URL Flat annotations are provided at first mention <u>Label Update: Effective 9/22/21</u> Drives to http:// The Emergency Use Authorization (EUA) Fact Sheet for Vaccination Providers has been updated to include information about booster doses. <u>Click here</u> to view. Changes include (but are not limited to) the following section: labeling.pfizer.com/ ShowLabeling.aspx? New Language in Teal id=14471&format=pdf 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 Tray • 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

remains consistent on every page of website

Drives to pg

Continue

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 ER-2021-5683-0951699 injury from fainting.

Safety Info

Dosing & Administration Home

Clinical Efficacy

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 AGE¹

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 USE²

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







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.

BIONTECH Pfizer

Home

Dosing & Administration

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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

Disease 2019 (COVID-19) fc. use in marriages 12 years or age and order, and and 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

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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-CBER-2021-5683-0951701 injury from fainting.

BIONTECH Pfizer

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Home

Dosing & Administration

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- 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

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Disease 2019 (COVID-19) fc. use in marriages 12 years or age and order, and and 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

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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 CBER-2021-5683-0951702 injury from fainting.

Information

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

BIONTECH & Pfiz

Quick Access to Important

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE¹

In individuals 16 years of one 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

Home

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:
 - o 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

Important Safety Information

Known history of a severe allergic reaction (eq. 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 (\geq 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.

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Q&A

Product Storage & Dry Ice

Safety Info

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE¹

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 USE²

Dosing & Administration

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

Home

Report an Adverse Event to VAERS*

Report an Adverse Event to Pfizer

Clinical Efficacy

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

Mandatory Requirements for Vaccine Administration Under Emergency Use Authorization²⁺

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

- 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.
- 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 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: <u>1-866-635-8337</u>

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 (210%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling

In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (21.5%), 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

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 Manufactured for

An der Goldgrube 12

55131 Mainz, Germany

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BIONTECH

Resources



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All mobile content reflects a responsive design to desktop

All annotations for desktop apply to mobile

<u>Label Update: Effective</u> 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.









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This site is intended for U.S. Healthcare

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

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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.







Indication & Authorized Use

Safety Info

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

EUA Letter & Fact Sheets (12 Years & Up)



FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE¹

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

Important Safety Information

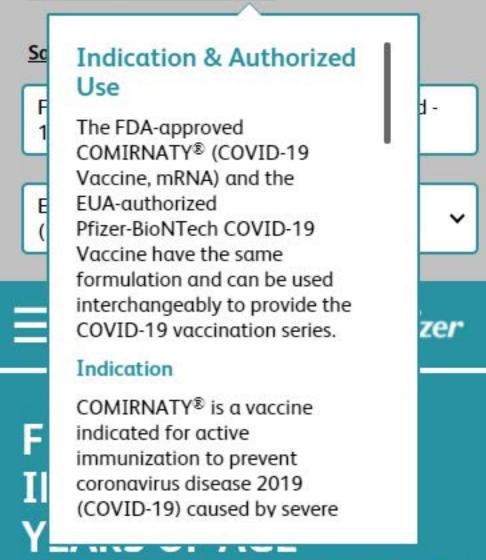


Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.

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 vacence.

Monitor vaccine recipients for the

Indication & Authorized Use



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

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 vacence.

Monitor vaccine recipients for the

Indication & Authorized Use

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

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

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 vacence.

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- a single booster dose in individuals:
 - 65 years of age and older

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- 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

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

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 vacence.

Monitor vaccine recipients for the

Indication & Authorized Use

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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:

- 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:

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

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 vacence.

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Indication & Authorized Use

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- 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

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

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 vacence.

Monitor vaccine recipients for the



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This site is intended for U.S. Healthcare

Indication & Authorized Use

Professionals.

(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/managinganaphylaxis.html).

risks of myocarditis and pericarditis, particularly within 7 days following the

second dose.

in place to avoid injury from fainting.

Immunocompromised persons, including

therapy, may have a diminished immune

The vaccine may not protect all vaccine

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%).

(12+ years of age).

Prevention (CDC). Visit

call 1-800-822-7967.

Indication

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years of age and older

immunocompromise

severe COVID-19

severe

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

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

https://vaers.hhs.gov/reportevent.html or

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

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

a two-dose primary series in individuals 12

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

65 years of age and older
18 through 64 years of age at high risk of

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

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

a two-dose primary series in individuals 12

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

18 through 64 years of age at high risk of

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 FDA-CBER 2021/25685 G0517 13 including severe COVID-19

a single booster dose in individuals: 65 years of age and older

including severe COVID-19

a single booster dose in individuals:

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

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%).

response to the vaccine.

recipients

individuals receiving immunosuppressant

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

Postmarketing data demonstrate increased

Safety Info Full Prescribing Information (FDA Approved -16 Years & Up) **EUA Letter & Fact Sheets** (12 Years & Up)

This site is intended for U.S. Healthcare

Indication & Authorized Use

Professionals.

BIONTECH FDA APPROVED FOR INDIVIDUALS > 16

YEARS OF AGE¹ 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 USE²

has not been approved or licensed

The emergency use of the product 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

emergency use of this product is

12 years of age and older; and the 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

the vaccination series without presenting any

safety or effectiveness concerns. The products

do not impact safety or effectiveness.

are legally distinct, with certain differences that

products can be used interchangeably to provide

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.

Mandatory Requirements for Vaccine Administration Under Emergency Use Authorization²⁺

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

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

vaccination information in the state/local

jurisdiction's Immunization Information

4. The vaccination provider is responsible for

mandatory reporting of the following to the

Vaccine Adverse Event Reporting System

vaccine administration errors whether or

not associated with an adverse event,

System (IIS) or other designated system.

In order to mitigate the risks of using this

this EUA is limited to the following (all

requirements must be met):

(VAERS):

online at

Death;

hospitalization;

Report an Adverse Event to Pfizer

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

 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

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

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.

administration of the vaccine to recipients.

and cases of COVID-19 that result in

Inpatient hospitalization or prolongation of existing

 A persistent or significant incapacity or substantial disruption of the ability to conduct normal life

hospitalization or death following

*Serious adverse events are defined as:

A life-threatening adverse event;

description section of the report.

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

using the contact information above.

Fax number: 1-866-635-8337

Vaccination providers may report to VAERS other adverse events that are not required to be reported

To the extent feasible, report adverse events to

by providing a copy of the VAERS form to Pfizer

Website: www.pfizersafetyreporting.com

Telephone number: <u>1-800-438-1985</u>

COMIRNATY® (COVID-19 Vaccine, mRNA) must

adhere to the same reporting requirements.²

Important Safety

Known history of a severe allergic reaction

(eg, anaphylaxis) to any component of

COMIRNATY® is a contraindication.

acute anaphylactic reaction occurs

Monitor vaccine recipients for the

increased risks of myocarditis and

Syncope (fainting) may occur in association with administration of

following the second dose.

injury from fainting.

response to the vaccine.

recipients.

pericarditis, particularly within 7 days

injectable vaccines, including this vaccine.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune

The vaccine may not protect all vaccine

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

and injection site swelling (10.6%).

administration of a booster dose in

participants 18 through 55 years of age,

reactions (≥10%) following the dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain

the most commonly reported adverse

(39.1%), chills (29.1%), and joint pain

In a clinical study of adolescents 12 through 15 years of age, the most

commonly reported adverse reactions

(49.2%), muscle pain (42.2%), fever

swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and

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

included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills

(24.3%), joint pain (20.2%), injection site

(25.3%).

nausea (0.4%).

(12+ years of age).

call 1-800-822-7967.

References

2021.

Procedures should be in place to avoid

following administration of the vaccine.

occurrence of immediate adverse reactions

[†]Vaccination providers administering

Pfizer Inc. using the contact information below or

VAERS and Pfizer Inc.

Inc.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an

Information

according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managinganaphylaxis.html). Postmarketing data demonstrate

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

(41.5%), joint pain (27.5%), fever (17.8%),

In clinical studies of participants 56 years

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

COMIRNATY[®] (COVID-19 Vaccine, mRNA).

Prescribing Information. Pfizer and BioNTech;

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 <u>1-800-438-1985</u>.

General Product Inquiries Call 1-877-829-2619. Shipment Support **US Trade Customer Service** Call 1-800-666-7248.

Pfizer BIONTECH Manufactured for BioNTech Manufactured by Manufacturing GmbH Pfizer Inc. An der Goldgrube 12 New York, NY 55131 Mainz, Germany 10017

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer. © 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0422

Marketing Authorization Holder

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educational purposes only.