URL Flat annotations are provided at first mention

Label Update: Effective 9/22/21

The Emergency Use Authorization (EUA) Fact Sheet for Vaccination Providers has been updated to include information about booster doses. Click here to view. Changes include (but are not limited to) the following section:

New Language in Teal

2.3 Vaccination Schedule

Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

Continue

Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf

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Drives to pg 2

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Indication

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Monitor 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/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

This site is intended for U.S. Healthcare Professionals. Indication & Authorized Use Safety Info

Full Prescribing Information (FDA Approved - 16 Years & Up)

EUA Letter & Fact Sheets (12 Years & Up)

Home | Dosing & Administration | Clinical Efficacy | Safety Info | Q&A | Product Storage & Dry Ice | Resources

BIONTECH Pfizer

Upon hovering, the pop up on pg 3 will appear

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE[1]

In individuals 16 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA),* has been approved for active immunization to prevent COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR EMERGENCY USE[2]

The emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or

Quick Access to Important Information

- Safety Information & Adverse Event Reporting
- Full Prescribing Information (FDA Approved - 16 Years & Up)
- EUA Fact Sheet for Vaccination Providers (12 Years & Up)

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Indication

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Monitor 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/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Indication

COMIRNATY® is a vaccine indicated 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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use to provide:

- a two-dose primary series in individuals 12 through 15 years
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older

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EUA Fact Sheet for Vaccination Providers (12 Years & Up)

Indication & Authorized Use

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Important Safety Information

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Monitor 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/clinical-considerations/managing-anaphylaxis.html).

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This site is intended for U.S. Healthcare Professionals. Indication & Authorized Use Safety Info

Full Prescribing Information (FDA Approved - 16 Years & Up)

EUA Letter & Fact Sheets (12 Years & Up)

Home Dosing & Administration

- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
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The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older to provide:

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- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
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BIONTECH Pfizer

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EUA Fact Sheet for Vaccination Providers (12 Years & Up)

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Indication & Authorized Use

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Indication

Important Safety Information

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Monitor 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/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE[1]

In individuals 16 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine, also known as

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Indication

COMIRNATY® is a vaccine indicated 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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use to provide:

- a two-dose primary series in individuals 12 through 15 years
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
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- a two-dose primary series in individuals 12 years of age and older
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age at risk of serious complications of COVID-19 in the setting of frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

Important Safety Information

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Monitor 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/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study evaluating administration of a booster dose in participants 18 through 55 years of age, the most commonly reported adverse reactions (≥10%) following the dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), and joint pain (25.3%).

In a clinical study of adolescents 12 through 15 years of age, the most commonly reported adverse reactions included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

Quick Access to Important Information

Drives to: http://labeling.pfizer.com/ShowLabeling.aspx?id=15623

Drives to: http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf

Drives to: http://labeling.pfizer.com/ShowLabeling.aspx?id=14472&format=pdf

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE[1]

In individuals 16 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA),* has been approved for active immunization to prevent COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR EMERGENCY USE[2]

The emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. [2]

***The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with certain differences that do not impact safety or effectiveness.**

Adverse Event Reporting

Report an Adverse Event to VAERS* | Report an Adverse Event to Pfizer

*This website is neither owned nor controlled by Pfizer. Pfizer does not endorse and is not responsible for the content or services of this site.

Mandatory Requirements for Vaccine Administration Under Emergency Use Authorization[2†]

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

1. The vaccine is authorized for use in individuals 12 years of age and older.
2. The vaccination provider must communicate to the individual receiving the vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving the 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 "the 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 the 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.

Website: www.pfizersafetyreporting.com

Fax number: 1-866-635-8337

Telephone number: 1-800-438-1985

†Vaccination providers administering COMIRNATY® (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.[2]

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Monitor 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/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study evaluating administration of a booster dose in participants 18 through 55 years of age, the most commonly reported adverse reactions (≥10%) following the dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), and joint pain (25.3%).

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Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

References

1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; 2021.
2. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Pfizer and BioNTech; 2021.

For more information

Pfizer Customer Service
Call 1-800-879-3477.

Medical Information
Visit PfizerMedicalInformation.com or call 1-800-438-1985.

General Product Inquiries
Call 1-877-829-2619.

Shipment Support
US Trade Customer Service
Call 1-800-666-7248.

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

Manufactured by
Pfizer Inc.
New York, NY 10017

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.

Label Update: Effective 9/22/21

The Emergency Use Authorization (EUA) Fact Sheet for Vaccination Providers has been updated to include information about booster doses. Click here to view. Changes include (but are not limited to) the following section:

New Language in Teal

2.3 Vaccination Schedule

Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals:

Important Safety Information +

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

This site is intended for U.S. Healthcare Pro

Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered intramuscularly at least 6 months after completing the primary series to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

Continue

Important Safety Information +

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

This site is intended for U.S. Healthcare Professionals.

Indication & Authorized Use

Safety Info

Full Prescribing Information (FDA Approved - 16 Years & Up)

EUA Letter & Fact Sheets (12 Years & Up)

BIONTECH Pfizer

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE[1]

In individuals 16 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine, also

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Monitor vaccine recipients for the

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Indication & Authorized Use

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The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Indication

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Indication & Authorized Use

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Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use to provide:

- a two-dose primary series in individuals 12 through 15 years
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Indication & Authorized Use

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Indication & Authorized Use

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Indication & Authorized Use

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Monitor vaccine recipients for the

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Indication & Authorized Use

Safety Info

Full Prescribing Information (FDA Approved -

Important Safety Information

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In a clinical study of adolescents 12 through 15 years of age, the most commonly reported adverse reactions included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Indication

COMIRNATY® is a vaccine indicated 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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use to provide:

- a two-dose primary series in individuals 12 through 15 years
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older to provide:

- a two-dose primary series in individuals 12 years of age and older
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age at risk of serious complications of COVID-19 in the setting of frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE[1]

In individuals 16 years of age and older, the **Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA),*** has been approved for active immunization to prevent COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR EMERGENCY USE[2]

The emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. [2]

*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with certain differences that do not impact safety or effectiveness.

Adverse Event Reporting

Report an Adverse Event to VAERS*

*This website is neither owned nor controlled by Pfizer. Pfizer does not endorse and is not responsible for the content or services of this site.

Report an Adverse Event to Pfizer

Mandatory Requirements for Vaccine Administration Under Emergency Use Authorization[2†]

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

1. The vaccine is authorized for use in individuals 12 years of age and older.
2. The vaccination provider must communicate to the individual receiving the vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving the 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 "the 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 the 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.

Website: www.pfizersafetyreporting.com

Fax number: 1-866-635-8337

Telephone number: 1-800-438-1985

†Vaccination providers administering COMIRNATY® (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.[2]

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine. Monitor 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/clinical-considerations/managing-anaphylaxis.html).

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.

Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study evaluating administration of a booster dose in participants 18 through 55 years of age, the most commonly reported adverse reactions (≥10%) following the dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), and joint pain (25.3%).

In a clinical study of adolescents 12 through 15 years of age, the most commonly reported adverse reactions included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Before administration of the vaccine, please see full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age), and Recipients and Caregivers Fact Sheet (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

References

1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; 2021.
2. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Pfizer and BioNTech; 2021.

For more information

Pfizer Customer Service
Call 1-800-879-3477.

Medical Information
Visit PfizerMedicalInformation.com or call 1-800-438-1985.

General Product Inquiries
Call 1-877-829-2619.

Shipment Support
US Trade Customer Service
Call 1-800-666-7248.

BIONTECH Pfizer

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An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY
10017

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.