal spasm, oedema and obstruction	6	8			6	8
Lower respiratory tract inflammatory and immunologic conditions	1	1	1	1		
Lower respiratory tract signs and symptoms	5	10	5	10		
Nasal congestion and inflammations	81	126	74	117	7	9
Nasal disorders NEC	26	35	24	32	2	3
Paranasal sinus disorders (excl infections and neoplasms)	22	29	21	28	1	1
Parenchymal lung disorders NEC		2				2
Pharyngeal disorders (excl infections and neoplasms)	72	110	42	69	30	41
Pleural infections and inflammations	1	1			1	1
Pneumothorax and pleural effusions NEC	2	2	1	1	1	1
Pulmonary oedemas	3	5			3	5
Pulmonary thrombotic and embolic conditions	2	3			2	3
Respiratory failures (excl neonatal)	1	1			1	1
Respiratory signs and symptoms NEC	2	5	2	4		1
Respiratory tract disorders NEC	11	13	11	13		
Tracheal disorders (excl infections and neoplasms)		1				1
Upper respiratory tract signs and symptoms	426	648	354	536	72	112
	1,113	1,637	866	1273	247	364

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Skin and subcutaneous tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Acnes	3	4	3	4		
Alopecias	3	3	3	3		
Angioedemas	6	13	1	1	5	12
Apocrine and eccrine gland disorders	188	261	172	238	16	23
Bullous conditions	13	19	12	18	1	1
Dermal and epidermal conditions NEC	67	87	64	81	3	6
Dermatitis and eczema	20	23	19	22	1	1
Dermatitis ascribed to specific agent		1		1		
Erythemas	106	151	92	132	14	19
Exfoliative conditions	5	5	3	3	2	2
Photosensitivity and photodermatosis conditions	4	7	4	7		
Pilar disorders NEC	3	5	2	4	1	1
Pruritus NEC	213	316	190	285	23	31
Psoriatic conditions		1		1		
Purpura and related conditions	11	11	10	10	1	1
Rashes, eruptions and exanthems NEC	329	465	295	408	34	57
Rosaceas	1	1	1	1		
Skin and subcutaneous conditions NEC	1	1	1	1		
Skin vasomotor conditions	2	3	1	1	1	2
Urticarias	176	247	138	201	38	46
	1,151	1,624	1011	1422	140	202

System Organ Class

**Social circumstances**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Disability issues	36	44	33	40	3	4
Social issues NEC	3	3	3	3		
	39	47	36	43	3	4

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System Organ Class

**Surgical and medical procedures**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Serious	
			I	C
Spine and spinal cord therapeutic procedures	1	1	1	1
	1	1	1	1

System Organ Class

**Vascular disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous			
			Nonserious		Serious	
			I	C	I	C
Accelerated and malignant hypertension	2	5			2	5
Arterial infections and inflammations	1	1	1	1		
Blood pressure disorders NEC	2	3	1	2	1	1
Circulatory collapse and shock	4	5			4	5
Haemorrhages NEC	3	5			3	5
Lymphoedemas	6	8	6	8		
Non-site specific embolism and thrombosis	5	5			5	5
Non-site specific vascular disorders NEC	3	5	3	5		
Peripheral embolism and thrombosis	6	6			6	6
Peripheral vascular disorders NEC	126	222	96	174	30	48
Peripheral vasoconstriction, necrosis and vascular insufficiency	16	33	15	31	1	2
Phlebitis NEC	1	1	1	1		
Site specific vascular disorders NEC	13	19	11	15	2	4
Varicose veins NEC	1	1	1	1		
Vascular hypertensive disorders NEC	45	72	27	44	18	28
Vascular hypotensive disorders	16	19	9	11	7	8
	250	410	171	293	79	117

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Country Where Event Occurred

**UNITED STATES MINOR OUTLYING ISLANDS**

System Organ Class

**Blood and lymphatic system disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Lymphatic system disorders NEC	1	1	1	1
	1	1	1	1

System Organ Class

**General disorders and administration site conditions**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Pain and discomfort NEC	1	1	1	1
Vaccination site reactions		1		1
	1	2	1	2

System Organ Class

**Injury, poisoning and procedural complications**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Product administration errors and issues	1	1	1	1
	1	1	1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

**Musculoskeletal and connective tissue disorders**

High Level Term	Interval Total # Spontaneous AE	Cumulative Total # Spontaneous AE	Spontaneous	
			Nonserious	
			I	C
Joint related signs and symptoms	1	1	1	1
	1	1	1	1

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 \* AE=Adverse Event  
 \* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

**Appendix 3 (Referred in Section 9.2 Overview of Signals)**

**Tabular summary of safety signals evaluated during the reporting interval**

**Product name: PF-07302048 (BNT162b2)**

**Reporting interval: 01-Jan-2021 to 31-Jan-2021**

Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Hypersensitivity reactions (other than anaphylaxis)	19 Dec 2020	Closed	13 Jan 2021	EMA request to include "Hypersensitivity" as an adverse reaction in EU SmPC at time of conditional approval	Potential hypersensitivity events (other than anaphylaxis) were assessed to determine if product labeling information needed to be updated for completeness.	Review of unblinded clinical study data; review of post-authorization data	At the time of conditional approval by EMA, Hypersensitivity was added as an adverse reaction (not important) to Section 4.8 of the EU SmPC per EMA request.  Core Position: "Hypersensitivity (e.g. rash, pruritus, urticaria, angioedema)" was added to the CDS and EUA PI as an adverse reaction

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Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Insomnia	19 Dec 2020	Closed	20 Jan 2021	EMA request to include as an adverse reaction in EU SmPC at time of conditional approval	To determine the company position on whether insomnia is an adverse reaction for the vaccine	Review of unblinded clinical study data; review of post-authorization data	At the time of conditional approval by EMA, Insomnia was added as an adverse reaction to Section 4.8 of the EU SmPC per EMA request.  Core Position: Based on review of clinical study and post-authorization data, Insomnia is determined not to be a risk and no further action is warranted at this time.

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Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Injection site pruritus	19 Dec 2020	Closed	20 Jan 2021	EMA request to include as an adverse reaction in EU SmPC at time of conditional approval	To determine the company position on whether injection site pruritus is an adverse reaction for the vaccine	Review of unblinded clinical study data; review of post-authorization data	At the time of conditional approval by EMA, Injection site pruritus was added as an adverse reaction to Section 4.8 of the EU SmPC per EMA request.  Core Position: Based on review of clinical study and post-authorization data, Injection site pruritus is determined not to be a risk and no further action is warranted at this time.
Pain in extremity	19 Dec 2020	Closed	20 Jan 2021	EMA request to include as an adverse reaction in EU SmPC at time of conditional approval	To determine the company position on whether pain in extremity is an adverse reaction for the vaccine	Review of unblinded clinical study data; review of post-authorization data	At the time of conditional approval by EMA, pain in extremity was added as an adverse reaction to Section 4.8 of the EU SmPC per EMA request.  Core Position: Based on review of clinical study and post-authorization data, Pain in extremity will be added to the CDS and US EUA PI as an adverse reaction

Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Facial paralysis	03 Dec 2020 opened as safety topic.  19 Dec 2020 reopened	Ongoing	N/A - Ongoing	Initially opened and closed following review of unblinded clinical study data (C4591001) (DLP 14 Nov 2020).  Re-opened at time of EMA conditional approval due to EMA request to include as adverse reaction in EU SmPC	Initially opened and closed following review of unblinded clinical study data (C4591001) (DLP 14 Nov 2020)  Re-opened due to EMA request to include as adverse reaction in EU SmPC at time of conditional approval	Review of unblinded clinical study data; review of post-authorization and epidemiological safety data (Observed vs Expected analyses)	At the time of conditional approval by the EMA, facial paralysis was added as an adverse reaction to Section 4.8 of the EU SmPC per EMA request.  Core position Based on the results of the evaluation to date, a causal association with BNT162b2 has not been established.

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Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Vomiting	16 Nov 2020  Re-opened 18 Jan 2021 following receipt of Dec 2020 SMSR PRAC assessment report	Closed	10 Feb 2021	Initially reviewed as a potential reactogenicity event in using unblinded clinical study data (DLP 14 Nov 2020)  Re-opened due to inquiry from a competent authority	In review of unblinded clinical study data (data lock date 14 Nov 2020), vomiting was not found to occur at an increased frequency in vaccine group compared to placebo group following vaccination.  December 2020 SMSR PRAC Assessment Report requested review of case reports of Vomiting and discuss whether a causal relationship can be established and if reactions would pose a higher risk on worsened outcome in the particularly frail or elderly patients with underlying morbidities.	Review of unblinded clinical study data  Review of post-authorization safety data.	Based on evaluation of the post-authorization data, Vomiting will be added to the CDS and local labels as adverse reaction

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Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Diarrhoea	16 Nov 2020  Re-opened 18 Jan 2021 following receipt of Dec 2020 SMSR PRAC assessment report	Closed	10 Feb 2021	Initially reviewed as a potential reactogenicity event in using unblinded clinical study data (DLP 14 Nov 2020)  Re-opened due to inquiry from a competent authority	In review of unblinded clinical study data (data lock date 14 Nov 2020), diarrhoea was not found to occur at an increased frequency in vaccine group compared to placebo group following vaccination.  Dec 2020 SMSR PRAC Assessment Report requested review of case reports of diarrhoea and discussion of whether a causal relationship can be established and if reactions would pose a higher risk on worsened outcome in the particularly frail or elderly patients with underlying morbidities.	Review of unblinded clinical study data.  Review of post-authorization safety data.	Based on evaluation of the post-authorization data, Diarrhea will be added to the CDS and local labels as an adverse reaction
Overdose	27 Dec 2020	Closed	20 Jan 2021	Post-authorization cases received of full-vial dosing per patient.	Review occurred to determine if there was further useful information with which to update Overdose section of labeling	Post-authorization medication errors of full vial dosing and co-reported adverse events were reviewed	No significant new safety information was associated with these cases of overdose therefore it was determined that no updates to Overdose section of labeling was warranted

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Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Paraesthesia	29 Dec 2020	Ongoing	N/A – ongoing	Inquiry from a competent authority due to post-authorization reports	Israel BOH query about paraesthesia prompted a review to determine if paraesthesia should be considered an adverse reaction PRAC requested review of Paraesthesia and Dysesthesia	Review of unblinded clinical study data.  Review of post-authorization safety data.	An evaluation of these events reported in the clinical study and post-authorization settings were conducted. The review is ongoing, and an update will be provided in the next SMSR.
Dizziness	18 Jan 2021	Ongoing	N/A – ongoing	Inquiry from a competent authority	Biweekly discussion with MHRA prompted a review to determine if dizziness should be considered an adverse reaction	Review of clinical study data.  Review of post-authorization safety data.	An evaluation of this event in the clinical study and post-authorization settings is ongoing and an update will be provided in the next SMSR.
Immune Thrombocytopenia	21 Jan 2021	Closed	26 Jan 2021	Inquiry from a competent authority	A fatal report associated with ITP was received; this and an FDA query prompted a review of thrombocytopenia	Review of unblinded clinical study data; review of post-authorization and epidemiological safety data (Observed vs Expected analyses)	There is insufficient evidence to conclude Immune thrombocytopenia/Thrombocytopenia is an adverse reaction for the vaccine
Eye Pain & Eye Swelling	22 Jan 2021	Closed	03 Feb 2021	Inquiry from a competent authority	Dec 2020 SMSR PRAC Assessment Report request prompted a review of the topic	Review of post-marketing safety data.	Based on review of post-authorization data, Eye pain and Eye swelling was determined not to be a risk for the vaccine after the data-lock (31 Jan 2021) of this SMSR

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Signal Term	Date Detected	Status (ongoing, or closed)	Date Closed (for closed signals)	Source or trigger of signal	Reason for evaluation and summary of key data	Method of signal evaluation	Action(s) taken or planned
Deaths including in elderly or frail individuals	18 Jan 2021	Closed	20 Jan 2021	Inquiry from a competent authority	Due to cluster of deaths in elderly and frail adults in Norway, as assessment of the cases was undertaken	Review of post-authorization data and epidemiological safety data	Based on review of post-authorization data and epidemiology background data, death was determined not to be a risk for the vaccine

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**Appendix 3.1 (Referred to in Section 9.2 Overview of Signals)**

**Summary of Signal Evaluations**

Table 1 presents signal evaluation summaries for PF-07302048 (BNT162b2) during the current reporting period.

**Table 1. Summary of Signal Evaluations During the Reporting Interval**

Signal	Summary of Evaluation
<b>Signals Determined to be Risks</b>	
Hypersensitivity reactions (other than anaphylaxis)	At the time of conditional approval in the EU, “Hypersensitivity” was included as an adverse reaction in the EU SmPC at the request of the EMA. Following the MAH’s addition of “Anaphylaxis” as an adverse reaction in the US EUA PI and as an Important identified risk in the US PVP and EU RMP, the MAH further evaluated adverse events indicative of less severe hypersensitivity reactions from the available unblinded clinical study data (C4591001, data-lock 14 Nov 2020) and post-authorization spontaneously reported adverse events. Based mostly on the post-authorization data, the MAH added “Hypersensitivity (e.g. rash, pruritus, urticaria, angioedema)” as an adverse reaction to the company CDS and US EUA PI in order to present a more complete description of the hypersensitivity reactions that may occur following vaccination with BNT162b2. These events are considered “not important” for purposes of the risk management and pharmacovigilance plans.
Pain in extremity	At the time of conditional approval in the EU, “Pain in extremity” was included as an adverse reaction in the EU SmPC at the request of the EMA. Following authorization, the MAH further evaluated this event and based on the available unblinded clinical study data (C4591001, data-lock 14 Nov 2020) and post-authorization spontaneously reported adverse events, determined that Pain in extremity is an adverse reaction that will be added to the CDS and US EUA PI. Pain in extremity is considered “not important” for purposes of the risk management and pharmacovigilance plans.
Diarrhoea	Diarrhoea was a pre-specified systemic reactogenicity event for Study C4591001, however at the time of authorization, the available unblinded clinical data (data lock 14 Nov 2020) showed no difference in frequency of reports of diarrhea between the vaccine and placebo groups. Following a request for review of the topic by the PRAC and an evaluation of the accrued post-authorization events of diarrhea, the MAH determined that diarrhea was an adverse reaction. This decision, made shortly after the data-lock of this SMSR, was largely based on the temporal relationship of the reports to vaccination, the duration of the event and the number of reports received. The CDS and local labels will be updated with this safety information. Diarrhoea is considered “not important” for purposes of the risk management and pharmacovigilance plans. Please refer to <a href="#">Appendix 3.4</a> for a cumulative overview of cases.
Vomiting	Vomiting was a pre-specified systemic reactogenicity event for Study C4591001, however at the time of authorization, the available unblinded clinical data (data lock 14 Nov 2020) showed low frequency of vomiting and no difference in frequency of reports of diarrhea between the vaccine and placebo groups. Following a request for review of the topic by the PRAC and an evaluation of the accrued post-authorization events of vomiting, the MAH determined that vomiting was an adverse reaction. This decision, made shortly after the data-lock of this SMSR, was largely based on the temporal relationship of the reports to vaccination, the duration of the event and the number of reports received. The CDS and local labels will be updated with this safety information. Vomiting is considered “not

	important” for purposes of the risk management and pharmacovigilance plans. Please refer to <a href="#">Appendix 3.4</a> for a cumulative overview of cases.
<b>Signals Determined not to be Risks</b>	
Insomnia	At the time of conditional approval in the EU, “Insomnia” was included as an adverse reaction in the EU SmPC at the request of the EMA. Following authorization, the MAH further evaluated the topic, reviewing the available unblinded clinical study data (C4591001, data-lock 14 Nov 2020) and post-authorization spontaneously reported adverse events. Based on review of this data, insomnia is determined not to be a risk, therefore it will not be added as an adverse reaction to the company CDS. No further action is warranted at this time and routine surveillance will continue.
Injection site pruritus	At the time of conditional approval in the EU, “Injection site pruritus” was included as an adverse reaction in the EU SmPC at the request of the EMA. Following authorization, the MAH further evaluated the topic, reviewing the available unblinded clinical study data (C4591001, data-lock 14 Nov 2020) and post-authorization spontaneously reported adverse events. Based on review of this data and the very low number of reports of the event in the clinical study and spontaneous settings, a causal relationship could not be established with BNT162b2 and injection site pruritus was determined not to be a risk, therefore it will not be added as an adverse reaction to the company CDS. No further action is warranted at this time and routine surveillance will continue.
Eye pain and Eye swelling	Following a request for review of the topic by the PRAC, the MAH evaluated these events through review of post-authorization adverse event reports. Most cases of eye pain were reported in the setting of headache, a known reactogenicity event and most cases of eye swelling were reported in the setting of angioedema and other known hypersensitivity events. Based on review of post-authorization data, a causal relationship was not established with BNT162b2 and eye pain and eye swelling were determined not to be risks, therefore they will not be added as adverse reactions to the company CDS. Please refer to <a href="#">Appendix 3.5</a> for a cumulative overview of cases. No further action is warranted at this time and routine surveillance will continue.
Immune thrombocytopenia	Following a fatal report of immune thrombocytopenia, the MAH reviewed and evaluated all cases of thrombocytopenia in the available unblinded clinical study data (C4591001, data-lock 14 Nov 2020) and in the post-authorization setting. Please refer to <a href="#">Appendix 3.3</a> for a cumulative overview of cases. Observed Based on the review, the low frequency of reports and the observed versus expected analysis, there is insufficient evidence to conclude that immune thrombocytopenia/thrombocytopenia is an adverse reaction for BNT162b2. This topic will continue to be closely monitored.
Deaths, including in elderly or frail individuals	Following a cluster of fatal reports in frail elderly patients in Norway, the MAH reviewed and evaluated all post-authorization cases of death and conducted observed versus expected analyses. Based on the review, death was determined not to be a risk for BNT162b2 and the cases of death in frail, elderly patients were assessed as most likely due to underlying co-morbidities.
Overdose	Post-authorization medication errors of full-vial dosing have been reported therefore the MAH review these events to determine if any associated adverse events reported in conjunction with the overdoses should be added to better characterize overdose in the vaccine labeling. Upon review of the reports of erroneous full-vial administration, no significant new safety information was associated with the cases therefore the MAH determined that no updates to the Overdose section of the product label were warranted at this time. Medication errors will continue to be monitored.

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<b>Signals ongoing</b>	
Facial paralysis	At the time of conditional approval in the EU, “Acute peripheral facial paralysis” was included as an adverse reaction in the EU SmPC at the request of the EMA. Following authorization, the MAH has been closely monitoring this topic via review and evaluation of clinical study data and post-authorization spontaneous reports. Please refer to <a href="#">Appendix 3.2</a> for a cumulative overview of cases. Observed vs expected analyses have also been conducted. Based on the results of the evaluation to date, a causal association with BNT162b2 has not been established. The MAH plans to obtain further neurological and pharmacovigilance consultation on this topic. In addition, data from the ongoing clinical study is anticipated to provide further insight into the event and any relationship with the vaccine. An update will be provided in the next monthly safety report.
Dizziness	A discussion with the MHRA prompted a specific evaluation of reports of dizziness in the clinical study and post-authorization settings. This review is ongoing and an update will be provided in the next SMSR.
Paraesthesia and Dysaesthesia	Following a query by the Israeli BOH regarding paraesthesia and a request by the PRAC to review paraesthesia and dysesthesia, an evaluation of these events reported in the clinical study and post-authorization settings were conducted. Please refer to <a href="#">Appendix 3.6</a> for a cumulative overview of cases. The review is ongoing and an update will be provided in the next SMSR.

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## **Pfizer-BioNTech COVID-19 Vaccine**

### **Facial paralysis**

#### **Report Prepared by:**

#### **BioNTech-Pfizer**

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## 1. INTRODUCTION

Peripheral facial nerve palsy is a weakness of the facial muscles innervated by cranial nerve VII, the facial nerve. Weakness can be complete (paralysis) or incomplete (paresis) and is usually unilateral. If the cause of the facial palsy is unknown, the disorder is known as idiopathic peripheral facial nerve palsy.<sup>1</sup>

At the time of the Emergency Use Authorization, the unblinded Phase 1/2/3 clinical study C4591001 data (data-lock date 14 Nov 2020) contained 4 cases of facial paralysis that occurred in the vaccine group and no cases in the placebo group. A causal association between the vaccine and facial palsy was not concluded.

Facial paralysis is an adverse event of special interest for this and most vaccines. However, the only vaccines that have been shown to have an association with an increased risk of facial paralysis was an inactivated intranasal influenza vaccine in Switzerland in 2000–2001<sup>2</sup> and a quadrivalent meningococcal conjugate vaccine (Menveo) – but only in the context of co-administration with other vaccines (no association with an increased risk when Menveo is administered alone).<sup>3</sup>

Facial paralysis has been reported with COVID-19, both as an isolated neurological finding and in association with Guillain Barre syndrome.<sup>4</sup>

## 2. METHODOLOGY

Pfizer's safety database was searched for Pfizer/BNT COVID-19 vaccine cases of adverse events (AEs) reported spontaneously to Pfizer, reported by the health authorities (HAs) and published in the medical literature containing the MedDRA version 23.1 PTs *Facial paralysis* or *Facial paresis* cumulatively to 31 January 2021.

Unblinded Study C4591001 data (data-lock 14 Nov 2020) was reviewed for cases of facial paralysis.

## 3. RESULTS

### 3.1. Post-authorization data

The search resulted 139 cases. One case (AER (b) (6)) is non-contributory because it is an invalid case from the media describing an overview of the COVID-19 vaccination program in Israel and did not identify a patient with facial paralysis.

The remaining 138 cases were individually reviewed and categorized using the Brighton Collaboration case definition of facial nerve palsy and levels of diagnostic certainty as in Table 1.<sup>1</sup>

**Table 1. Brighton Collaboration Levels of diagnostic certainty for 139 cases of Facial paralysis or Facial paresis**

Level or Category	Definition: Peripheral facial nerve palsy (Idiopathic peripheral facial nerve palsy)	Number of cases (%)
Level 1	Acute onset, decreased ability to wrinkle the forehead OR raise the eyebrows at the affected site (If unknown aetiology, remains unexplained after excluding known causes by review of clinical history AND physical examination AND laboratory investigations AND radiological studies)	5 (3.6%)
Level 2	Not applicable (If unknown aetiology, remains unexplained after excluding known causes by review of clinical history AND physical examination AND laboratory investigations)	1 (0.7%)
Level 3	Not applicable (If unknown aetiology, remains unexplained after excluding known causes by review of clinical history AND physical examination)	0 (0%)
Category 4	Reported event of facial nerve palsy or Bell's palsy; insufficient evidence to meet the case definition	114 (82.6%)
Category 5	Not a case of facial nerve palsy or Bell's palsy	19 (13.8%)

Upon review of the 138 cases, 19 were assessed as Category 5, not cases of facial nerve palsy because they described other disorders, for example, facial paraesthesia without weakness (8 cases) and stroke or transient ischemic attack symptoms (6 cases). One of the Category 5 cases was a fatal case: an 83-year-old man in the UK taking metformin for diabetes who received a dose of the vaccine on 13 Jan 2021 and developed a left facial droop and weakness the same day. A CT showed a right thalamic bleed and the patient died on 21 Jan 2021 of aspiration pneumonia.

The 5 cases assessed as Level 1 and one case assessed as Level 2 are summarized in Table 2.

**Table 2. Level 1 and 2 Facial paralysis or Facial palsy cases**

Level	AER Initial receipt date Country/Age/Sex Relevant medical hx Batch/Lot	PTs Summary
Level 1	(b) (6) 13 Jan 2021 UK/26 yrs/Female COVID-19 6 months prior EY0553	<b>Facial paralysis, Facial paresis, Ear pain, Disease recurrence, Headache, Hypoaesthesia</b>  8 days following first dose of vaccine in unspecified arm, developed right facial paralysis preceded by a few days of right ear pain. She was unable to wrinkle her forehead; was treated with steroids, acyclovir and eye drops; and had full resolution after 11-12 days

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**Table 2. Level 1 and 2 Facial paralysis or Facial palsy cases**

Level	AER Initial receipt date Country/Age/Sex Relevant medical hx Batch/Lot	PTs Summary
Level 1	(b) (6) 10 Jan 2021 Israel/23 yrs/Female None reported Not reported	<b>Facial paralysis, Pain in extremity</b>  On the same day of her first dose of vaccine in unspecified arm, developed pain in right ear and weakness in right facial muscles with difficulty in eating, closing the right eye and blurriness and lacrimation. She had diminished sensation in right face and decreased sense of taste; forehead had about 50% movement and labs were normal; treated with steroids and eye ointment; outcome unknown at time of report
Level 1	(b) (6) 07 Jan 2021 US/61 yrs/Male Glucose intolerance EK5780	<b>Facial paralysis, Lacrimation increased, Vision blurred</b>  5 days following vaccination in left arm, developed weakness, swelling and sagging on left side of face, eye tearing and water leaking out of mouth. He was unable to raise his left eyebrow; was treated with steroids, acyclovir and tetracycline; had not recovered by the time of report
Level 1	(b) (6) 06 Jan 2021 US/35 yrs/Female No EH9899	<b>Facial paralysis, Hypoaesthesia oral, Paraesthesia oral, Pain in extremity, Tachycardia, Blood pressure increased</b>  On the same day as vaccination in left arm, developed numbness of tongue and left sided facial palsy. She was unable to raise her left eyebrow; was treated with steroids and valacyclovir; had not recovered by the time of report
Level 1	(b) (6) 28 Dec 2020 Israel/75 yrs/Male L-sided facial palsy (1984) Not reported	<b>Facial paralysis</b>  On the same day as his first vaccination (arm unspecified), developed right-sided facial paralysis. He had asymmetry in forehead wrinkles; was treated with steroids and eye drops; had not recovered at the time of report
Level 2	(b) (6) 08 Jan 2021 UK/43 yrs/Female Concomitant influenza vaccination EJ0553	<b>Fatigue, Nausea, Facial paralysis, Vaccination site pain, Vaccination site swelling, Headache, Pyrexia, Palpitations, Myalgia, Vaccination site erythema, Spinal pain, Sensory disturbance, Pyrexia</b>  On the same day as her influenza and COVID-19 vaccine (arm not specified), developed a 'mild facial palsy' with intermittent facial paraesthesias; she had a negative COVID-19 swab 6 days after vaccines; the palsy resolved within 2 days

The remaining 113 cases are assessed as Category 4 because they report facial nerve palsy without provision of enough detail to exclude known causes by clinical history, physical exam, labs or imaging.

Of the 113 cases, 102 are coded with PT Facial paralysis, 8 with PT Facial paresis and 3 with both PT Facial paralysis and Facial paresis. The majority of the reports are from the US (57) and UK (32), followed by Israel (8), Romania (3), Germany (2), Cyprus (2), and

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Afghanistan, Croatia, Czech Republic, Italy, Portugal, Puerto Rico, Spain, Sweden and UAE (1 each).

Of the 113 cases, 109 are serious and 4 are non-serious. None are reports of death. Of the 103 cases with information on sex, 76 are female and 27 males. Of the 93 cases reporting age, the range was from 20 to 90 years (mean 49.4, median 48).

Latency was not specified in 22 of the reports, but of the remaining reports,

- 29 patients reported symptoms beginning on the same day as vaccination,
- 57 patients reported symptoms beginning between 0-3 days after vaccination
- 17 patients reported symptoms beginning between 4 and 7 days after vaccination
- 17 patients reported symptoms from 8 to 16 days after vaccination.

A minority of the cases (21) provide information on a diagnostic work-up. Fourteen patients were tested for COVID-19 (all negative), 10 had head imaging (MRIs or CT scans) and 5 had had other lab work.

Treatment was described in 39 patients with 35 receiving steroids (13 of which also received antivirals), 2 patients receiving unspecified medication, 1 receiving aspirin and 1 receiving diphenhydramine. Five of the 39 patients also used eye drops.

In terms of outcome, 52 patients had not recovered at the time of the report, 14 were recovering at the time of the report and 30 outcomes are unknown, Seventeen patients recovered by the time of the report (2 with sequelae); 6 of the 17 recovered in < 1 day , 4 within 3 days and 1 within 2 weeks.

### **3.2. Unblinded clinical study data**

Unblinded clinical study data from C4591001 (data-lock 14 Nov 2020) supporting the initial regulatory submission documents for BNT162b2 included 4 cases of facial paralysis in the vaccine group and none in the placebo group in a total safety population of 43,252 participants. In 3 participants, facial paralysis occurred, respectively, on Day 3, Day 9 and Day 48 following dose 2 and in 1 participant, facial paralysis occurred on Day 37 after dose 1. Three of the participants recovered and the remaining case was recovering at the last follow-up.

## **4. EPIDEMIOLOGY**

The MAH conducted unadjusted observed to expected ratio (O/E) analyses for the 119-facial palsy/paralysis cases meeting Level 1-4 Brighton definition criteria.

Expected case counts were derived using two estimated background incidence rates,

1. a rate of 28.3/100,000 PY from a European review paper and

2. a rate of 84.8/100,000 PY derived from Pfizer internal analyses of US electronic health record database.

An estimated 35,291,860 doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 31 January 2021. This estimate was derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized.<sup>5</sup> For periods when more than one vaccine was authorized for use in each country, the doses administered were assumed to be divided equally by the number of vaccines approved. This estimate does not reflect exposure in persons vaccinated in countries that did not publicly report.

Expected counts were determined assuming 4 risk periods of variable duration reflecting different assumptions regarding the anticipated interval between the vaccination and the potential event: 3, 7, and 21 days and total duration of follow up. Of note, within each period, the same number of observed cases is used across all risk periods and includes all events reported, regardless of proximity of event to date of vaccination.

**Table 2. Observed to Expected Ratio of Spontaneously Reported Bell's palsy (Brighton Level 1-4) through 31 Jan 2021**

Cumulative (N=119)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
23.840/100,000 PY <sup>a</sup>				
Expected cases	66.3	141.7	304.6	370.3
O/E	1.796	0.840	0.391	0.321
(95% CI)	1.488, 2.149	0.696, 1.005	0.324, 0.468	0.266, 0.385
84.800/100,000 PY <sup>b</sup>				
Expected N	235.7	503.9	1083.4	1317
O/E	0.505	0.236	0.110	0.090
(95% CI)	0.418, 0.604	0.196, 0.283	0.091, 0.131	0.075, 0.108

a. Willame, et al 2021

b. Study C4591004

The ratio of observed to expected cases exceeds 1 and the lower level of the 95% CI is higher than 1 in the analyses using the (lower) European review paper background rate and a 3-day risk window, suggesting a higher than expected count. Importantly, all observed cases in the numerator of the ratio using the 3-day window for person time to generate the expected count, are assumed to have started within 3 days of vaccination, regardless of the actual time to onset.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an

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underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are more likely to be reported and potentially reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, the background rates used in this analysis are derived from one large US electronic health records database, one large US insurance claims database, or literature review. It is possible that the delivery of health care, population demographics, and underlying health status of the US populations included in the background rate estimates differ from those expected in the persons administered the vaccine. However, to date, the majority of exposure derives from the US. Further, sensitivity analysis was conducted to demonstrate the range of event rates depending on the case definitions among population for background rate calculation.

A final limitation concerns the time at risk for a given event during which an excess of risk occurs in the case of causal association. Three periods (3 days, 7 days, and 21 days) were selected to provide a range of evaluation (i.e. sensitivity analyses) for the number of expected cases, however, observed cases were included regardless of proximity to vaccination which may lead to overestimate if the observed cases occurred outside of the risk period.

## 5. SUMMARY AND CONCLUSION

The clinical study cases of facial paralysis are unbalanced (vaccine > placebo) but the frequency is not higher than an expected background rate of the event. Very few of the spontaneous reports of facial paralysis and facial palsy provide detail about any diagnostic work-up performed on the patients so no conclusions can be made about etiology of the palsy. Most patients who were treated, appeared to be treated empirically. Most occurrences were reported to occur within 0-3 days of vaccination. A time to onset of 1 day or less makes an immune process a less likely contributor to the facial nerve dysfunction. The most conservative O/E analysis (risk window of 3 days, use of lowest background rate) suggests an observed count greater than expected. Overall, the data provides inconclusive evidence of a causal association with BNT162b2. Further evaluation is planned once the remaining clinical study data is available and consultation with a neurology expert is anticipated to gather more insight.

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- <sup>1</sup> Rath, Barbara et al. Facial nerve palsy including Bell's palsy: Case definitions and guidelines for collection, analysis and presentation for immunization safety data. *Vaccine* 35 (2017): 1972-1983
- <sup>2</sup> Mutsch M, Zhou W, Rhodes P, et al. Use of the Inactivated Intranasal Influenza Vaccine and the Risk of Bell's Palsy in Switzerland. *New England Journal of Medicine*. 2004;350(9):896-903.
- <sup>3</sup> Tseng H-F, Sy LS, Ackerson BK, et al. Safety of Quadrivalent Meningococcal Conjugate Vaccine in 11- to 21-Year-Olds. *Pediatrics*. 2017;139(1):e20162084.
- <sup>4</sup> Lima MA, Silva MTT, Soares CN, et al. Peripheral facial nerve palsy associated with COVID-19. *J Neurovirol*. 2020;10.1007/s13365-020-00912-6.
- <sup>5</sup> <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates> (accessed 02 January 2021).

**RESPONSE TO SWISSMEDIC SAFETY QUERY**

**(b) (6) (ARGUS # (b) (6) ) RE THROMBOCYTOPENIA**

**2021-01-29 68225 COMIRNATY CASE OF THROMBOCYTOPENIA**

**February 2021**

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## INTRODUCTION

Reference is made to Swissmedic request received 29 Jan 2021 regarding case (b) (6) (b) (6) (Argus # (b) (6)). This was a non-fatal serious case, of which Pfizer had received a report from Swissmedic via E2b on 28 January 2021. The case is the hospitalization of a 77-year old male patient for further investigation of a newly-developed progressive severe thrombocytopenia (Tc 28 G/l) on 12 January 2021.

Swissmedic states that in this one case of thrombocytopenia reported in Switzerland, there is a plausible temporal correlation of 8 days for the occurrence of the medical condition with regards to the administration of Comirnaty. The relationship was classified as “possible”, due to additional international reports (N=11 reports including one death [a 56-year-old man] who developed acute severe ITP shortly after the Covid-19 vaccination (Pfizer-BioNTech) and died 16 days after the vaccination from the consequences of ITP).

## SWISSMEDIC REQUEST

*Please provide us by February 5, 2021 a safety report including a statement on the observed cases and the need to take any possible measures.*

## SPONSOR RESPONSE

This response provides background information on immune thrombocytopenia, presents data on reports of thrombocytopenia from BNT162b2 clinical study C4591001 and the Pfizer global safety database and presents epidemiological data on immune thrombocytopenia. Taking into account the millions of doses of BNT162b2 administered, the absence of a signal for thrombocytopenia in the non-clinical and clinical studies and the cases of thrombocytopenia in the post-authorization setting in the context of the epidemiological data presented, a causal association between thrombocytopenia and BNT162b2 cannot be concluded at this time.

## BACKGROUND

Primary immune thrombocytopenic purpura (ITP), or immune thrombocytopenia is an autoimmune disorder, caused by antibody and possibly T-cell-mediated platelet destruction by tissue macrophages and suppression of platelet production. It is characterized by isolated thrombocytopenia in the absence of other causes or disorders that may be associated with thrombocytopenia. The most important clinical risk of primary ITP is an increased risk of bleeding, although bleeding symptoms may not always be present<sup>1</sup>

Primary ITP is a diagnosis of exclusion in which nonimmune causes of thrombocytopenia must first be excluded.<sup>1</sup> Secondary forms of ITP can occur with autoimmune connective tissue diseases, lymphoproliferative disorders, and acute and chronic infections. Mild-to-moderate thrombocytopenia is frequently reported in patients with systemic lupus erythematosus, although severe thrombocytopenia is rare. In addition, there are case reports and case series describing ITP in patients with other autoimmune connective tissue and rheumatologic disorders including Sjogren’s syndrome, rheumatoid arthritis, and antiphospholipid antibody syndrome. The role of an infectious agent in the induction of adult

chronic ITP has been studied and confirmed, and recent studies have provided evidence that chronic infections with *H pylori* and hepatitis C can also initiate ITP<sup>2</sup>

The age-adjusted prevalence of ITP is estimated to be 9.5 per 100,000 in the United States.<sup>3</sup> In a study involving hematologists in Oklahoma, the average annual prevalence was 11.2 per 100,000.<sup>4</sup> Epidemiologic studies on ITP suffer from a lack of a uniform definition of the disease that would allow for reasonable comparisons between published studies. This may explain the widely different estimates of ITP prevalence in populations ranging from 5.6 to 20 per 100,000.<sup>2</sup>

## IMMUNE THROMBOCYTOPENIA AND VACCINATION

An association between live virus vaccines, mainly MMR (measles, mumps and rubella) vaccination, and ITP has been widely described in the literature. The absolute risk of developing ITP after MMR vaccine is estimated to be approximately 1 in 21,000–100,000 inoculations. ITP associated with vaccination is generally a mild disease, with few serious bleeding episodes or long-term sequelae.<sup>5</sup> ITP can also occur after vaccination against pneumococcus, *Haemophilus influenzae B*, varicella zoster virus, and hepatitis B. The immunological response may generate antibodies that cross-react with platelet antigens or immune complexes that bind to platelet Fc receptors, or thrombocytopenia may be due to infection of megakaryocytes or progenitors or result from peripheral consumption of platelets. More than 80% of patients recover within 2 months, typically within 2 to 3 weeks, with fewer than 10% evolving into chronic ITP.<sup>1</sup>

## THROMBOCYTOPENIA AND COVID-19

Thrombocytopenia has recently been described as a frequent feature during the pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), identified in up to 36% of patients. The severity of thrombocytopenia has since been linked to the severity of COVID-19 and to its mortality. It was also a frequent feature of the SARS-CoV-1 infectious epidemic of 2003 when it was reported in 40–50% of the patients.<sup>6</sup>

Several pathophysiological processes leading to thrombocytopenia with COVID-19 have been proposed. Viral infection and inflammation results in lung damage, and damaged lung tissues and pulmonary endothelial cells may activate platelets in the lungs, leading to aggregation and formation of microthrombi, which increases platelet consumption.<sup>7</sup> Direct infection of bone marrow cells by the virus inhibits platelet synthesis, and pro-inflammatory mechanisms including cytokine and chemokine release may result in an increase of platelet consumption and destroy bone marrow progenitor cells leading to a decrease in platelet production.<sup>6,7</sup> Thrombocytopenia might also result from immunological peripheral destruction of platelets, as demonstrated in viral infections including HIV and Hepatitis C, and cases of ITP associated with SARS-CoV-2 infection have recently been reported. Although ITP appears to be rare in COVID-19, it is an important complication that can lead to disability and higher mortality.<sup>6,8</sup>

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## RESULTS – CLINICAL STUDY CASES

There were no reports of ITP reported in the unblinded safety data included in the Emergency Use Application (data cut off 14 November 2020). In a blinded review of the clinical database as of 19 January 2021 there were 3 reports of thrombocytopenia without a diagnosis of ITP, all serious and all assessed as non-related. One SAE (Patient ID: 10871121) was associated with cirrhosis, the next case (Patient ID: 11701217) was associated with cellulitis (non-serious), and in the final serious case (Patient ID: 11161045) there was no definitive cause identified. Specifically, the participant is a 66-year-old man without significant medical history who completed 2 doses of blinded study vaccine and presented with shortness of breath and chest pain. Upon evaluation the participant reported that he had 4 months of rectal bleeding. The patient's medical history was corrected in the clinical study database to note that the participant's rectal bleeding initiated prior to vaccination dose #1.

Upon evaluation 39 days after his last vaccination, he was found to be anemic (Hgb 4.7 gm/dl; normal range 14.0-17.4 gm/dl) and thrombocytopenic ( $20 \times 10^3$ ; Normal range  $150-400 \times 10^3$ ). He received transfusions of packed RBC and platelets. A colonoscopy did not show significant finding. An EGD found esophageal candidiasis. A bone marrow biopsy was reported as clinically insignificant. He tested negative for COVID-19.

## RESULTS – POST-AUTHORIZATION CASES

The Pfizer safety database was searched for spontaneously reported BNT/Pfizer COVID-19 post-authorization vaccine adverse event reports containing PTs under the HLT Thrombocytopenias (MedDRA v 23.1) that have been reported to 30 January 2021. This search strategy includes immune thrombocytopenia and thrombocytopenia (non-specific). Eighteen (18) case reports were retrieved from a total of 21,496 spontaneous reports in the database.

The 18 cases were individually reviewed and assessed using the Brighton Collaboration<sup>10</sup> diagnostic criteria for thrombocytopenia. The case definition of thrombocytopenia (TP) as an adverse event following immunization proposed by this working group is summarized below:

### Level 1 of diagnostic certainty (confirmed TP):

Platelet count less than  $150 \times 10^9/L$

And confirmed by blood smear examination or the presence of clinical signs and symptoms of spontaneous bleeding.

### Level 2 of diagnostic certainty (unconfirmed TP):

Platelet count less than  $150 \times 10^9/L$

### Level 3 of diagnostic certainty:

Not applicable

Of the 18 cases, 10 cases were assessed as BC Level 1, 5 as BC Level 3 and 3 cases were determined to be non-contributory to the evaluation.

The 3 non-contributory cases are:

1. AER (b) (6) was found to be a duplicate report to AER (b) (6)
2. AER (b) (6) described a 59-year-old man in the US who did not report thrombocytopenia following vaccination with BNT162b2, rather, despite his medical history of thrombocytopenia he received vaccination on 04 Jan 2021 and had no adverse effects.
3. AER (b) (6) described a 21-year-old woman in the US who developed a rash on her legs 4 days following vaccination that “was similar to that seen with thrombocytopenia.” No actual thrombocytopenia was reported to have occurred.

The remaining 15 cases are described below.

**Table 1. Brighton Collaboration Diagnostic Certainty Assessment of Level 1 (10 cases)**

AER	PTs
<b>Initial receipt date</b>	
<b>Country/Age/Sex</b>	<b>Case Summary</b>
<b>Batch/Lot</b>	
1	<b>Immune thrombocytopenia, Epistaxis</b>
(b) (6)	
28 Jan 2021	This patient with a history of macrocytic anemia of unknown etiology, chronic renal failure, coronary artery disease, hypertension, valvular cardiomyopathy and transient thrombocytopenia in 2018, 2019 and 2020 was taking atorvastatin, bisoprolol, phenprocoumon, ramipril, tamsulosin and torasemide. He received BNT162b2 vaccine on 04 Jan 2021 and was admitted to the hospital for thrombocytopenia following a nosebleed and the appearance of mucosal petechiae. On 12 Jan, his platelets count was 28K (17 Nov 2020 platelet count was 166K). On 14 Jan, he had a bone marrow aspiration (no evidence of myelodysplastic disease or infiltrative process) and due to the peripheral consumption of thrombocytes was thought to have immune thrombocytopenia. He was treated with IVIG and PO prednisone 100 mg (course not specified) and was able to be discharged on 16 Jan in good condition. According to the reporter there was no indication of an infection, autoimmune disease or a drug-related cause. His platelet count nadir was 17K on 13 Jan and on 19 Jan his platelet count was 183K.
Switzerland/77/Male	
EJ6796	

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**Table 1. Brighton Collaboration Diagnostic Certainty Assessment of Level 1 (10 cases)**

AER	PTs
<b>Initial receipt date</b>	
<b>Country/Age/Sex</b>	<b>Case Summary</b>
<b>Batch/Lot</b>	
2	(b) (6)
25 Jan 2021	<b>Cardio-respiratory arrest, Depressed level of consciousness, Atrial fibrillation, Renal failure, Thrombocytopenia, Acute respiratory failure, Confusional state, Fall, Arrhythmia supraventricular, Dysarthria, Cognitive disorder, Malaise, Anxiety</b>
France/96/Female	This patient with multiple co-morbidities including osteoporosis, kyphoscoliosis, narrow cervical spinal canal (quadriplegia), hypothyroidism, junctional tachycardia, malnutrition, on Vitamin D, gabapentin, levothyroxine and zopiclone received BNT162b2 vaccine on 07 Jan 2021. On 08 Jan, she experienced confusion and anxiety. On 12 Jan, she had atrial fibrillation (rate 150) alternating with sinus bradycardia and cardiorespiratory decompensation (O2 saturation 60%). On 15 Jan, she had renal failure, hyperkalemia, hyponatremia and thrombocytopenia (96K). On 16 Jan, she had dyspnea and on 17 Jan, she died. Of note, she had a negative COVID-19 CRP test on 15 Jan
EJ6795	
3	(b) (6)
22 Jan 2021	<b>Thrombocytopenia</b>
UK/78/Male	This patient with a history of coronary artery disease and diabetes received BNT162b on 08 Jan 2021. He had had his influenza vaccination on 14 Sep 2020. On 20 Jan, he had thrombocytopenia (2K) from a reportedly normal platelet count on an unspecified date. No further details were provided, and the outcome was not recovered.
Not reported	
4	(b) (6)
22 Jan 2021	<b>Thrombocytopenia</b>
UK/78/Male	This patient with a history of Type 1 diabetes and an immunodeficiency on insulin received BNT162b2 on 08 Jan 2021. On 20 Jan, he had a platelet count of 2K and was hospitalized for platelet transfusion and steroid treatment. Outcome was not recovered.
Not reported	
5	(b) (6)
22 Jan 2021	<b>Thrombocytopenia</b>
UK/Not reported/Male	This patient with no reported age nor medical history received BNT162b2 on an unspecified date and was admitted to the hospital on 21 Jan with a platelet count of 2K. Outcome was unknown.
Not reported	NOTE, The UK DSU has been asked if (b) (6), (b) (6) and (b) (6) may be duplicate reports

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**Table 1. Brighton Collaboration Diagnostic Certainty Assessment of Level 1 (10 cases)**

AER	PTs	
Initial receipt date		
Country/Age/Sex	Case Summary	
Batch/Lot		
6	(b) (6)	<b>Thrombocytopenia, Cerebrovascular accident, Cerebral haemorrhage, Brain injury, Memory impairment</b>
21 Jan 2021		
US/39/Female		This patient, a physician, with no medical history received BNT162b2 on 18 Dec 2020 and on 30 Dec had a stroke due to an intracranial bleed reported to be due to thrombocytopenia (platelet count 36K). She received 6 units of blood and 4-5 units of platelets. Approximately 7 days later, the thrombocytopenia resolved however the patient is having trouble remembering things due to the brain injury. She has recovered with sequelae. Of note, it was reported that she was not diagnosed with COVID-19 prior to the vaccine nor had she had antibody testing.
EJ1685		
7	(b) (6)	<b>Immune thrombocytopenia, Off label use, Product use issue, Petechiae, Ecchymosis, Platelet count decreased</b>
19 Jan 2021		
US/31/Female		This patient, a nurse, with a history of eczema on no medications had dose 1 of BNT162b2 on 23 Dec 2020 and dose 2 on 09 Jan 2021. On 15 Jan she went to the emergency room due to petechiae and ecchymoses and was found to have a platelet count of 22K. She was treated with pulse dexamethasone 40mg/day for 4 days and her platelet count increased to 230K.
Not reported		
8	(b) (6)	<b>Immune thrombocytopenia, Petechiae, Contusion, Thrombocytopenia, Fall</b>
18 Jan 2021		
UK/35 y/Male		This patient, a physician, with a history of mild seasonal asthma treated with salbutamol and beclomethasone inhaler and possible allergy to NSAIDs (lip swelling), received BNT162b2 on 17 Dec 2020. On 27 Dec, he had a minor fall and developed a large bruise on his back. On 28 Dec, blood tests showed normal clotting indices, Hgb and WBC but platelets of 6K. He consulted with a hematologist and started 60 mg of prednisolone daily. On 29 Dec, he had lower extremity petechiae and his platelets were 3K. He had no active bleeding and was not hospitalized. He continued steroids and a repeat platelet count (unspecified day) was normal (253K). His hematology tests including viral screen, autoantibodies, lactate dehydrogenase and blood film were normal. A COVID-19 test on 30 Dec was negative. An abdominal US was normal. He planned to follow-up with hematology to investigate other possible etiologies of thrombocytopenia, but the hematologists thought it was ITP, likely due to the vaccine. His steroids were tapered slowly. He was recovering from the events
EJ0553		

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**Table 1. Brighton Collaboration Diagnostic Certainty Assessment of Level 1 (10 cases)**

AER	PTs
Initial receipt date	
Country/Age/Sex	Case Summary
Batch/Lot	
9	(b) (6)
15 Jan 2021	<b>Posterior reversible encephalopathy syndrome, Upper gastrointestinal haemorrhage, Haemorrhage intracranial, Thrombocytopenia, Central vision loss</b>
UK/82 y/Male	This patient, who was taking the following concomitant medications: metformin, beclomethasone/formoterol fumarate inhaler, ramipril, omeprazole, furosemide, allopurinol, apixaban, bisoprolol, prednisolone, cefalexin, ferrous sulfate, gliclazide, thiamine and simvastatin and was on Day 3 of cephalexin for an acute urinary tract infection, received BNT162b2 on 16 Dec 2020. On the night of 16 Dec, he developed central vision loss. He was hospitalized on 17 Dec and tests showed: Hgb 48, platelets 12K, CT head with intracranial bleed, MRI head showed posterior reversible encephalopathy syndrome with a small focus of acute hemorrhage. He was also diagnosed with an upper GI bleed. It was unknown if the thrombocytopenia resolved.
Not reported	
10	(b) (6)
05 Jan 2021	<b>Immune thrombocytopenia, Haemorrhage intracranial, Cerebral haemorrhage, Hemorrhagic stroke</b>
US/56 y/Male	This patient, a physician, with a history of hypertension and no history of COVID-19, and on no medications, received dose 1 of BNT162B2 on 18 Dec 2020. On 21 Dec, he presented to the ED due to bruising on his hands and feet and generalized small blood tinged spots on his body for 2 days. He had no other symptoms. He was found to have a platelet count of <1K. He was admitted for Idiopathic Thrombocytopenic Purpura (ITP) and received treatment for 2 weeks including platelet transfusions, IVIG, steroids, rituximab and eltrombopag. His platelet count remained low and on 03 Jan, he was reported to have had an emergency splenectomy. On the same day, he had an intracranial bleed and a craniectomy but died due to the intracranial bleed. An autopsy was performed on 05 Jan, results were not provided. He had a SARS-CoV-2 test while hospitalized and results were unknown although it was reported that he never had COVID-19.
EH9899	

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**Table 2. Brighton Collaboration Diagnostic Certainty Assessment of Level 3 (5 cases)**

AER		PTs
	Initial receipt date	Case Summary
	Country/Age/Sex	
	Batch/Lot	
1	(b) (6)	<b>Immune thrombocytopenia</b>
	22 Jan 2021	This patient of unspecified age and gender with a history of cardiac transplant and immune thrombocytopenia received BNT162b2 on an unspecified date and 2 days later had immune thrombocytopenia with an unreported platelet count. No further details were reported. The outcome is unknown.
	France/Not reported/Not reported	
	Not reported	
2	(b) (6)	<b>Thrombocytopenia</b>
	21 Jan 2021	This patient with a history of hypothyroidism and splenectomy received BNT162b2 on an unspecified date. On the same day, she had a nosebleed, bleeding gums and bruising of her arms. She was diagnosed with immune thrombocytopenia and treated with romiplostim. No further details were reported.
	UK/Not reported/Female	
	EK4243	
3	(b) (6)	<b>Death, Immune thrombocytopenia</b>
	19 Jan 2021	This report contains little information. A patient of unspecified age, gender with an unspecified medical history received BNT162b2 on an unspecified date and died on an unspecified date after developing acute immune thrombocytopenia on an unknown date. It was unknown if an autopsy was performed and the cause of death was unknown. The reporter questioned if someone with a platelet condition like essential thrombocytosis should be vaccinated. This case will be updated if additional information is received.
	US/Not reported/Not reported	
	Not reported	
4	(b) (6)	<b>Thrombocytopenia, Pulmonary embolism, Febrile neutropenia</b>
	09 Jan 2021	This patient of unspecified age and gender, with an unspecified medical history experienced thrombocytopenia, pulmonary embolism and neutropenia on an unspecified date following vaccination with BNT162b2. The patient died. It is not known if an autopsy was performed. Attempts have been made to obtain additional information, but none has been received at the time of this writing; the case will be updated if additional information received.
	US/not reported/not reported	
	Not reported	

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**Table 2. Brighton Collaboration Diagnostic Certainty Assessment of Level 3 (5 cases)**

AER		PTs
Initial receipt date		Case Summary
Country/Age/Sex		
Batch/Lot		
5	(b) (6)	<b>Immune thrombocytopenia, Thrombotic thrombocytopenic purpura</b>
21 Dec 2020		This patient with no medical history or history of COVID-19, received dose 1 of BNT162B2 on 17 Dec 2020. On 20 Dec 2020, he went to the emergency room for unreported symptoms and was found to have severe Idiopathic thrombocytopenic purpura (ITP). It was further reported that on 21 Dec he had thrombotic thrombocytopenic purpura (TTP). He was treated with steroids and platelet transfusions. A COVID-19 test on 21 Dec 2020 was negative. He was hospitalized for 3 days; his platelet count was reported to have returned to normal.
US/22 y/Male		
Not reported		

**EPIDEMIOLOGY ANALYSES**

Observed versus expected analyses were conducted to compare the number of observed events in the spontaneous adverse event reporting database to the expected number of events in a background population for a given duration of person years of follow up, under the null hypothesis of no association with the vaccine.

Based on an estimate of nearly 34 million BNT162b2 vaccine administrations as of 30 January 2021 for 1,456,409. 8 person years of total follow up, observed to expected analyses were conducted.<sup>8,9,10,11,12</sup> Analyses assumed a background rate of 3.3 incident<sup>13</sup> events of immune thrombocytopenia per 100,000 PY, independent effects of first and second dose, and equal proportions of authorized vaccines if multiple vaccines were authorized for use. The crude ratio of the count of observed cases (n=1) to expected cases was determined using person time accrued during the 3-, 7-, and 21-day risk windows after vaccination resulting in ratios of 11.71 ( 95% CI: 0.96 – 2.82, n<sub>expected</sub> = 8.8), 0.80 (95% CI: 0.45 – 1.32, n<sub>expected</sub> = 18.7) and 0.38 (95% CI: 0.21 – 0.62, n<sub>expected</sub> = 39.9).

Although the O/E ratio exceeds 1 under the 3-day risk window assumption, the lower limit of the 95% CI does not exceed 1 for any of the risk windows, indicating that the observed count is not higher than expected. Regardless of the risk window all 15 cases were included in the numerator, however of the 13 cases for which time to onset was reported, 5 occurred within 3 days, 1 between 4 and 7 days and 7 between 8 and 21 days.

There are several limitations to consider when interpreting these analyses. The analyses did not adjust for differences in characteristics between persons being administered the vaccine and populations from which the background rate is derived such as age and comorbidities. At this time, national/local guidelines typically recommend prioritizing vaccine administration

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for healthcare workers at high-risk of COVID-19 exposure and persons with underlying conditions who are at risk of serious COVID-19 illness, including the elderly and those with underlying health conditions. The spontaneous reports system likely underestimates the true number of observed events in vaccinated persons due to incomplete reporting or a lag in reporting.

On the other hand, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine, eg, due to news media reports, are more likely to be reported than other events. With respect to the expected number of events, estimates concerning both exposure to vaccine and the background rate have limitations. This exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the total person years of vaccine exposure used to determine the expected count of events is potentially underestimated.

Further, the delivery of health care, population demographics, and underlying health status of the populations included in the background rate estimates differ from those expected in the persons administered the vaccine.

## SUMMARY AND CONCLUSION

The clinical study cases of thrombocytopenia were not conclusive for a diagnosis of ITP. The investigators all thought the events were not related to the blinded vaccine administration. In the one case where Pfizer does not have a definitive cause specified (Patient ID: 11161045), the rectal bleeding for 4 months would have pre-dated vaccination. The time course is consistent with the profound anemia (Hgb 4.7 gm/dl) found upon presentation. Additionally, the presence of esophageal candidiasis in the case is an unusual finding in a normal healthy person not on immunosuppressive therapy. HIV and hepatitis C testing are indicated for further evaluation.

As of 30 January 2021, there were 18 post-authorization reports of thrombocytopenia in the safety database which contained a total of 21,496 AE reports for BNT162b2. Three of the 18 reports were non-contributory to this assessment. AER (b) (6) appears to be a duplicate to AER (b) (6) and neither AER (b) (6) nor AER (b) (6) describe thrombocytopenia following vaccination. Of the remaining 15 reports, it is possible that 3 of them are describing the same patient based on the details provided (AER (b) (6), AER (b) (6) and AER (b) (6)).

Of the 10 Level 1 cases, 5 were from the UK, 3 from the US, and one each from France and Switzerland. Ages were provided in 9 cases and ranged from 31 to 96 years of age; there were 3 females and 7 males. Three intracranial bleeds were reported and 2 deaths due to bleeding. The remaining outcomes were recovered (4), not recovered (2) or unknown (2). Nadir platelet counts in the cases ranged from <1K to 96K and latency from vaccination to thrombocytopenia ranged from <1 day to 12 days. At least 6 of the patients had co-morbidities, including an elderly man who was on a course of antibiotics for a UTI. The remaining patients were reportedly healthy prior to the thrombocytopenia. It is not known if any of the patients had other propensities toward thrombocytopenia, for example, recent viral

infection, undiagnosed autoimmune disorder, or family history of thrombocytopenia indicating a hereditary disorder.

Of the 5 Level 3 cases, 3 were from the US, 1 from the UK and 1 from France. Age was only reported in 1 case (22 years) and sex was reported in 2 cases (1 male, 1 female). Outcome was only reported in 1 case (recovered). Latency from vaccination to thrombocytopenia was reported in 3 cases (same day, 2 days and 3 days). AER (b) (6) (PTs Thrombocytopenia, Pulmonary embolism, Febrile neutropenia) does not provide a platelet count and based on the PTs coded, is unlikely to represent ITP. AER (b) (6) (PTs Immune thrombocytopenia, Thrombotic thrombocytopenic purpura) does not provide a platelet count and is coded with two very different platelet disorder terms, however, based on the treatment (steroids and platelet transfusion) and recovery described, seems more likely to be ITP than TTP. AER (b) (6) describes a history of splenectomy for unspecified reasons which may include a history of thrombocytopenia.

The number of reports of life-threatening thrombocytopenia do not exceed the expected background rate. However, underreporting of adverse events is a known limitation of passive surveillance systems. Taking into account the millions of doses administered, the absence of a signal for thrombocytopenia in the non-clinical and clinical studies and the number and strength of thrombocytopenia cases in the post-authorization setting in the context of the epidemiological data presented, a causal association between thrombocytopenia and BNT162b2 cannot be concluded at this time. This topic will continue to be monitored and changes to the vaccine safety information will be proposed if warranted. The benefit risk of the vaccine remains favorable.

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## CUMULATIVE REVIEW OF DIARRHOEA AND VOMITING

### 1. INTRODUCTION

As per the Assessment report request: “It is not accepted to close Diarrhoea and Vomiting as signals. Both vomiting and diarrhoea have been reported in some Norwegian fatal cases. Note that Nausea is currently labelled as common adverse reaction in SmPC Section 4.8, based on RCT data, and the vaccines effects may be more pronounced/exaggerated in the post marketing setting, especially as an older and more frail population is being vaccinated. The applicant should review the case reports of diarrhoea and vomiting and discuss whether a causal relationship can be established. In particular, the Applicant should evaluate whether these generally non-serious (in healthy subjects) reactions would pose a higher risk on worsened outcome in the particularly frail or elderly patients with underlying morbidities.”

### 2. METHOD

The Pfizer safety database was searched for all BNT162b2 vaccine cases received through 18 January 2021 using the MedDRA version 23.1 PTs Diarrhoea and/or Vomiting.

These PTs were also used to search adverse events in subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the clinical trial Phase 2/3 safety population of ~38,000 participants (with a data cut-off date of 14 November 2020). This included a total of 18,801 subjects receiving BNT162b2 and 18,785 subjects receiving placebo.

### 3. RESULTS

A total of 966 spontaneous cases were retrieved out of a total 14,746 cases (6.7%) from the Pfizer safety database using the search criteria above reporting 573 cases of Diarrhoea and 512 cases of Vomiting.

One hundred sixty-one (161) of these 966 cases reported both of these events.

The most frequently co-reported PTs in 966 cases were: Nausea (395), Headache (345), Pyrexia (272), Chills (248), Fatigue (223), Pain (136), Dizziness (122), Myalgia (111), and Vaccination site pain (99).

There were 764 females, 162 males, and in 40 cases gender was not reported.

Six hundred-seven (607) cases were reported as non-serious and three hundred fifty-nine (359) as serious.

Cases originated mainly from the United States (433), the United Kingdom (387), Germany (27) and Spain (20).

Age’s distribution was as following: Less than or equal to 17 years (3); 18-30 years (143); 31-50 years (376); 51-64 years (198); 65-74 years (46); Greater than or equal to 75 years (109), and age was unknown in 91 cases (mean = 48.1 years; n = 865). An outcome was

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reported as: recovered or recovering in 503 cases, recovered with sequelae in 19 cases, not recovered in 302 cases, fatal in 15 cases, and unknown in 127 cases.

As of note, 58 cases reported limited information on the outcome of the event, concomitant medications, latency, and pre-existing medical history.

When reported, the most commonly reported batch numbers were: EJ0553 (62 cases), EK5730 (48 cases), EH9899 (42 cases), EJ1685 (37 cases), EJ6796 (32 cases), EE8492 (30 cases), EJ1688 (29 cases), EK9291 (25 cases), EL0140 (24 cases), and EE8493 (22 cases).

When reported, the time from vaccination to the onset of events was within the same vaccination day (for 206 events), one day after vaccination day (for 418 events), and two days after vaccination day (for 117 events).

When reported, the duration was reported as following: from 15 minutes to 5 hours 30 minutes (for 20 ), from 6 hours to within 2 days (for 114 events), from within 2 days to 2 days (for 30 events), from 3 days to 4 days (for 20 events ), from 5 days to 15 days (for 11 events ).

The past medical history of pre-existing Gastrointestinal condition (e.g. liver/pancreas related disorders, Crohn/s disease, Irritable Bowel Syndrome, etc..) and/or other conditions which could cause/precipitate diarrhea/vomiting (e.g. different types of cancers, alcoholism, general physical health deterioration) were reported in 78 cases.

As of note, 155 cases reported Elderly population (age is equal or more than 65 years old). Diarrhoea was reported in 92 cases, and Vomiting was reported in 85 cases. The most frequently co-reported events in this elderly dataset were very similar to the co-reported events in the overall dataset described above: Nausea (48), Pyrexia (27), Headache (26), Chills (23), Fatigue (22), Dizziness (15), Pain (14), Malaise (13), Pain in extremity (13) and Vaccination site pain (12).

There were 14 Fatal cases reported for elderly patients; these cases are described in detail in the Table below.

AER number	Age/Gender	PTs/Co-reported PTs	Conmeds	Medical history	Latency	Batch
(b) (6)	unk/unk	diarrhoea/none	unk	unk	unk	unk
(b) (6)	81/F	vomiting; diarrhoea/dyspnoea; depressed level of consciousness; malaise; influenza like illness	apixaban bisoprolol bumetanide lactulose latanoprost morphine sulfate olanzapine pantoprazole paracetamol pivmecillinam hydrochloride ramipril selenium oxide spironolactone	heart attack, cerebral ischaemia, aortic stenosis, atelectasis, osteopetrosis, antidiuretic hormone increased, urinary tract infection, dilated cardiomyopathy , palliative care, atrial	4 days	EJ6796

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				fibrillation, heart failure, gastric acid increased, oedema, pain, pain back, anxiety, glaucoma secondary, obstipation, pacemaker, increased cognitive impairment and possibly dementia, state of health has gradually deteriorated		
(b) (6)	unk/F	vomiting; diarrhoea/none	influenza vaccine	urinary tract infection and delirium,	1 day	EJ1677
(b) (6)	81/fF	vomiting/malaise	unk	vascular dementia (advanced dementia), dementia alzheimer's type (vascular and alzheimer's mixed dementia), oral intake reduced (patient known to not be eating or drinking), fluid intake reduced, (patient known to not be eating or drinking), general physical health deterioration (patient known to be declining)	4 days	EJ1688
(b) (6)	80/F	vomiting/none	unk	vascular dementia, type 2 diabetes mellitus, hypertension, chronic kidney disease stage 3, ischemic heart disease	2 days	EJ1688
(b) (6)	93/F	vomiting/ vaccination site pain; malaise; illness	unk	vascular dementia with frailty, type 2 diabetes mellitus, essential hypertension, claudication in legs	2 days	unk
(b) (6)	79/F	vomiting/none	influenza vaccine about 27 days prior	autoimmune encephalopathy of paraneoplastic origin and suspected	1 day	EJ6796

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				urothelial carcinoma of the bladder		
(b) (6)	79/M	diarrhoea/nausea, blood pressure decreased	unk	cerebral infarction, chronic kidney disease, ongoing diabetes, mild cognitive impairment, pulmonary sarcoidosis, and cardiac arrest	1 day	EJ6795
(b) (6)	90/F	vomiting/confusional state, apathy, decreased appetite, vaccination site inflammation, coordination abnormal, vaccination site swelling	nitroglycerin, oxazepam, metoclopramide, zopiclone verapamil calcium carbonate, colecalciferol and clopidogrel	hypertension, orthostatic hypotension, osteoporosis, heart attack, malnutrition, hypertrophic obstructive cardiomyopathy, transient ischemic attack (tia), dementia (cognitive disorder), non-st-elevation myocardial infarction (nSTEMI) and fractures (falling tendency)	1 day	EJ6795
(b) (6)	85/F	diarrhoea, vomiting/malaise, pyrexia	fentanyl, paracetamol influenza vaccine about 3 months prior	dementia, and vitamin b12 deficiency	1 day	EJ1688
(b) (6)	89/M	vomiting	amlodipine, atorvastatin, isosorbide mononitrate, omeprazole, morphine, prednisone, influenza vaccine (about 3 months prior), ticagrelor, and steroids	metastatic lung neoplasm, myocardial ischaemia, type 2 diabetes mellitus, chronic lymphocytic leukaemia	4 days	EJ0553
(b) (6)	82/F	vomiting/ respiratory rate increased nausea acute coronary syndrome intracardiac thrombus	acetylsalicylic acid, magnesium, levothyroxine, lithium, citalopram, cyanocobalamin, folic acid, pyridoxine and simvastatin	ongoing mental disorder and ongoing hypercholesteremia	1 day	EJ6795
(b) (6)	91/M	vomiting/syncope, malaise, cardiac fibrillation, ventricular fibrillation, arrhythmia	unk	copd (chronic obstructive pulmonary disease), arterial hypotension and diabetes mellitus	1 day	EJ6796

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(b) (6)	80/F	vomiting/ acute kidney injury	unk	chronic renal insufficiency, hypertension, dementia, alcohol abuse, hip prosthesis	unk	EJ6796

In subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the clinical trial Phase 2/3 safety population, diarrhea was reported in 187 subjects (1%) in the BNT162b2 group and 146 subjects (0.8%) in the placebo group; vomiting was reported in 44 subjects (0.2%) in the BNT162b2 group and 28 subjects (0.1%) in the placebo group.

**Cases reporting Serious Events of Diarrhea and Vomiting from Clinical trial C4591001**

There was one (1) SAE of Diarrhoea reported during the study in an 80 year-old female from the United States; Diarrhoea was the only reported event. She received her first dose on 11 August 2020. Her complex medical history included Type 2 diabetes, hypertension, diabetic neuropathy, allergic rhinitis, and chronic constipation, hypercholesterolemia, COPD, hypothyroidism, urinary incontinence, depression, gout, dry mouth, gastroesophageal reflux disease, atrial fibrillation, on concomitant medications for her conditions. She initially reported diarrhea on 17 August 2020 (6 days post Dose 1); no treatment was given at that time. The diarrhea continued of diarrhea- confusion, left side abdominal pain and debility on 27 August 2020; she was hospitalized on the same date. Blood culture was performed, it was not positive and serotyping was not done. There was no antipyretic medication used. She was doing well and had fully recovered on 29 August 2020. She received the 2<sup>nd</sup> dose on 01 September 2020. The investigator did not consider the event related to the vaccine.

**4. CONCLUSION**

In subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the clinical trial Phase 2/3 safety population, diarrhea was reported in 187 subjects (1%) in the BNT162b2 group and 146 subjects (0.8%) in the placebo group; vomiting was reported in 44 subjects (0.2%) in the BNT162b2 group and 28 subjects (0.1%) in the placebo group. There was one SAE of Diarrhoea reported in the CT (recovered; unrelated).

The majority of spontaneous cases were reported in adults from the age of 18 years through 64 years, the most commonly reported outcome for relevant events was recovered or recovering (503 cases), and the majority of the relevant events occurred one day after vaccination (418 event) with duration from 6 hours to within 2 days (114 events).

The most commonly co-reported events were similar between elderly dataset and the overall dataset and included Nausea, Headache, Pyrexia, Chills, Fatigue, Pain, Dizziness, Myalgia, Malaise, Pain in extremity, and Vaccination site pain, most of which are common vaccines reactogenicity events.

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Within elderly dataset, there were 14 fatalities reported for patients, 13 of whom had very complex medical histories, on many concomitant medications which confounded a causality assessment.

Considering the totality of data, based on the information reported from post marketing data, the adverse events of Diarrhoea and Vomiting will be added to the product's label.

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## APPENDIX 3.5 CUMULATIVE REVIEW OF EYE PAIN AND EYE SWELLING

### Method

The Pfizer safety database was searched for all BNT162b2 vaccine cases received through 20 January 2021 using the MedDRA version 23.1 using the search criteria: PT: Eye pain, PT: Eye swelling.

### Results

Overall a total of 144 cases were retrieved using the search criteria mentioned above. Six patients reported both PTs (Eye pain and Eye swelling).

Among them there were 125 female, 24 males and gender was not reported for 7 subjects. Age of the patients ranged from 19 to 89 years (mean (44)). Ten were > 65 years of age and for 12 subjects the age was not reported.

Case outcome was reported as recovered/recovering/recovered with sequelae (?) in 55 patients, not recovered at time of reporting in 85 and unreported in 16 patients. The countries that reported the greatest number of cases are UK (68) and US (65).

A total of 87 cases have been assessed as non-serious and 69 as serious.

Medical history was reported in 92 patients and some of the reported comorbidities were: asthma (12), allergy (13), cardiac disorder (13), thyroid disorder (8), depression (11), diabetes (5), headache/migraine, epilepsy/seizure (2); of note few cases report in the past medical history events that may lead to eye pain/eye swelling (conjunctivitis/Sinusitis, blindness unilateral/cataract/glaucoma, eye disorder, facial paralysis/migraine, Intracranial pressure increased / Papilloedema). Eleven reported COVID-19 infection in the medical history (5 confirmed and 6 suspect).

Time to onset, when reported ranged from the same vaccination day to 15 days after vaccination. Of note the cases that reported longer time to onset were the subjects that presented the symptom associated with facial paralysis (7 cases).

Duration of the event, when reported ranged from 2 hours to 4 days (median 1 day).

The analysis will be divided by single PT.

### EYE PAIN

#### Result

A total of 96 BNT162b2 vaccine AE reports with the PT Eye pain were retrieved using the search criteria mentioned above. Among them 52 cases were assessed as non-serious and 44 as serious. The age was reported for 92 subjects and ranged between 19 to 84 years. Two of the patients were >65 years old and 6 did not report age.

Gender was reported as follows: 76 female, 16 males and unreported gender for 4 patients.

Concomitant medication was reported for 51 patients.

Most cases were reported from UK (45) followed by US (35).

The vast majority of cases (81/96, 84%) reported eye pain either in the context of reactogenic events or hypersensitivity reaction. Specifically: a total of 63 patients reported eye pain in the context of vaccine reactogenic events as headache, pyrexia, nausea, fatigue, pyrexia,

myalgia, asthenia, feeling hot, lymphadenopathy, vomiting among others; while a total of 18 patients reported eye pain in the context of anaphylaxis, angioedema, hypersensitivity reaction.

In a minority of cases (15/96, 16%) eye pain was associated with eye-specific issues (4 cases: episcleritis, iridocyclitis, eye hemorrhage, eye irritation), in 5 cases eye pain was associated with facial paralysis and in 7 cases it was reported either as a only symptom or associated to non-specific symptoms as ear pain, lacrimation increase, muscle twitching, hypoesthesia, neuralgia.

## EYE SWELLING

### Result

A total of 66 BNT162b2 vaccine AE reports with the PT Eye swelling were retrieved using the above-mentioned criteria. A total of 39 cases were assessed as non-serious and 27 as serious. Gender was reported as follows: 54 female, 9 males, for 3 gender was not reported. Medical history was reported for 41 patients among them, of note to mention are the following as may have play a role in the symptomatology: allergy/hypersensitivity (9), asthma (6), hypertension (6), thyroid problems (5), diabetes (3), facial paralysis (1). Four cases reported COVID-19 infection (2 not confirmed). A total of 30 subjects reported concomitant medication.

The age was reported for 60 subjects and ranged between 25 to 89 years and comprise 53 adult, 7 elderly, 6 unknown age.

Most cases were reported from UK (34) followed by UK (25).

A total of 56 cases (56/66, 84.8%) reported eye swelling in the context of allergic reaction, anaphylaxis or angioedema. In 5 cases the eye swelling was associated with other vaccine reactogenic event as myalgia, pyrexia, nausea and in 1 case was associated to nasopharyngitis. Two additional cases reported eye swelling associated with facial paralysis and for 2 subjects, eye swelling was reported either alone or associated with eye ptosis.

### Conclusion

Most cases describing eye swelling were reported in the context of allergic symptoms such as anaphylaxis and angioedema and most cases of eye pain occurred in the setting of vaccine reactogenic events. Few cases reported eye pain or swelling as a component of facial paralysis or specific eye disorders (episcleritis, iridocyclitis, eye hemorrhage).

The analysis of this safety topic does not suggest a causal association as an independent event with BNT162b2 vaccine and no changes to the CDS are warranted.

## **APPENDIX 3.6 CUMULATIVE REVIEW OF PARAESTHESIA AND DYSAESTHESIA**

The MAH is requested to provide cumulative overviews, including details of the time to onset, duration and outcome and an assessment of the causal relationship with the vaccine and a discussion on the need to update the product information, of cases reporting: Paraesthesias and dysaesthesias.

### **1. METHOD**

The Pfizer safety database was searched for all spontaneous BNT162b2 vaccine cases received through 31 January 2021 using the MedDRA version 23.1 PTs Paraesthesia and Dysaesthesia.

In the clinical trial Phase 2/3 study C4591001 unblinded data tables, these PTs were also reviewed in subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the safety population of ~38,000 participants (with a data cut-off date of 14 November 2020). This included a total of 18,801 subjects receiving BNT162b2 and 18,785 subjects receiving placebo.

### **2. RESULTS**

#### **2.1. Paraesthesia**

A total of 1164 spontaneous cases were reported cumulatively through 31 January 2021 reporting a total of 1310 Paraesthesia related PTs: Paraesthesia (868 events), Paraesthesia oral (377 events), Vaccination site paraesthesia (29 events), Pharyngeal paraesthesia (27 events), Intranasal paraesthesia (3 events), Dental paraesthesia (2 events), and Eye paraesthesia, Hemiparaesthesia, Paraesthesia ear, Paraesthesia mucosal (1 each). As of note, some cases reported multiple PTs.

There were 1006 females, 118 males, and in 40 cases gender was not reported.

Six hundred sixty-eight (668) cases were reported as non-serious, and four hundred ninety-six (496) cases were reported as serious.

Cases originated mainly from the United States (434), the United Kingdom (347), Italy (107), and Portugal (35).

Age's distribution was as following: 18-30 years (118); 31-50 years (599); 51-64 years (265); 65-74 years (31); Greater than or equal to 75 years (18), and age was unknown in 133 cases (mean = 44.5 years; n = 1031).

The most frequently (>50) co-reported PTs in these 1164 cases were: Hypoaesthesia (217 cases), Headache (214), Dizziness (167), Fatigue, Nausea (146 each), Pain in extremity (113), Chills (109), Vaccination site pain (96), Dyspnoea (91), Myalgia (88), Pain, Pyrexia (86), Hypoaesthesia oral (77), Asthenia (75), Tachycardia (67), Arthralgia (66), Pruritus (64), Feeling hot (63), Malaise (61), Palpitations (60), Rash (58), Heart rate increased (55), Dysgeusia, Flushing (52 each), and Erythema (51).

When reported, the outcome per the Paraesthesia event was reported as following: recovered or recovering (for 765 events), recovered with sequelae (for 13 events), and not recovered (for 267 events).

The time from vaccination to the onset of Paraesthesia events was within the same vaccination day (for 644 events), one day after vaccination day (for 345 events), and two days after vaccination day (for 39 events); it was longer than 2 days or unknown for the remaining events.

When reported (for 235 events out of 1312 events in total), the duration for Paraesthesia events was as following: from 5 minutes to 1 hour (for 46 events), from 1 hour 15 minutes to within the same day (for 30 events), from 1 day to 2 days (for 137 events), and from 3 days to 2 weeks (for 22 events).

As of note, there was no pattern between the side(s) of the body where Paraesthesia occurred in relation to the side of the body where vaccine was administered.

In subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the clinical trial Phase 2/3 safety population, the following paraesthesia events were reported:

- Injection site paraesthesia (2 in BNT162b2 group vs. 1 in the placebo group);
- Paraesthesia (16 in BNT162b2 group vs. 17 in the placebo group) and
- Paraesthesia oral (2 in BNT vs 2 in placebo group).

## 2.2. Dysaesthesia

A total of 13 spontaneous cases were reported cumulatively through 31 January 2021 reporting Dysaesthesia (13 events) and Oral dysaesthesia (1 event). As of note, one case reported two Dysaesthesia events. There were 11 females and 2 males. Seven (7) cases were serious, and six (6) were non-serious. Cases originated mainly (2 each) from Germany, France, Italy, and the United States.

Age's distribution was as following: 18-30 years (1 case); 31-50 years (8); 51-64 years (4); mean = 45.2 years; n = 13.

The most frequently co-reported PTs in 13 cases (>1) were: Fatigue, Headache, Hypertension, Hypoaesthesia, Pyrexia (2 each).

When reported, the outcome per event was reported as following: recovered or recovering (for 10 events) and not recovered (for 2 events).



The time from vaccination to the onset of events was within the same vaccination day (for 12 events), and three days later (for 2 events). The duration was reported only for 3 events out of 14 events as 15 minutes (1), 30 minutes (1), and 3 days (1).

There were no Dysaesthesia related PTs reported in subjects reporting at least 1 adverse event from dose 1 to 1 month after dose 2 in the clinical trial Phase 2/3 safety population.

### 3. CONCLUSION

Paraesthesia was uncommonly reported by subjects in the clinical study and did not differ in frequency between vaccine and placebo groups. Dysaesthesia was not an AE reported in the clinical trial.

In spontaneous reports, paraesthesia events are more commonly reported than dysaesthesia events. The majority of spontaneous cases for both, paraesthesia and dysaesthesia events, were reported in adults 18 years through 64 years, reflecting the current targeted population for vaccination in most regions.

The majority of the paraesthesia events (765 out of 1316 events) and dysaesthesia events (10 out of 14 events) reported an outcome as recovered by the time of reporting and were not long-lasting.

The majority of the events occurred soon after vaccination, and paraesthesias were largely reported with AEs that reflect systemic reactogenicity events (e.g. headache, fatigue, nausea, myalgia, chills, pyrexia), mild hypersensitivity events (e.g. rash, pruritus), and in many cases, stress or anxiety events (e.g. palpitations, tachycardia, heart rate increased, flushing). Serious neurological events do not appear to be associated with the reports of paraesthesia and dysaesthesia.

Considering the totality of the data, including the number of reports received in the context of the millions of doses of vaccine administered, the MAH will monitor dysaesthesia and paraesthesia related events and will revise the product's labeling documents if an evaluation of the data yields significant new information.

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**APPENDIX 4. CUMULATIVE APPROVAL/AUTHORISATION STATUS**

Product Detail Set Name	Marketing Authorization Holder	Country	Approval Date	Authorization Type
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer/BioNTech	United Kingdom	01-Dec-20	Temporary authorization under regulation 174
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Bahrain	03-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Israel	06-Dec-20	Special import approval Clause 29
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Canada	09-Dec-20	Interim Order
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Qatar	10-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Saudi Arabia	10-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Mexico	11-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United States	11-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Kuwait	13-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Oman	13-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Lebanon	14-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Singapore	14-Dec-20	Pandemic Special Access Route
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Costa Rica	15-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Ecuador	15-Dec-20	Importation Authorization
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	United Arab Emirates	15-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Chile	16-Dec-20	Special import for emergency use article 99

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Product Detail Set Name	Marketing Authorization Holder	Country	Approval Date	Authorization Type
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Panama	16-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Jordan	17-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Serbia	17-Dec-20	Import License
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Switzerland	19-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Austria	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Belgium	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Bulgaria	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Croatia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Cyprus	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Czech Republic	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Denmark	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Estonia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Finland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	France	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Germany	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Greece	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Hungary	21-Dec-20	Conditional marketing authorization approval

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Product Detail Set Name	Marketing Authorization Holder	Country	Approval Date	Authorization Type
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Iceland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Ireland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Italy	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Latvia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Liechtenstein	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Lithuania	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Luxembourg	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Malta	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Netherlands	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Norway	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Poland	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Portugal	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Romania	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Slovakia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Slovenia	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Spain	21-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Sweden	21-Dec-20	Conditional marketing authorization approval

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Product Detail Set Name	Marketing Authorization Holder	Country	Approval Date	Authorization Type
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Argentina	22-Dec-20	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Iraq	27-Dec-20	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Colombia	06-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Malaysia	08-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Tunisia	11-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Philippines	14-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Uruguay	21-Jan-21	EUA
Pfizer-BioNTech COVID-19 mRNA vaccine	Pfizer	Australia	24-Jan-21	Conditional marketing authorization approval
Pfizer-BioNTech COVID-19 mRNA vaccine	BioNTech	Hong Kong	25-Jan-21	Conditional marketing authorization approval

EUA= Emergency Use Authorization

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## APPENDIX 5. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Anti-acetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

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coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

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tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

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fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

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infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lamb's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

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increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphaea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

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neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

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brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

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neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticular vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

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## APPENDIX 5.1 OBSERVED VERSUS EXPECTED ANALYSIS FOR ADVERSE EVENTS OF SPECIAL INTEREST

For this report, MAH has conducted unadjusted observed to expected ratio (O/E) analyses for the following AESI: Acute disseminated encephalomyelitis (ADEM), acute kidney injury, acute myocardial infarction/myocardial infarction, acute respiratory distress syndrome (ARDS), autoimmune thyroiditis, Bell's palsy, chronic fatigue syndrome/ME/PVFS, death, deep vein thrombosis, encephalitis, erythema multiforme, fibromyalgia, Guillain-Barre syndrome, idiopathic thrombocytopenia (broad and narrow), multiple sclerosis, myocarditis, narcolepsy, optic neuritis, pericarditis, pulmonary embolus, rheumatoid arthritis and polyarthritis, seizures/convulsions/seizure disorders (inc. febrile), stroke/cerebrovascular stroke/stroke and other cerebrovascular events; transverse myelitis, type 1 diabetes. Observed to expected analysis of spontaneous reports of anaphylaxis are reported separately below.

Of note, these reported cases were processed from the safety database via the respective MedDRA search criteria. Other than anaphylaxis and Bell's palsy, events have not undergone adjudication (e.g. assessment per Brighton Collaboration criteria for level of diagnostic certainty), which is considered appropriate in a setting where the goal of the O/E analysis is signal detection.<sup>1</sup>

Expected case counts were derived from estimated background incidence rates and post-vaccination follow up exposure time (EnCEPP, 2020).<sup>2</sup> For AESI background rates, where a plausible range of background rates was identified, two ratios were calculated to reflect the available data and impact of different case definitions. Sources of background rates include the literature as well as analyses conducted within electronic health records.

An estimated 35,291,860 doses of Pfizer-BioNTech COVID 19 Vaccine were administered globally through 31 January 2021. This estimate was derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized.<sup>3</sup> For periods when more than one vaccine was authorized for use in each country, the doses administered were assumed to be divided equally by the number of vaccines approved. This estimate does not reflect exposure in persons vaccinated in countries that did not publicly report.

For each event, O/E ratios were determined for the cumulative and interval periods. Expected counts were determined assuming 4 risk periods of variable duration reflecting different assumptions regarding the anticipated interval between the vaccination and the potential event: 3, 7, and 21 days and total duration of follow up. Of note, within each period, the same number of observed cases is used across all risk periods and includes all events reported, regardless of proximity of event to date of vaccination.

The tables below summarize, for each event, 8 ratios of observed to expected cases determined reflecting the two background rates and 4 risk windows for the cumulative and interval periods.

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**Table 1. Observed to Expected Ratio of Spontaneously Reported Acute disseminated encephalomyelitis (ADEM) through 31 Jan 2021**

Cumulative (N=2)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
5.25/100,000 PY <sup>a</sup>				
Expected cases	14.6	31.2	67.1	81.5
O/E ratio	0.137	0.064	0.03	0.025
(95% CI)	0.017, 0.495	0.008, 0.232	0.004, 0.108	0.003, 0.089
16.30/100,000 PY <sup>b</sup>				
Expected cases	45.3	96.9	208.3	253.2
O/E ratio	0.044	0.021	0.01	0.008
(95% CI)	0.005, 0.159	0.003, 0.075	0.001, 0.035	0.001, 0.029

Interval (N=2)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
5.25/100,000 PY <sup>a</sup>				
Expected cases	12.9	27.2	55	59.5
O/E ratio	0.155	0.074	0.036	0.034
(95% CI)	0.019, 0.562	0.009, 0.266	0.004, 0.131	0.004, 0.121
16.30/100,000 PY <sup>b</sup>				
Expected cases	39.9	84.3	170.7	184.8
O/E ratio	0.05	0.024	0.012	0.011
(95% CI)	0.006, 0.181	0.003, 0.086	0.001, 0.042	0.001, 0.039

a. Willame, et al 2021

b. Study C4591004

**Table 2. Observed to Expected Ratio of Spontaneously Reported Acute kidney injury through 31 Jan 2021**

Cumulative (N=13)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
1,344.13/100,000 PY <sup>a</sup>				
Expected cases	3736.2	7986.9	17173.1	20875.7
O/E ratio	0.003	0.002	0.001	0.001
(95% CI)	0.002, 0.006	0.001, 0.003	0.000, 0.001	0.000, 0.001

Interval (N=13)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
1,344.13/100,000 PY <sup>a</sup>				
Expected cases	3293.5	6954	14074.4	15240.8

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O/E ratio (95% CI)	0.004 0.002, 0.007	0.002 0.001, 0.003	0.001 0.000, 0.002	0.001 0.000, 0.001
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a. Study C4591004

**Table 3. Observed to Expected Ratio of Spontaneously Reported Acute myocardial infarction/Myocardial infarction through 31 Jan 2021**

Cumulative (N=50)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
201.80/100,000 PY <sup>a</sup> Expected cases	560.9	1199.1	2578.3	3134.2
O/E ratio (95% CI)	0.089 0.066, 0.118	0.042 0.031, 0.055	0.019 0.014, 0.026	0.016 0.012, 0.021
583.900/100,000 PY <sup>b</sup> Expected cases	1623	3469.6	7460.1	9068.5
O/E ratio (95% CI)	0.031 0.023, 0.041	0.014 0.011, 0.019	0.007 0.005, 0.009	0.006 0.004, 0.007

Interval (N=43)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
201.80/100,000 PY <sup>a</sup> Expected cases	494.5	1044	2113	2288.2
O/E ratio (95% CI)	0.087 0.063, 0.117	0.041 0.030, 0.055	0.02 0.015, 0.027	0.019 0.014, 0.025
583.900/100,000 PY <sup>b</sup> Expected cases	1430.7	3020.9	6114	6620.7
O/E ratio (95% CI)	0.03 0.022, 0.040	0.014 0.010, 0.019	0.007 0.005, 0.009	0.006 0.005, 0.009

a. PFE\_SE\_PNG

b. Study C4591004

**Table 4. Observed to Expected Ratio of Spontaneously Reported Acute respiratory distress syndrome (ARDS) through 31 Jan 2021**

Cumulative (N=2)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
746.650/100,000 PY <sup>a</sup> Expected cases	2075.4	4436.6	9539.5	11596.2
O/E ratio (95% CI)	0.001 0.000, 0.003	0 0.000, 0.002	0 0.000, 0.001	0 0.000, 0.001

Interval (N=2)				
Background rate	Risk Period			
	3 Days	7 Days	21 Days	No risk window

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	(245,031 PY)	(517,359 PY)	(1,047,101 PY)	(1,133,880 PY)
746.650/100,000 PY <sup>a</sup>				
Expected cases	1829.5	3862.9	7818.2	8466.1
O/E ratio	0.001	0.001	0	0
(95% CI)	0.000, 0.004	0.000, 0.002	0.000, 0.001	0.000, 0.001

a. Study C4591004

**Table 5. Observed to Expected Ratio of Spontaneously Reported Autoimmune thyroiditis through 31 Jan 2021**

Cumulative (N=1)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
6.200/100,000 PY <sup>a</sup>				
Expected cases	17.2	36.8	79.2	96.3
O/E ratio	0.058	0.027	0.013	0.01
(95% CI)	0.001, 0.323	0.001, 0.151	0.000, 0.070	0.000, 0.058
30.200/100,000 PY <sup>b</sup>				
Expected cases	83.9	179.4	385.8	469
O/E ratio	0.012	0.006	0.003	0.002
(95% CI)	0.000, 0.066	0.000, 0.031	0.000, 0.014	0.000, 0.012

Interval (N=1)

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
6.200/100,000 PY <sup>a</sup>				
Expected cases	15.2	32.1	64.9	70.3
O/E ratio	0.066	0.031	0.015	0.014
(95% CI)	0.002, 0.367	0.001, 0.174	0.000, 0.086	0.000, 0.079
30.200/100,000 PY <sup>b</sup>				
Expected cases	74	156.2	316.2	342.4
O/E ratio	0.014	0.006	0.003	0.003
(95% CI)	0.000, 0.075	0.000, 0.036	0.000, 0.018	0.000, 0.016

a. PFE\_SE\_PNG

b. Study C4591004

**Table 6. Observed to Expected Ratio of Spontaneously Reported Bell's palsy (Brighton Level 1-4) through 31 Jan 2021**

Cumulative (N=119)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
23.840/100,000 PY <sup>a</sup>				
Expected cases	66.3	141.7	304.6	370.3
O/E ratio	1.796	0.840	0.391	0.321
(95% CI)	1.488, 2.149	0.696, 1.005	0.324, 0.468	0.266, 0.385

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84.800/100,000 PY <sup>b</sup>				
Expected cases	235.7	503.9	1083.4	1317
O/E ratio	0.505	0.236	0.110	0.090
(95% CI)	0.418, 0.604	0.196, 0.283	0.091, 0.131	0.075, 0.108

**Interval (N=98)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
23.840/100,000 PY <sup>a</sup>				
Expected cases	58.4	123.3	249.6	270.3
O/E ratio	1.678	0.795	0.393	0.363
(95% CI)	1.362, 2.045	0.645, 0.968	0.319, 0.478	0.294, 0.442
84.800/100,000 PY <sup>b</sup>				
Expected cases	207.8	438.7	887.9	961.5
O/E ratio	0.472	0.223	0.110	0.102
(95% CI)	0.383, 0.575	0.181, 0.272	0.090, 0.135	0.083, 0.124

- a. Willame, et al 2021
- b. Study C4591004

**Table 7. Observed to Expected Ratio of Spontaneously Reported Chronic Fatigue Syndrome/ME/PVFS through 31 Jan 2021**

**Cumulative (N=3)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
13.160/100,000 PY <sup>a</sup>				
Expected cases	36.6	78.2	168.1	204.4
O/E ratio	0.082	0.038	0.018	0.015
(95% CI)	0.017, 0.240	0.008, 0.112	0.004, 0.052	0.003, 0.043

**Interval (N=3)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
13.160/100,000 PY <sup>a</sup>				
Expected cases	32.2	68.1	137.8	149.2
O/E ratio	0.093	0.044	0.022	0.02
(95% CI)	0.019, 0.272	0.009, 0.129	0.004, 0.064	0.004, 0.059

- a. Vincent, et al 2012

**Table 8. Observed to Expected Ratio of Spontaneously Reported Death (any causes)/Death through 31 Jan 2021**

**Cumulative (N=419)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)

1,116.400/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	3103.2 0.135 0.122, 0.149	6633.7 0.063 0.057, 0.070	14263.5 0.029 0.027, 0.032	17338.8 0.024 0.022, 0.027
1,235.900/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	3435.4 0.122 0.111, 0.134	7343.8 0.057 0.052, 0.063	15790.3 0.027 0.024, 0.029	19194.8 0.022 0.020, 0.024

**Interval (N=410)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
1,116.400/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	2735.5 0.15 0.136, 0.165	5775.8 0.071 0.064, 0.078	11689.8 0.035 0.032, 0.039	12658.6 0.032 0.029, 0.036
1,235.900/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	3028.3 0.135 0.123, 0.149	6394 0.064 0.058, 0.071	12941.1 0.032 0.029, 0.035	14013.6 0.029 0.026, 0.032

a. <https://wonder.cdc.gov>

b. Study C4591004

**Table 9. Observed to Expected Ratio of Spontaneously Reported Deep vein thrombosis through 31 Jan 2021**

**Cumulative (N=12)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
50.00/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	139 0.086 0.045, 0.151	297.1 0.04 0.021, 0.071	638.8 0.019 0.010, 0.033	776.5 0.015 0.008, 0.027
120.00/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	333.6 0.036 0.019, 0.063	713 0.017 0.009, 0.029	1533.2 0.008 0.004, 0.014	1863.7 0.006 0.003, 0.011

**Interval (N=12)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
50.00/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	122.5 0.098 0.051, 0.171	258.7 0.046 0.024, 0.081	523.6 0.023 0.012, 0.040	566.9 0.021 0.011, 0.037
120.00/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	294 0.041 0.021, 0.071	620.8 0.019 0.010, 0.034	1256.5 0.01 0.005, 0.017	1360.7 0.009 0.005, 0.015

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a. Heit, 2015

**Table 10. Observed to Expected Ratio of Spontaneously Reported Encephalitis through 31 Jan 2021**

Cumulative (N=2)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
1.100/100,000 PY <sup>a</sup>				
Expected cases	3.1	6.5	14.1	17.1
O/E ratio	0.654	0.306	0.142	0.117
(95% CI)	0.079, 2.363	0.037, 1.105	0.017, 0.514	0.014, 0.423
12.800/100,000 PY <sup>b</sup>				
Expected cases	35.6	76.1	163.5	198.8
O/E ratio	0.056	0.026	0.012	0.01
(95% CI)	0.007, 0.203	0.003, 0.095	0.001, 0.044	0.001, 0.036

Interval (N=1)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
1.100/100,000 PY <sup>a</sup>				
Expected cases	2.7	5.7	11.5	12.5
O/E ratio	0.371	0.176	0.087	0.08
(95% CI)	0.009, 2.067	0.004, 0.979	0.002, 0.484	0.002, 0.447
12.800/100,000 PY <sup>b</sup>				
Expected cases	31.4	66.2	134	145.1
O/E ratio	0.032	0.015	0.007	0.007
(95% CI)	0.001, 0.178	0.000, 0.084	0.000, 0.042	0.000, 0.038

a. PFE\_SE\_PNG  
 b. Study C4591004

**Table 11. Observed to Expected Ratio of Spontaneously Reported Erythema multiforme through 31 Jan 2021**

Cumulative (N=3)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
86.200/100,000 PY <sup>a</sup>				
Expected cases	239.6	512.2	1101.3	1338.8
O/E ratio	0.013	0.006	0.003	0.002
(95% CI)	0.003, 0.037	0.001, 0.017	0.001, 0.008	0.000, 0.007

Interval (N=3)				
Background rate	Risk Period			
	3 Days	7 Days	21 Days	No risk window

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	(245,031 PY)	(517,359 PY)	(1,047,101 PY)	(1,133,880 PY)
86.200/100,000 PY <sup>a</sup>				
Expected cases	211.2	446	902.6	977.4
O/E ratio	0.014	0.007	0.003	0.003
(95% CI)	0.003, 0.042	0.001, 0.020	0.001, 0.010	0.001, 0.009

a. Study C4591004

**Table 12. Observed to Expected Ratio of Spontaneously Reported Fibromyalgia through 31 Jan 2021**

**Cumulative (N=5)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
430.000/100,000 PY <sup>a</sup>				
Expected cases	1195.2	2555.1	5493.8	6678.3
O/E ratio	0.004	0.002	0.001	0.001
(95% CI)	0.001, 0.010	0.001, 0.005	0.000, 0.002	0.000, 0.002

**Interval (N=5)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
430.000/100,000 PY <sup>a</sup>				
Expected cases	1053.6	2224.6	4502.5	4875.7
O/E ratio	0.005	0.002	0.001	0.001
(95% CI)	0.002, 0.011	0.001, 0.005	0.000, 0.003	0.000, 0.002

a. Creed, 2020

**Table 13. Observed to Expected Ratio of Spontaneously Reported Guillain-Barré syndrome (GBS) through 31 Jan 2021**

**Cumulative (N=10)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
2.060/100,000 PY <sup>a</sup>				
Expected cases	5.7	12.2	26.3	32
O/E ratio	1.746	0.817	0.38	0.313
(95% CI)	0.837, 3.212	0.392, 1.502	0.182, 0.699	0.150, 0.575
85.000/100,000 PY <sup>b</sup>				
Expected cases	236.3	505.1	1086	1320.1
O/E ratio	0.042	0.02	0.009	0.008
(95% CI)	0.020, 0.078	0.009, 0.036	0.004, 0.017	0.004, 0.014

**Interval (N=9)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)

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2.060/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	5 1.783 0.815, 3.385	10.7 0.844 0.386, 1.603	21.6 0.417 0.191, 0.792	23.4 0.385 0.176, 0.731
85.000/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	208.3 0.043 0.020, 0.082	439.8 0.02 0.009, 0.039	890 0.01 0.005, 0.019	963.8 0.009 0.004, 0.018

- a. Willame, et al 2021
- b. Study C4591004

**Table 14. Observed to Expected Ratio of Spontaneously Reported Idiopathic Thrombocytopenia (broad and narrow) through 31 Jan 2021**

Background rate	Cumulative (N=4)			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
21.760/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	60.5 0.066 0.018, 0.169	129.3 0.031 0.008, 0.079	278 0.014 0.004, 0.037	338 0.012 0.003, 0.030
3.820/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	10.6 0.377 0.103, 0.965	22.7 0.176 0.048, 0.451	48.8 0.082 0.022, 0.210	59.3 0.067 0.018, 0.173

Background rate	Interval (N=3)			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
21.760/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	53.3 0.056 0.012, 0.164	112.6 0.027 0.005, 0.078	227.8 0.013 0.003, 0.038	246.7 0.012 0.003, 0.036
3.820/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	9.4 0.321 0.066, 0.937	19.8 0.152 0.031, 0.444	40 0.075 0.015, 0.219	43.3 0.069 0.014, 0.202

- a. Willame, et al 2021

**Table 15. Observed to Expected Ratio of Spontaneously Reported Multiple Sclerosis (MS) through 31 Jan 2021**

Background rate	Cumulative (N=8)			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)

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11.600/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	32.2 0.248 0.107, 0.489	68.9 0.116 0.050, 0.229	148.2 0.054 0.023, 0.106	180.2 0.044 0.019, 0.087
84.000/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	233.5 0.034 0.015, 0.068	499.1 0.016 0.007, 0.032	1073.2 0.007 0.003, 0.015	1304.6 0.006 0.003, 0.012

Interval (N=8)

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
11.600/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	28.4 0.281 0.122, 0.555	60 0.133 0.058, 0.263	121.5 0.066 0.028, 0.130	131.5 0.061 0.026, 0.120
84.000/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	205.8 0.039 0.017, 0.077	434.6 0.018 0.008, 0.036	879.6 0.009 0.004, 0.018	952.5 0.008 0.004, 0.017

- a. PFE\_SE\_PNG  
 b. Study C4591004

**Table 16. Observed to Expected Ratio of Spontaneously Reported Myocarditis through 31 Jan 2021**

Cumulative (N=5)

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
4.400/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	12.2 0.409 0.133, 0.954	26.1 0.191 0.062, 0.446	56.2 0.089 0.029, 0.208	68.3 0.073 0.024, 0.171
30.400/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	84.5 0.059 0.019, 0.138	180.6 0.028 0.009, 0.065	388.4 0.013 0.004, 0.030	472.1 0.011 0.003, 0.025

Interval (N=5)

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
4.400/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	10.8 0.464 0.151, 1.082	22.8 0.22 0.071, 0.513	46.1 0.109 0.035, 0.253	49.9 0.1 0.033, 0.234
30.400/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	74.5 0.067 0.022, 0.157	157.3 0.032 0.010, 0.074	318.3 0.016 0.005, 0.037	344.7 0.015 0.005, 0.034

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- a. Elfstrom, 2007
- b. Study C4591004

**Table 17. Observed to Expected Ratio of Spontaneously Reported Narcolepsy through 31 Jan 2021**

Cumulative (N=1)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
1.080/100,000 PY <sup>a</sup>				
Expected cases	3	6.4	13.8	16.8
O/E ratio	0.333	0.156	0.072	0.06
(95% CI)	0.008, 1.856	0.004, 0.868	0.002, 0.404	0.002, 0.332
9.100/100,000 PY <sup>b</sup>				
Expected cases	25.3	54.1	116.3	141.3
O/E ratio	0.04	0.018	0.009	0.007
(95% CI)	0.001, 0.220	0.000, 0.103	0.000, 0.048	0.000, 0.039

Interval (N=1)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
1.080/100,000 PY <sup>a</sup>				
Expected cases	2.6	5.6	11.3	12.2
O/E ratio	0.378	0.179	0.088	0.082
(95% CI)	0.010, 2.105	0.005, 0.997	0.002, 0.493	0.002, 0.455
9.100/100,000 PY <sup>b</sup>				
Expected cases	22.3	47.1	95.3	103.2
O/E ratio	0.045	0.021	0.01	0.01
(95% CI)	0.001, 0.250	0.001, 0.118	0.000, 0.058	0.000, 0.054

- a. Willame, et al 2021
- b. PFE\_SE\_PNG

**Table 18. Observed to Expected Ratio of Spontaneously Reported Optic neuritis (ON) through 31 Jan 2021**

Cumulative (N=2)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
3.420/100,000 PY <sup>a</sup>				
Expected cases	9.5	20.3	43.7	53.1
O/E ratio	0.21	0.098	0.046	0.038
(95% CI)	0.025, 0.760	0.012, 0.356	0.006, 0.165	0.005, 0.136
20.800/100,000 PY <sup>b</sup>				
Expected cases	57.8	123.6	265.7	323

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O/E ratio (95% CI)	0.035 0.004, 0.125	0.016 0.002, 0.058	0.008 0.001, 0.027	0.006 0.001, 0.022
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**Interval (N=2)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
3.420/100,000 PY <sup>a</sup> Expected cases	8.4	17.7	35.8	38.8
O/E ratio (95% CI)	0.239 0.029, 0.862	0.113 0.014, 0.408	0.056 0.007, 0.202	0.052 0.006, 0.186
20.800/100,000 PY <sup>b</sup> Expected cases	51	107.6	217.8	235.8
O/E ratio (95% CI)	0.039 0.005, 0.142	0.019 0.002, 0.067	0.009 0.001, 0.033	0.008 0.001, 0.031

- a. Willame, et al 2021
- b. Study C4591004

**Table 19. Observed to Expected Ratio of Spontaneously Reported Pericarditis through 31 Jan 2021**

**Cumulative (N=9)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
18.000/100,000 PY <sup>a</sup> Expected cases	50	107	230	279.6
O/E ratio (95% CI)	0.18 0.082, 0.341	0.084 0.038, 0.160	0.039 0.018, 0.074	0.032 0.015, 0.061
37.200/100,000 PY <sup>b</sup> Expected cases	103.4	221	475.3	577.8
O/E ratio (95% CI)	0.087 0.040, 0.165	0.041 0.019, 0.077	0.019 0.009, 0.036	0.016 0.007, 0.030

**Interval (N=7)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
18.000/100,000 PY <sup>a</sup> Expected cases	44.1	93.1	188.5	204.1
O/E ratio (95% CI)	0.159 0.064, 0.327	0.075 0.030, 0.155	0.037 0.015, 0.077	0.034 0.014, 0.071
37.200/100,000 PY <sup>b</sup> Expected cases	91.2	192.5	389.5	421.8
O/E ratio (95% CI)	0.077 0.031, 0.158	0.036 0.015, 0.075	0.018 0.007, 0.037	0.017 0.007, 0.034

- a. Elfstron, 2020
- b. Study C4591004

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**Table 20. Observed to Expected Ratio of Spontaneously Reported Pulmonary embolus through 31 Jan 2021**

Cumulative (N=10)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
30.000/100,000 PY <sup>a</sup>				
Expected cases	83.4	178.3	383.3	465.9
O/E ratio	0.12	0.056	0.026	0.021
(95% CI)	0.058, 0.221	0.027, 0.103	0.013, 0.048	0.010, 0.039
80.000/100,000 PY <sup>a</sup>				
Expected cases	222.4	475.4	1022.1	1242.5
O/E ratio	0.045	0.021	0.01	0.008
(95% CI)	0.022, 0.083	0.010, 0.039	0.005, 0.018	0.004, 0.015

Interval (N=9)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
30.000/100,000 PY <sup>a</sup>				
Expected cases	73.5	155.2	314.1	340.2
O/E ratio	0.122	0.058	0.029	0.026
(95% CI)	0.056, 0.232	0.027, 0.110	0.013, 0.054	0.012, 0.050
80.000/100,000 PY <sup>a</sup>				
Expected cases	196	413.9	837.7	907.1
O/E ratio	0.046	0.022	0.011	0.01
(95% CI)	0.021, 0.087	0.010, 0.041	0.005, 0.020	0.005, 0.019

a. Heit, 2015

**Table 21. Observed to Expected Ratio of Spontaneously Reported Rheumatoid arthritis, polyarthritis through 31 Jan 2021**

Cumulative (N=6)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
64.700/100,000 PY <sup>a</sup>				
Expected cases	179.8	384.5	826.6	1004.9
O/E ratio	0.033	0.016	0.007	0.006
(95% CI)	0.012, 0.073	0.006, 0.034	0.003, 0.016	0.002, 0.013
1,230.900/100,000 PY <sup>b</sup>				
Expected cases	3421.5	7314.1	15726.4	19117.1
O/E ratio	0.002	0.001	0	0
(95% CI)	0.001, 0.004	0.000, 0.002	0.000, 0.001	0.000, 0.001

Interval (N=5)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)

64.700/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	158.5 0.032 0.010, 0.074	334.7 0.015 0.005, 0.035	677.5 0.007 0.002, 0.017	733.6 0.007 0.002, 0.016
1,230.900/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	3016.1 0.002 0.001, 0.004	6368.2 0.001 0.000, 0.002	12888.8 0 0.000, 0.001	13956.9 0 0.000, 0.001

a. PFE\_SE\_PNG  
 b. Study C4591004

**Table 22. Observed to Expected Ratio of Spontaneously Reported Seizures / convulsions/Seizure disorders (inc. febrile) through 31 Jan 2021**

**Cumulative (N=52)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
82.900/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	230.4 0.226 0.169, 0.296	492.6 0.106 0.079, 0.138	1059.2 0.049 0.037, 0.064	1287.5 0.04 0.030, 0.053
941.700/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	2617.6 0.02 0.015, 0.026	5595.6 0.009 0.007, 0.012	12031.5 0.004 0.003, 0.006	14625.5 0.004 0.003, 0.005

**Interval (N=45)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
82.900/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	203.1 0.222 0.162, 0.296	428.9 0.105 0.077, 0.14	868 0.052 0.038, 0.069	940 0.048 0.035, 0.064
941.700/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	2307.5 0.02 0.014, 0.026	4872 0.009 0.007, 0.012	9860.5 0.005 0.003, 0.006	10677.7 0.004 0.003, 0.006

a. PFE\_SE\_PNG  
 b. Study C4591004

**Table 23. Observed to Expected Ratio of Spontaneously Reported Stroke/Cerebrovascular stroke/Stroke and other cerebrovascular events through 31 Jan 2021**

**Cumulative (N=46)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)

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198.400/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	551.5 0.083 0.061, 0.111	1178.9 0.039 0.029, 0.052	2534.8 0.018 0.013, 0.024	3081.3 0.015 0.011, 0.02
914.300/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	2541.4 0.018 0.013, 0.024	5432.8 0.008 0.006, 0.011	11681.4 0.004 0.003, 0.005	14200 0.003 0.002, 0.004

**Interval (N=41)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
198.400/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	486.1 0.084 0.061, 0.114	1026.4 0.04 0.029, 0.054	2077.4 0.02 0.014, 0.027	2249.6 0.018 0.013, 0.025
914.300/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	2240.3 0.018 0.013, 0.025	4730.2 0.009 0.006, 0.012	9573.6 0.004 0.003, 0.006	10367.1 0.004 0.003, 0.005

- a. PFE\_SE\_PNG
- b. Study C4591004

**Table 24. Observed to Expected Ratio of Spontaneously Reported Transverse myelitis through 31 Jan 2021**

**Cumulative (N=2)**

Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
0.970/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	2.7 0.742 0.090, 2.680	5.8 0.347 0.042, 1.253	12.4 0.161 0.020, 0.583	15.1 0.133 0.016, 0.480
6.800/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	18.9 0.106 0.013, 0.382	40.4 0.049 0.006, 0.179	86.9 0.023 0.003, 0.083	105.6 0.019 0.002, 0.068

**Interval (N=1)**

Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
0.970/100,000 PY <sup>a</sup> Expected cases O/E ratio (95% CI)	2.4 0.421 0.011, 2.344	5 0.199 0.005, 1.110	10.2 0.098 0.002, 0.549	11 0.091 0.002, 0.507
6.800/100,000 PY <sup>b</sup> Expected cases O/E ratio (95% CI)	16.7 0.06 0.002, 0.334	35.2 0.028 0.001, 0.158	71.2 0.014 0.000, 0.078	77.1 0.013 0.000, 0.072

- a. Willame, et al 2021
- b. Study C4591004

**Table 25. Observed to Expected Ratio of Spontaneously Reported Type I diabetes through 31 Jan 2021**

Cumulative (N=6)				
Background rate	Risk Period			
	3 Days (277,964 PY)	7 Days (594,204 PY)	21 Days (1,277,635 PY)	No risk window (1,553,100 PY)
38.900/100,000 PY <sup>a</sup>				
Expected cases	108.1	231.1	497	604.2
O/E ratio	0.055	0.026	0.012	0.01
(95% CI)	0.020, 0.121	0.010, 0.056	0.004, 0.026	0.004, 0.022
233.200/100,000 PY <sup>b</sup>				
Expected cases	648.2	1385.7	2979.4	3621.8
O/E ratio	0.009	0.004	0.002	0.002
(95% CI)	0.003, 0.020	0.002, 0.009	0.001, 0.004	0.001, 0.004

Interval (N=4)				
Background rate	Risk Period			
	3 Days (245,031 PY)	7 Days (517,359 PY)	21 Days (1,047,101 PY)	No risk window (1,133,880 PY)
38.900/100,000 PY <sup>a</sup>				
Expected cases	95.3	201.3	407.3	441.1
O/E ratio	0.042	0.02	0.01	0.009
(95% CI)	0.011, 0.107	0.005, 0.051	0.003, 0.025	0.002, 0.023
233.200/100,000 PY <sup>b</sup>				
Expected cases	571.4	1206.5	2441.8	2644.2
O/E ratio	0.007	0.003	0.002	0.002
(95% CI)	0.002, 0.018	0.001, 0.008	0.000, 0.004	0.000, 0.004

- a. PFE\_SE\_PNG
- b. Study C4591004

For both cumulative and interval data, O/E for all events and risk windows other than Bell’s palsy and Guillain-Barre using the 3-day risk window and the lower background rate estimate are below 1, indicating a lower number of observed events than expected. In most cases this ratio is much less than 1, which may due to several factors including differences in characteristics between persons being vaccinated and those in the background rate populations, e.g., age distributions and comorbidities, underreporting of events via the passive surveillance system, etc. For Bells palsy the lower level of the 95% CI is higher than 1 in the analyses using the background rate reported in the literature and a 3-day risk window, suggesting a higher than expected count. Importantly, all observed cases in the numerator of the ratio using the 3-day window for person time to generate the expected count are assumed to have started within 3 days of vaccination, regardless of the actual time to onset.

Several limitations of the observed to expected comparison must be noted. With respect to observed cases, case ascertainment through the spontaneous reports likely reflect an underreporting due to incomplete reporting or a lag in reporting. Additionally, spontaneous

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surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine are more likely to be reported and potentially reported despite not meeting the clinical definition. Conversely, events that have not been previously associated with a vaccine are likely to be underreported.

With respect to the expected case counts, estimates concerning both exposure to vaccine and the background rate have limitations. Our exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus the exposure is underestimated.

The expected count also assumes that the expected incidence rate in the vaccinated population is the same as that in the population used to calculate the background rate. However, the background rates used in this analysis are derived from one large US electronic health records database, one large US insurance claims database, or literature review. It is possible that the delivery of health care, population demographics, and underlying health status of the US populations included in the background rate estimates differ from those expected in the persons administered the vaccine. However to date, the majority of exposure derives from the US. Further, sensitivity analyses were conducted to demonstrate the range of event rates depending on the case definitions among population for background rate calculation.

A final limitation concerns the time at risk for a given event during which an excess of risk occurs in the case of causal association. Three periods (3 days, 7 days, and 21 days) were selected to provide a range of evaluation (i.e. sensitivity analyses) for the number of expected cases, however, observed cases were included regardless of proximity to vaccination which may lead to overestimate if the observed cases occurred outside of the risk period.

## **OBSERVED TO EXPECTED ANALYSES FOR ANAPHYLAXIS**

Given that anaphylaxis is an identified risk, the goal of an observed to expected comparison would not be signal identification but risk estimation. Risk of anaphylaxis is reported per dose administered in comparison with rates observed for other vaccines rather than in an unexposed population.

The MAH has conducted unadjusted observed to expected ratio (O/E) analyses for the 438 cumulative cases of anaphylaxis occurring outside of a clinical trial setting reported in the global safety database meeting Brighton Level 1 or 2. A background rate<sup>4</sup> of 1.31 per million doses was assumed.

An estimated 35,291,860 doses of Pfizer-BioNTech COVID 19 vaccine have been administered through 31 January 2021. This estimate is derived from publicly available information reported by countries where Pfizer-BioNTech vaccine is authorized.<sup>3</sup> For periods when more than one vaccine was authorized for use in each country, the doses administered were assumed to be divided equally by the number of vaccines approved. This estimate does not reflect exposure in persons vaccinated in countries that did not publicly report.

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For each event, expected counts were determined by multiplying the number of doses administered by the expected rates per dose.

An O/E ratio of 9.47 (95% CI, 8.61 – 10.40) was observed for BNT162b2 compared with the background rate for anaphylaxis cases (Brighton Level 1 or 2) observed in the US.<sup>4</sup>

There are several limitations to consider when interpreting these analyses. The analyses did not adjust for differences in characteristics between persons being administered the vaccine and populations from which the background rate is derived such as age and comorbidities. At this time, national/local guidelines typically recommend prioritizing vaccine administration for healthcare workers at high-risk of COVID-19 exposure and persons with underlying conditions who are at risk of serious COVID-19 illness, including the elderly and those with underlying health conditions. The spontaneous reports system likely underestimates the true number of observed events in vaccinated persons due to incomplete reporting or a lag in reporting.

On the other hand, spontaneous surveillance systems are prone to reporting bias whereby events that have been previously identified as potentially related to vaccine, eg, due to news media reports, are more likely to be reported than other events. With respect to the expected number of events, estimates concerning both exposure to vaccine and the background rate have limitations. This exposure estimate assumes that the number of reported administrations is complete and accurate when in fact not all countries administering vaccine have reported counts of vaccine administration to the data source. Thus, the total doses of vaccine administration used to determine the expected count of events is potentially underestimated.

Further, the delivery of health care, population demographics, and underlying health status of the populations included in the background rate estimates differ from those expected in the persons administered the vaccine.

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<sup>1</sup> Mahaux O, Bauchau V, Van Holle L. Pharmacoepidemiological considerations in observed-to-expected analyses for vaccines. *Pharmacoepidemiol Drug Saf* 2016; 25(2):215–22.

<sup>2</sup> The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). Guide on Methodological Standards in Pharmacoepidemiology (Revision 8). EMA/95098/2010.

<sup>3</sup> <https://ourworldindata.org/covid-vaccinations#daily-vaccination-rates> (accessed 02 January 2021).

<sup>4</sup> McNeil M, Weintraub E, et al. Risk of anaphylaxis after vaccination in children and adults. *J Allergy Clin Immunol* 2016; 137(3): 868–78.



## **APPENDIX 6. LITERATURE REVIEW IN THE REPORTING PERIOD (METHODOLOGY)**

A web-based literature review service is used to review medical literature from clinical and non-clinical literature sources for significant safety information relevant to authorized Pfizer medicinal product.

The following bibliographic databases are searched in this order:

1. MEDLINE®
2. Embase

Each search uses controlled vocabulary terms that are unique to each database. For each database, the search focuses on the following:

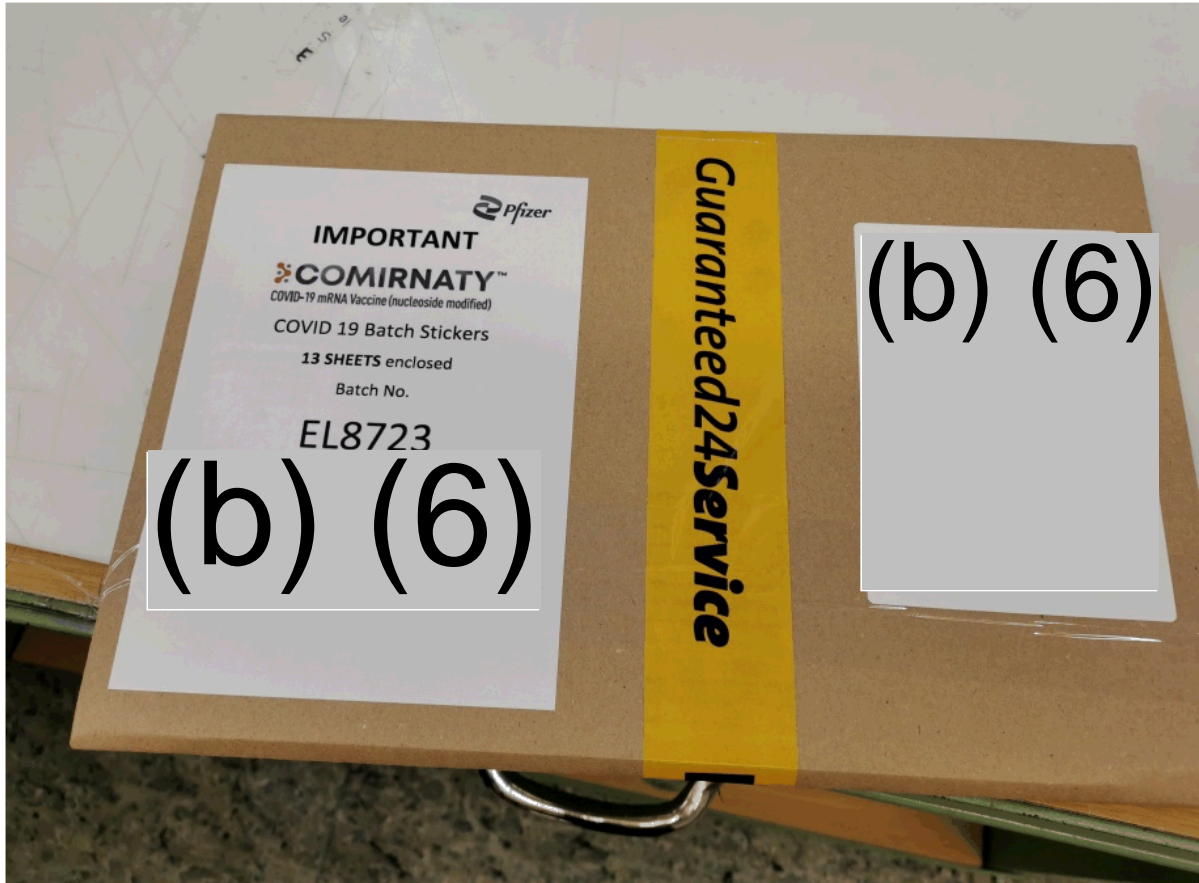
- AEs, effects and outcomes
- Generic name of the drug
- Prenatal and perinatal exposure and exposure through breast milk
- Drug interactions
- Clinical studies
- Epidemiology and meta-analyses
- Poisoning and toxicity
- Drug resistance and drug tolerance
- Toxicity tests

Searches are limited by date and by literature type. Reviews, editorials, and news reports (i.e., works consisting of an announcement or statement of recent or current events of new data and matters of interest in the field of medicine or science) are excluded because they are not peer-reviewed.

### APPENDIX 7. TRACEABILITY TOOLS (STICKERS)



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