Label Update: Effective 10/20/21

The Emergency Use Authorization (EUA) Fact Sheet for Vaccination Providers has been updated to include additional information about booster doses. Click here to view. For questions, visit PfizerMedicalInformation.com or call 1-800-438-1985. Changes include (but are not limited to) the following section:

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

Updated 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 with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

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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 to individuals 12 through 15 years
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 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 with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination

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 to individuals 12 years of age and older
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 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 with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination

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.

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

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

drive to: http://labeling.pfizer.com/ShowLabeling.aspx?

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 to individuals 12 through 15 years
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS O

In individuals 16 years of age and older, the Pfizer-BioNTech COVI
COMIRNATY® (COVID-19 Vaccine, mRNA),* has been approve
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
an Emergency Use Authorization (EUA) to prevent Coronavirus Disease
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.**

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Adverse Event Reporting

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

EUA Fact Sheet for Recipients and Caregivers (12 Years & Up)

Product Storage & Dry Ice

Website for Recipients and Caregivers

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

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%).

- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 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 with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination

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 to individuals 12 years of age and older
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS O

In individuals 16 years of age and older, the Pfizer-BioNTech COVI COMIRNATY® (COVID-19 Vaccine, mRNA),* has been approve 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 an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 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.**

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- Adverse Event Reporting
- nation ears & Up)
- EUA Fact Sheet for Vaccination Providers (12 Years & Up)
- EUA Fact Sheet for Recipients and Caregivers (12 Years & Up)
- Product Storage & Dry Ice
- Website for Recipients and Caregivers

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

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%).

booster dose of the vaccine used for primary vaccination

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 to individuals 12 years of age and older
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 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 with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS O

In individuals 16 years of age and older, the Pfizer-BioNTech COVI COMIRNATY® (COVID-19 Vaccine, mRNA),* has been approve COVID-19 caused by SARS-CoV-2.[1]

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Adverse Event Reporting

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

EUA Fact Sheet for Recipients and Caregivers (12 Years & Up)

Product Storage & Dry Ice

Website for Recipients and Caregivers

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

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%).

Label Update: Effective 10/20/21

The Emergency Use Authorization (EUA) Fact Sheet for Vaccination Providers has been updated to include additional information about booster doses. Click here to view. For questions, visit PfizerMedicalInformation.com or call 1-800-438-1985. Changes include (but are not limited to) the following section:

Updated Language in Teal

2.3 Vaccination Schedule

Booster Dose:

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may

Important Safety Information +

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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.

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 with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous

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.

- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

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

Important Safety Information

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

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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.

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 to individuals 12 through 15 years
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 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 with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination

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 to individuals 12 years of age and older
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- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 65 years of age and older
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This site is intended for U.S. Healthcare Professionals.

Indication & Authorized Use

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

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 vaccine.

Monitor vaccine recipients for the

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

Indication & Authorized Use

Authorized Use

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

- a two-dose primary series to individuals 12 through 15 years
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of 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 vaccine.

Monitor vaccine recipients for the

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Indication & Authorized Use

- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination

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:

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

Important Safety Information +

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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 single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19

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

Important Safety Information +

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Monitor vaccine recipients for the

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Indication & Authorized Use

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- 18 through 64 years of age at high risk of severe COVID-19
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- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination

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