Label Update Effective: 10/20/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine Recipients and Caregivers Fact Sheet has been updated to include information about booster doses. Click here to view.

Updated information is in purple.

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose

The vaccine may not protect everyone.
Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

The vaccine may not protect everyone.

**EMERGENCY USE AUTHORIZATION INFORMATION**

The emergency uses of the vaccine have not been approved or licensed by FDA, but have 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. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(a)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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**Indication & Authorized Use**

**HOW IS THE VACCINE GIVEN?**

The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose.

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**Important Safety Information**

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
COMIRNATY® (COVID-19 Vaccine, mRNA) is **FDA APPROVED** for 16 years old & up

COMIRNATY® (COVID-19 Vaccine, mRNA) is also known as Pfizer-BioNTech COVID-19 Vaccine*

On December 11, 2020, the US Food and Drug Administration (FDA) authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 of years and older. On August 23, 2021, COMIRNATY® (COVID-19 Vaccine, mRNA)* received FDA approval.

*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.
HOW IS THE VACCINE GIVEN?
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:
- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

WHAT IS THE INDICATION AND AUTHORIZED USE?
The FDA-approved COMIRNATY® COVID-19 Vaccine, mRNA1, and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 primary vaccination or a booster dose.

COMIRNATY® COVID-19 Vaccine, mRNA1 is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

Important Safety Information
You should not get the vaccine if you:
- have a severe allergic reaction after a previous dose of this vaccine
- have a severe allergic reaction to any ingredient of this vaccine

Tell the vaccination provider about all of your medical conditions, including if you:
- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone.

Side effects reported with the vaccine include:
- There is a remote chance that the vaccine could cause a severe allergic reaction.
- A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.
- Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness.
- If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart.
- Side effects that have been reported with the vaccine include:
  - severe allergic reactions: non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; fainting in association with injection of the vaccine.
  - These may not be all possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Data on administration of this vaccine at the same time as other vaccines has not yet been studied by the FDA. If you are considering receiving this vaccine with other vaccines, discuss your options with your healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. 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://www.vaers.hhs.gov or call 1-800-822-7977. In addition, you can report side effects to Pfizer Inc. at www.vaccinesafetyreporting.com or by calling 1-800-438-1985. FDA-CBER-2021-5683-0950678

Click here for full Prescribing Information (16 years of age and older) EUA Fact Sheet for Vaccination Providers (12+ years of age), and Robocalls and Caregivers Fact Sheet (12+ years of age).
It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older.

It is also authorized under EUA 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.
Label Update Effective: 10/20/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine Recipients and Caregivers Fact Sheet has been updated to include information about booster doses. Click here to view.

Updated information is in teal.

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

The vaccine may not protect everyone.
Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

The vaccine may not protect everyone.

EMERGENCY USE AUTHORIZATION INFORMATION

The emergency uses of the vaccine have not been approved or licensed by FDA, but have 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. The emergency uses are 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.
The Vaccine is Authorized for Ages 12 Years & Up

The emergency uses of the vaccine have not been approved or licensed by FDA, but have 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. The emergency uses are 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.

What you need to know about the vaccine

Frequently Asked Questions

Indication & Authorized Use

HOW IS THE VACCINE GIVEN?
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series. 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who

Important Safety Information

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
Important Safety Information

You should not give the vaccine to you if:
- you have had a severe allergic reaction after a previous dose of this vaccine
- you have had a severe allergic reaction to any ingredient of this vaccine

Tell the vaccination provider about all of your medical conditions, including:
- any allergies
- any history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- a fever
- any bleeding disorders or if you are on a blood thinner
- if you are immunocompromised or are on a medicine that affects your immune system
- if you are pregnant, plan to become pregnant, or are breastfeeding
- if you have received another COVID-19 vaccine
- if you have ever had an anaphylactic reaction to an injection

The vaccine may not protect everyone.

Side effects reported with the vaccine include:
- A severe allergic reaction that would usually occur within a few minutes to one hour after receiving a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.
- Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness.
- If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine.

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. If you are considering receiving this vaccine with other vaccines, discuss your options with your healthcare provider.
• It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older.
• It is also authorized under EUA 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series
What you need to know about the vaccine

**Frequently Asked Questions**

**Getting Your Dose**
- What is the recommended dose of vaccine?
- Is it necessary to receive the vaccine dose on time?
- Should there be an interval between doses or can they be given simultaneously?
- Are there specific precautions to follow for the COVID-19 vaccine or can you go about your daily activities normally?

**Getting Both Your Second Dose**
- Is it necessary to receive both doses of the vaccine?
- How long should the interval between the first and second dose be?
- Are there specific precautions to follow for the COVID-19 vaccine or can you go about your daily activities normally?

**Screening More About the Vaccine**
- What is the active ingredient in the COVID-19 vaccine?
- What is the relative risk of developing the COVID-19 disease after receiving the vaccine?
- Are there any side effects after receiving the vaccine?
- How long does it take to develop immunity after receiving the vaccine?

**INDICATION & AUTHORIZED USE**

**FOR THE DOCTOR**
- The COVID-19 vaccine is indicated for use in individuals 12 years of age and older. The vaccine is not recommended for use in individuals who have had a severe allergic reaction to any component of the vaccine.
- The vaccine is administered intramuscularly as a single dose of 0.5 mL. The dose should be administered into the deltoid muscle for individuals aged 12 to 55 years and into the anterolateral thigh for older individuals.
- The vaccine is recommended for use in individuals who are at high risk for severe illness or death due to COVID-19, including those with underlying medical conditions that put them at an increased risk of severe illness or death, and those living in long-term care facilities.

**FOR THE PATIENT**
- This vaccine is given intramuscularly as a single dose of 0.5 mL. The dose should be administered into the deltoid muscle for individuals aged 12 to 55 years and into the anterolateral thigh for older individuals.
- The vaccine is recommended for use in individuals who are at high risk for severe illness or death due to COVID-19, including those with underlying medical conditions that put them at an increased risk of severe illness or death, and those living in long-term care facilities.

**IMPORTANT SAFETY INFORMATION**

**FOR THE DOCTOR**
- The COVID-19 vaccine is contraindicated for use in individuals who have had a severe allergic reaction to any component of the vaccine.
- The vaccine is administered intramuscularly as a single dose of 0.5 mL. The dose should be administered into the deltoid muscle for individuals aged 12 to 55 years and into the anterolateral thigh for older individuals.
- The vaccine is recommended for use in individuals who are at high risk for severe illness or death due to COVID-19, including those with underlying medical conditions that put them at an increased risk of severe illness or death, and those living in long-term care facilities.

**FOR THE PATIENT**
- This vaccine is given intramuscularly as a single dose of 0.5 mL. The dose should be administered into the deltoid muscle for individuals aged 12 to 55 years and into the anterolateral thigh for older individuals.
- The vaccine is recommended for use in individuals who are at high risk for severe illness or death due to COVID-19, including those with underlying medical conditions that put them at an increased risk of severe illness or death, and those living in long-term care facilities.

**Vaccine Administration: When You Need to Be Done**

**FOR THE DOCTOR**
- The COVID-19 vaccine is administered intramuscularly as a single dose of 0.5 mL. The dose should be administered into the deltoid muscle for individuals aged 12 to 55 years and into the anterolateral thigh for older individuals.
- The vaccine is recommended for use in individuals who are at high risk for severe illness or death due to COVID-19, including those with underlying medical conditions that put them at an increased risk of severe illness or death, and those living in long-term care facilities.

**FOR THE PATIENT**
- This vaccine is given intramuscularly as a single dose of 0.5 mL. The dose should be administered into the deltoid muscle for individuals aged 12 to 55 years and into the anterolateral thigh for older individuals.
- The vaccine is recommended for use in individuals who are at high risk for severe illness or death due to COVID-19, including those with underlying medical conditions that put them at an increased risk of severe illness or death, and those living in long-term care facilities.
Label Update Effective: 10/20/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine Recipients and Caregivers Fact Sheet has been updated to include information about booster doses. Click here to view.

Updated information is in purple.

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Important Safety Information

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any
 Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

**Important Safety Information**

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any other vaccine
The vaccine may not protect everyone.

**EMERGENCY USE AUTHORIZATION INFORMATION**

The emergency uses of the vaccine have not been approved or licensed by FDA, but have 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. The emergency uses are 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.

**Important Safety Information**

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any
Important Safety Information

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine
Important Safety Information

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone.

Side effects reported with the vaccine include:
Important Safety Information

- There is a remote chance that the vaccine could cause a severe allergic reaction.
  - A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.
  - Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness.
  - If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after

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Important Safety Information

- Receiving the vaccine:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart

- Side effects that have been reported with the vaccine include:
  - severe allergic reactions; non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; fainting in association with injection of the vaccine

- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call
Important Safety Information

the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. If you are considering receiving this vaccine with other vaccines, discuss your options with your healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. 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://www.vaers.hhs.gov or call 1-800-822-7967. In addition, you can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Click here for 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).
HOW IS THE VACCINE GIVEN?
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

• A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine.
Important Safety Information

WHAT IS THE INDICATION AND AUTHORIZED USE?

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 primary vaccination or a booster dose.

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under EUA 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®:
Important Safety Information

- 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA 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
Important Safety Information

Information of the vaccine used for the primary series

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.
Label Update Effective: 10/20/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine Recipients and Caregivers Fact Sheet has been updated to include information about booster doses. Click here to view.

Updated information is in teal.

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Important Safety Information

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any
Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

Important Safety Information

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any
The vaccine may not protect everyone.

**EMERGENCY USE AUTHORIZATION INFORMATION**

The emergency uses of the vaccine have not been approved or licensed by FDA, but have 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. The emergency uses are 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.

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any other ingredient of this vaccine
The Vaccine is Authorized for Ages 12 Years & Up

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Important Safety Information

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine
Important Safety Information

You should **not** get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone.

Side effects reported with the vaccine include:
Important Safety Information

- There is a remote chance that the vaccine could cause a severe allergic reaction.
  - A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.
  - Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness.
  - If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after
**Important Safety Information**

- Receiving the vaccine:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart

- Side effects that have been reported with the vaccine include:
  - severe allergic reactions; non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; fainting in association with injection of the vaccine

- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or your
Important Safety Information

If you have any side effects that bother you or do not go away, please consult your healthcare provider.

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. If you are considering receiving this vaccine with other vaccines, discuss your options with your healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. 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://www.vaers.hhs.gov or call 1-800-822-7967. In addition, you can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Click here for 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).
**Important Safety Information**

**Authorized Use & Indication**

**HOW IS THE VACCINE GIVEN?**
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

**Booster Dose:**

- A single booster dose of the vaccine may be administered at least 6 months after completion of a 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 vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.
WHAT IS THE INDICATION AND AUTHORIZED USE?

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 primary vaccination series or a booster dose.

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under EUA 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
Important Safety Information

- 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA 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
Important Safety Information

Schedule are based on the labeling information of the vaccine used for the primary series.

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA 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. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.