URL Flat annotations are

provided at first mention FDA APPROV for 16 years old & u

COMIRNATY® (COVID-19 Vacci)

On December 11, 2020, the US the Pfizer-BioNTech COVID-19 August 23, 2021, COMIRNATY

*The licensed DOMIRNATY® vaccine has the products can be used interchange concerns. The products are legally dis

STAY INFORMED

≥COMIRNAT (COVID-19 Vaccine, mRNA

Tray remains consistent on every page of website

Label Update Effective: 09/22/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pizer-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 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 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

The vaccine may not protect everyone.

CONTINUE

INDICATION & AUTHORIZED USE

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

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

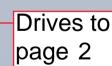
Tell the vaccination provider about all of your medical conditions, including if you:

- 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

Drives to http:// labeling.pfiz er.com/ ShowLabelin g.aspx? id=14472&fo rmat=pdf

FDA APPROVED

16 Years & Up











Opens tray

following

(see

page)

FDA APPROVED 16 Years & Up

AUTHORIZED USE 12 Years & Up

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.

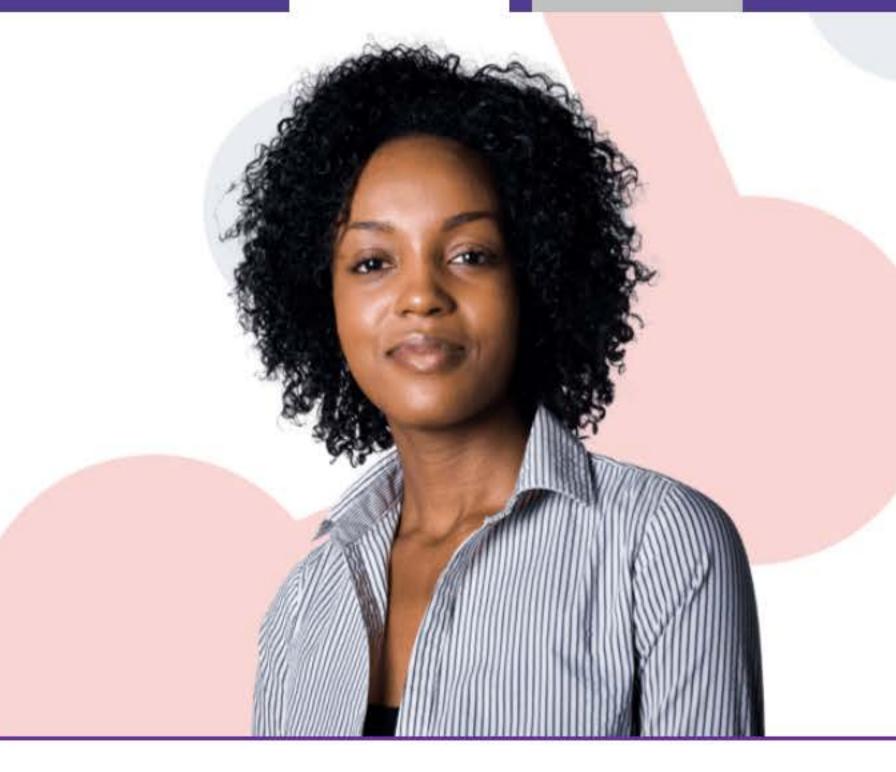
*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with certain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

STAY INFORMED

CDC VACCINE FINDER*

SHARE THE NEWS





INDICATION & AUTHORIZED USE

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



HOW IS THE VACCINE GIVEN?

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

Indication & Authorized Use

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

FDA APPROVED 16 Years & Up

12 Years & Up

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 are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered 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

WHAT IS THE INDICATION AND **AUTHORIZED USE?**

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

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
- o a two-dose primary series in individuals 12 through 15 years
- o a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- o 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
- o 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 EUA from FDA to provide:

- · a two-dose primary series in individuals 12 years of age and older
- · a third primary series dose for 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
- o 18 through 64 years of age at high risk of severe COVID-19
- o 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

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:

- · There is a remote chance that the vaccine could cause a severe allergic reaction.
 - o 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
 - o 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
 - o 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:
 - o chest pain
 - shortness of breath
 - o feelings of having a fast-beating, fluttering, or pounding heart
- · Side effects that have been reported with the vaccine include:
 - o 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 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).

Drives to https:// labeling.pfiz er.com/ ShowLabelin g.aspx? id=15623&fo rmat=pdf

Drives to http:// labeling.pfiz er.com/ ShowLabelin g.aspx? id=14471&fo rmat=pdf

Drives to: http:// labeling.pfiz er.co m/ ShowLabelin g.a spx? id=14472&fo rma t=pdf



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.

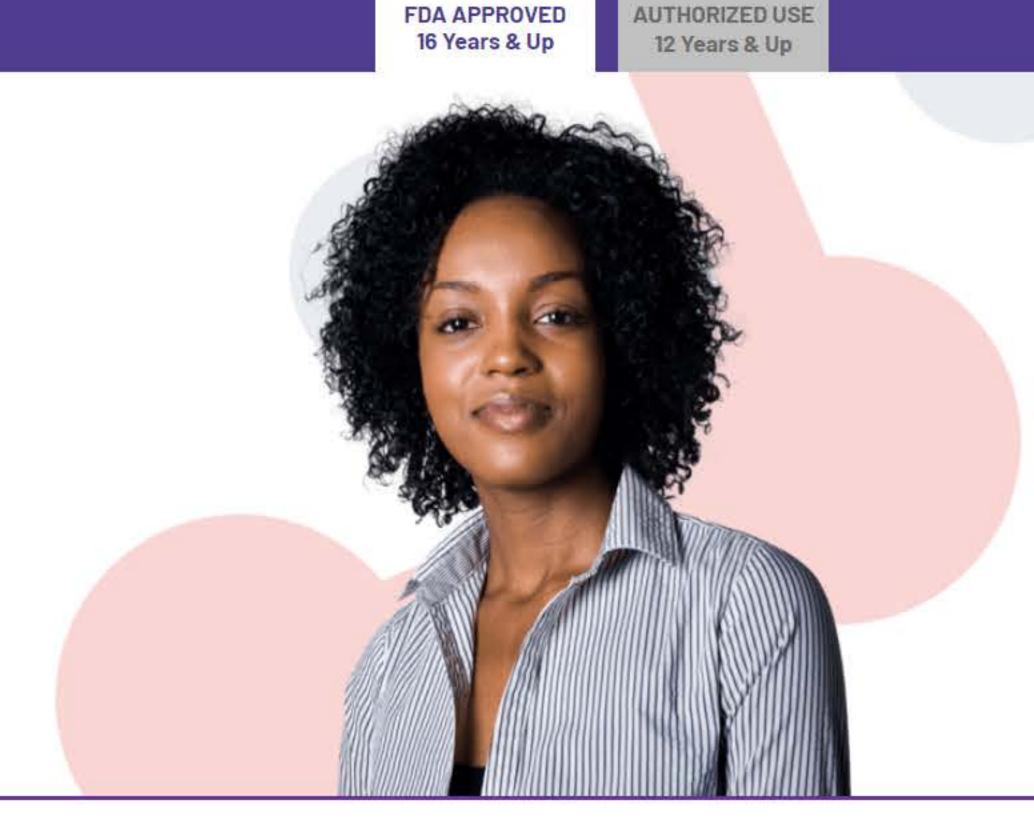
*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with certain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

STAY INFORMED

CDC VACCINE FINDER*

SHARE THE NEWS





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 are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered 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

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 vaccination series.

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:
 - o a two-dose primary series in individuals 12 through 15 years
 - o 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
 - o 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 EUA from FDA to provide:

- · a two-dose primary series in individuals 12 years of age and older
- · a third primary series dose for 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

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: 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
- o 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

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).

- o 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
- o feelings of having a fast-beating, fluttering, or pounding heart
- · Side effects that have been reported with the vaccine include:
- o 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 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.

Vaccine Authenticity: What You Need to Know

Around the world, Pfizer and BioNTech are working in partnership with government agencies to safely and efficiently distribute the vaccine. There are currently no legitimate COVID-19 vaccines produced by any manufacturer that are available for purchase by individuals.

We urge everyone to be wary of any offers for COVID-19 vaccinations that do not come from an authorized source - meaning, from anyone other than a healthcare provider or local government health agency.

The vaccine:

- . Is NOT sold online. Any sales of COVID-19 vaccines over the Internet, including from online pharmacies, are not legitimate
- Cannot be purchased in individual doses
- Is not taken by mouth and is not available in a capsule or tablet form
- Can only be administered by licensed healthcare professionals at government-authorized vaccination centers such as doctors' offices, authorized pharmacies, outpatient clinics, community vaccination locations, and hospitals.



For More Information

Call your healthcare provider for any additional questions **General Product Inquiries** Call 1-877-829-2619.

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

VISIT CDC.GOV* ☑

Learn more about the COVID-19 vaccination on the Centers for Disease Control and Prevention COVID-19 page.

*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.





Manufactured by

Terms of Use | Privacy Policy | Contact Us

© 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0430

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

Pfizer Inc. New York, NY 10017

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

BIONTECH & Pfizer

AUTHORIZED USE 12 Years & Up

The Vaccine is Auth

The emergency use of the produ authorized by FDA, under an Em 2019 (COVID-19) for use in indiv product is only authorized for the authorization of emergency use of unless the declaration is terminat

CDC VACCINE FINDER*

What you need

Tray remains consistent on every page of website

Frequently Asked

Label Update Effective: 09/22/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pizer-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 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 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

The vaccine may not protect everyone.

CONTINUE

Drives to page 2

What Is Emergency Use Authorization?

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System

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 are determined to have

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





FDA APPROVED 16 Years & Up

AUTHORIZED USE 12 Years & Up

The Vaccine is Authorized for Ages 12 Years & Up

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.

CDC VACCINE FINDER*



Opens tray (see following page)

What you need to know about the vaccine Frequently Asked Questions

What Is Emergency Use Authorization?

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 are determined to have

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

Report vaccine side effects to FDA/CDC

Vaccine Adverse Event Reporting System



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 are determined to have certain kinds of immunocompromise

Booster Dose: A single booster dose of the vaccine may be administered 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

WHAT IS THE INDICATION AND AUTHORIZED

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 vaccination series,

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 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
- o 18 through 64 years of age at high risk of severe COVID-19
- o 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 EUA from FDA to provide:

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

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:

- . 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
- . 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 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.yaers.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

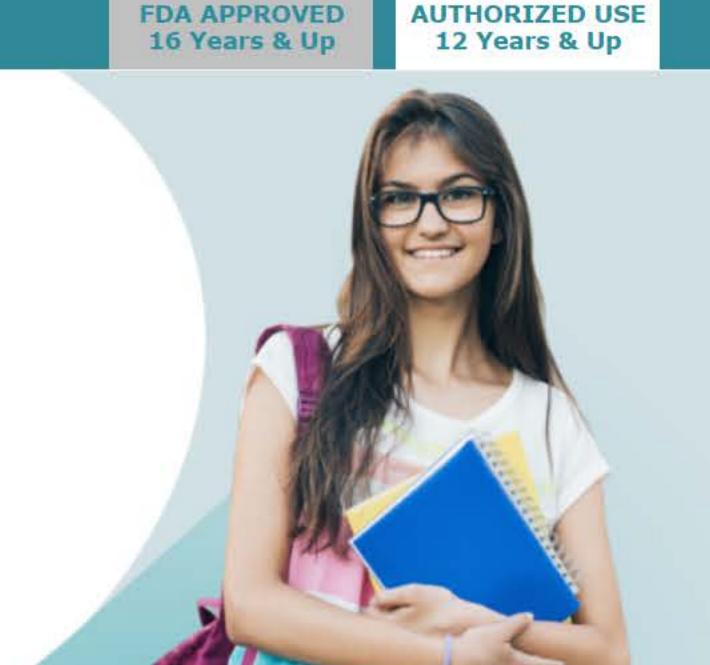
Click here for full Prescribing Information (16+ years of age), EUA Fact Sheet for Vaccination Providers (12+ years of age) and Recipients and Caregivers Fact Sheet (12+ years of age).



The Vaccine is Authorized for Ages 12 Years & Up

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.

CDC VACCINE FINDER*



What you need to know about the vaccine

Frequently Asked Questions

What Is Emergency Use Authorization?

According to the FDA, "During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives."

Getting Your Vaccine Open all What if I am immunocompromised? What should you mention to your vaccination provider before you get the vaccine? Open all Getting Ready for Your Second Dose When do I receive my second dose of the vaccine? What if the second dose cannot be provided at 3 weeks (21 days)? Are the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY® interchangeable with other COVID-19 vaccines? Knowing More About the Vaccine Open all Will the vaccine give me COVID-19? What are the risks of the vaccine? What should I do about side effects? Who should not get the vaccine? What are the ingredients in the vaccine? Is there preservative in the vaccine? Are the components of the vaccine vial made with latex? How did Pfizer ensure diversity in conducting the vaccine clinical trial?

Vaccine Adverse Event Reporting System (VAERS) and Pfizer Inc.

Report vaccine side effects to FDA/CDC

REPORT AN ADVERSE EVENT TO VAERS REPORT AN ADVERSE EVENT TO PFIZER **FACT SHEET FOR RECIPIENTS AND**

- CAREGIVERS
- advice about adverse events. · You are encouraged to report negative side effects of and the Centers for Disease Control and Prevention

Patients should always ask their doctors for medical

vaccines to the U.S. Food and Drug Administration (FDA) (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

INDICATION & AUTHORIZED USE

HOW IS THE VACCINE GIVEN?

Where can I learn more?

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 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 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 vaccination series.

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:

- o a two-dose primary series in individuals 12 through 15 years
 - o 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 o 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 EUA from FDA to provide: a two-dose primary series in individuals 12 years of age and older
- · a third primary series dose for 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

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:

- 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 o 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:
- o 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:

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

- o 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
- 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).

manufacturer that are available for purchase by individuals.

locations, and hospitals.

55131 Mainz, Germany

Marketing Authorization Holder

Is not taken by mouth and is not available in a capsule or tablet form

Vaccine Authenticity: What You Need to Know

Around the world, Pfizer and BioNTech are working in partnership with government agencies to safely and efficiently distribute the vaccine. There are currently no legitimate COVID-19 vaccines produced by any

We urge everyone to be wary of any offers for COVID-19 vaccinations that do not come from an authorized source - meaning, from anyone other than a healthcare provider or local government health agency.

• Can only be administered by licensed healthcare professionals at government-authorized vaccination centers - such as doctors' offices, authorized pharmacies, outpatient clinics, community vaccination

The vaccine: . Is NOT sold online. Any sales of COVID-19 vaccines over the Internet, including from online pharmacies, are not legitimate Cannot be purchased in individual doses

General Product Inquiries Call 1-877-829-2619. **Medical Information** Visit PfizerMedicalInformation.com For more information or call 1-800-438-1985. Learn more about COVID-19 vaccination on the Centers ☑ VISIT CDC.GOV* for Disease Control and Prevention (CDC) website.

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

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

BIONTECH Pfizer © 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0430 Terms of Use | Privacy Policy | Contact Us Manufactured for Manufactured by BioNTech Manufacturing GmbH Pfizer Inc. An der Goldgrube 12 New York, NY 10017

This site is intended only for US residents. The products discussed in this site may have different product labeling in different countries. The information provided is for educational purposes only and is not



mobile

AA airnatycom-preview.dev.pfizerstatic.io



Indication | Important Safety Info | Report | All | All mobile content reflects a responsive design to desktop | 4 | Fact Shee | for desktop | apply to

Label Update Effective: 09/22/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pizer-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 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.

COTION OF THE CHIEF THEFT

Important Safety Information



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









AA airnatycom-preview.dev.pfizerstatic.io



Indication | Important Safety Info | Report Adverse Event > |

Prescribing Info 16 Years & Up | Fact Sheet 12 Years & Up >

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 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

The vaccine may not protect everyone.



Important Safety Information



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









FDA APPROVED 16 Years & Up AUTHORIZED USE 12 Years & Up

COMIRNATY® (COVID-19 Vaccine, mRNA) is

FDA APPROVED

for 16 years old & up

STAY INFORMED

CDC VACCINE FINDER*

SHARE THE NEWS



(COVID-19 Vaccine, mRNA)



Important Safety Information



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

blood thinner

- (inflammation of the lining outside the heart)
- · have a fever have a bleeding disorder or are on a

· 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.

There is a remote chance that the vaccine could cause a severe

Side effects reported with the vaccine include:

o A severe allergic reaction would usually occur within a few minutes to one hour after

allergic reaction,

- 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

ı

- heartbeat, a bad rash all over your body, dizziness, and
- weakness o 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 The chance of of the vaccine,
 - 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: o chest pain o shortness of breath

o feelings of having a fast-

reported with the vaccine include:

- beating, fluttering, or pounding heart · Side effects that have been
 - o 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
- if you have any side effects that bother you or do not go away Data on administration of this vaccine at

provider or your healthcare provider

- 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
- call <u>1-800-822-7967</u>. 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).

Indication & Authorized Use

Prevention (CDC), Visit https://www.vaers.hhs.gov or

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 to

• 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

· 65 years of age and older

individuals:

high risk of serious complications of COVID-19 including severe COVID-19

- WHAT IS THE INDICATION AND **AUTHORIZED USE?** The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19
- vaccination series.

Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used

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

interchangeably to provide the COVID-19

- · It is approved as a 2-dose series for prevention of COVID-19 in individuals 16
- · It is also authorized under EUA to provide: o a two-dose primary series in

individuals 12 through 15 years o a third primary series dose in

- individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise o a single booster dose in individuals:
- 65 years of age and older o 18 through 64 years of age at high risk of severe COVID-19
- occupational exposure to SARS CoV-2 puts them at high risk of serious complications of COVID-19

 18 through 64 years of age whose frequent institutional or

- including severe COVID-19 The Pfizer-BioNTech COVID-19 Vaccine
- has received EUA from FDA to provide:
 - a two-dose primary series in individuals 12 years of age and older

 a third primary series dose for 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
- o 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 FDA-CBER-2021-5683-0951890

of severe COVID-19

FDA APPROVED AUTHORIZED USE 16 Years & Up 12 Years & Up COMIRNATY® (COVID-19 Vaccine, mRNA) is

> STAY INFORMED CDC VACCINE FINDER*

FDA APPROVED

for 16 years old & up

SHARE THE NEWS

COMIRNAT

(COVID-19 Vaccine, mRNA)

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.

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 are determined to have certain kinds of immunocompromise. Booster Dose: A single booster dose of the vaccine may be administered to individuals: 65 years of age and older

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:

o a two-dose primary series in individuals

individuals 12 years of age and older

CoV-2 puts them at high risk of

including severe COVID-19

a two-dose primary series in individuals 12

The Pfizer-BioNTech COVID-19 Vaccine has

received EUA from FDA to provide:

serious complications of COVID-19

years of age and older a third primary series dose for 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 o 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

 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

nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; fainting in association with injection of

 These may not be all the possible side effects of the vaccine, Serious and

unexpected side effects may occur. The

provider if you have any side effects that

being studied in clinical trials, Call the vaccination provider or your healthcare

Data on administration of this vaccine at the

submitted to FDA, If you are considering

receiving this vaccine with other vaccines,

Patients should always ask their healthcare providers for medical advice about adverse

events, Report negative side effects of

Administration (FDA) and the Centers for

Disease Control and Prevention (CDC), Visit

1-800-822-7967, In addition, you can report side

www.pfizersafetyreporting.com or by calling

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).

Vaccine Authenticity:

What You Need to Know

Around the world, Pfizer and BioNTech

are working in partnership with

vaccines to the US Food and Drug

https://www.vaers.hhs.gov or call

effects to Pfizer Inc. at

1-800-438-1985,

discuss your options with your healthcare

provider.

same time as other vaccines have not yet been

bother you or do not go away

possible side effects of the vaccine are still

the vaccine

Is NOT sold online. Any sales of COVID-19 vaccines over the Internet, including from online pharmacies, are not legitimate Cannot be purchased in individual doses Is not taken by mouth and is not available in a capsule or tablet form Can only be administered by licensed healthcare

professionals at government-

outpatient clinics, community

For More Information

Call your healthcare provider

for any additional questions

General Product Inquiries

Call 1-877-829-2619.

Medical Information

vaccination locations, and

hospitals.

such as doctors' offices, authorized pharmacies,

authorized vaccination centers -

*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.

Terms of Use

© 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0430

Manufactured by

New York, NY 10017

Pfizer Inc.

This site is intended only for US residents. The products discussed in this site may have different product labeling in different countries. The information provided is for educational purposes only and is not intended to replace discussions with a healthcare provider.

 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

WHAT IS THE INDICATION AND AUTHORIZED

The FDA-approved COMIRNATY® (COVID-19) Vaccine, mRNA) and the FDA-authorized

Pfizer-BioNTech COVID-19 Vaccine under

interchangeably to provide the COVID-19

same formulation and can be used

12 through 15 years

vaccination series.

Emergency Use Authorization (EUA) have the

including severe COVID-19

USE?

who have been determined to have certain kinds of immunocompromise a single booster dose in individuals: o 65 years of age and older o 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-

o a third primary series dose in

IMPORTANT SAFETY INFORMATION

had a severe allergic reaction after a

had a severe allergic reaction to any

Tell the vaccination provider about all of your

have had myocarditis (inflammation of the

have a bleeding disorder or are on a blood

medicine that affects your immune system

are pregnant, plan to become pregnant, or

 have received another COVID-19 vaccine have ever fainted in association with an

Side effects reported with the vaccine include:

The vaccine may not protect everyone.

are immunocompromised or are on a

heart muscle) or pericarditis (inflammation

You should not get the vaccine if you:

previous dose of this vaccine

medical conditions, including if you:

of the lining outside the heart)

ingredient of this vaccine

have any allergies

are breastfeeding

have a fever

thinner

injection

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

Myocarditis (inflammation of the heart

in some people who have received the

vaccine, In most of these people,

symptoms began within a few days

muscle) and pericarditis (inflammation of

the lining outside the heart) have occurred

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:

feelings of having a fast-beating,

Side effects that have been reported with

severe allergic reactions; non-severe

allergic reactions such as rash, itching,

myocarditis (inflammation of the heart

fluttering, or pounding heart

hives, or swelling of the face;

hospital

chest pain

o shortness of breath

the vaccine include:

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

government agencies to safely and efficiently distribute the vaccine. There are currently no legitimate COVID-19 vaccines produced by any manufacturer that are available for purchase by individuals. We urge everyone to be wary of any offers for COVID-19 vaccinations that

do not come from an authorized

government health agency.

The vaccine:

source - meaning, from anyone other

than a healthcare provider or local

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

VISIT CDC.GOV*

Learn more about the COVID-19 vaccination on the Centers for Disease Control and Prevention COVID-19

page.

ď

BIONTECH

FDA-CBER-2021-5683-0951891

Manufactured for

BioNTech Manufacturing

Contact Us

Privacy Policy

55131 Mainz, Germany Marketing Authorization The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.

An der Goldgrube 12

GmbH

Holder



AA A irnatycom-preview.dev.pfizerstatic.io



Label Update Effective: 09/22/21

The COMIRNATY® (COVID-19 Vaccine, mRNA) and Pizer-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 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.

authorization revoked sooner

Important Safety Information



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









AA 🔒 irnatycom-preview.dev.pfizerstatic.io



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 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

The vaccine may not protect everyone.



authorization revoked sooner

Important Safety Information



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







Prescribing Info 16 Years & Up



FDA APPROVED 16 Years & Up AUTHORIZED USE 12 Years & Up

The Vaccine is Authorized for Ages 12 Years & Up

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.

Important Safety Information



- had a severe allergic reaction after a previous dose of this vaccine
 - had a severe aller gic 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

have any allergies have had myocarditis (inflammation

your medical conditions, including if you:

- 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

immune system · are pregnant, plan to become pregnant, or are breastfeeding

• are immunocompromised or are on a medicine that affects your

- have received another COVID-19 vaccine
- have ever fainted in association
- with an injection The vaccine may not protect everyone.
- include: There is a remote chance that the

Side effects reported with the vaccine

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 fastbeating, fluttering, or pounding heart Side effects that have been reported with the vaccine include:
 - as rash, itching, hives, or swelling of the face;
 - myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection

severe allergic reactions; nonsevere allergic reactions such

- 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 healthcare provider if you have any side effects that bother you or do not go away

ı.

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

Data on administration of this vaccine at the same time as other vaccines have not

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). **Authorized Use & Indication** HOW IS THE VACCINE GIVEN? The vaccine will be given to you as an injection into the muscle,

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

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 to

administered as a 2-dose series, 3 weeks

• 18 through 64 years of age at high risk of severe COVID-19 • 18 through 64 years of age whose

· 65 years of age and older

individuals:

Primary Series: The vaccine is

frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

WHAT IS THE INDICATION AND **AUTHORIZED USE?** The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the FDAauthorized Pfizer-BioNTech COVID-19

Vaccine under Emergency Use Authorization (EUA) have the same

formulation and can be used

vaccination series, 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

interchangeably to provide the COVID-19

years of age and older It is also authorized under EUA 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

o a single booster dose in individuals: 0 65 years of age and older 18 through 64 years of age at high 0

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 EUA from FDA to provide:

- · a two-dose primary series in individuals 12 years of age and older a third primary series dose for
 - 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 0 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

Authorized Use | Important Safety Info ✓ Fact Sheet 12 Years & Up ✓ Report Adverse Event Prescribing Info 16 Years & Up **P**fizer BIONTECH FDA APPROVED **AUTHORIZED USE** 16 Years & Up 12 Years & Up The Vaccine is Authorized for Ages 12 Years & Up 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 CDC VACCINE FINDER*

What you need to know

Frequently Asked Questions

According to the FDA, "During a public health emergency, the FDA can use its

authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose,

criteria are met, including that there are

Emergency Use Authorization (EUA)

treat, or prevent serious or life-

threatening diseases when certain

no adequate, approved, and available

about the vaccine

What Is Emergency Use

Authorization?

alternatives."

What if Lam

get the vaccine?

Open all

Dose

Open all

Getting Your Vaccine

immunocompromised?

What should you mention to your

vaccination provider before you

Getting Ready for Your Second

When do I receive my second

What if the second dose cannot

be provided at 3 weeks (21 days)?

Are the Pfizer-BioNTech COVID-

Knowing More About the Vaccine

Will the vaccine give me COVID-

What are the risks of the

What should I do about side

Who should not get the vaccine? +

What are the ingredients in the

Is there preservative in the

Are the components of the

vaccine vial made with latex?

How did Pfizer ensure diversity in

+

conducting the vaccine clinical

Where can I learn more?

Report vaccine side effects to

FDA/CDC Vaccine Adverse Event

REPORT AN ADVERSE EVENT TO

REPORT AN ADVERSE EVENT TO

Patients should always ask their doctors for

 You are encouraged to report negative side effects of vaccines to the U.S. Food and

Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

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

medical advice about adverse events.

Reporting System (VAERS) and

19 Vaccine and COMIRNATY®

interchangeable with other

COVID-19 vaccines?

Open all

19?

vaccine?

effects?

vaccine?

vaccine?

trial?

Pfizer Inc.

7

VAERS

PFIZER.

FACT SHEET FOR

RECIPIENTS AND

CAREGIVERS

or call 1-800-822-7967.

HOW IS THE VACCINE GIVEN?

into the muscle.

INDICATION & AUTHORIZED USE

The vaccine will be given to you as an injection

Primary Series: The vaccine is administered as

may be administered at least 4 weeks after the second dose to individuals who are determined

to have certain kinds of immunocompromise.

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

WHAT IS THE INDICATION AND AUTHORIZED

Emergency Use Authorization (EUA) have the

COMIRNATY® (COVID-19 Vaccine, mRNA) is an

prevention of COVID-19 in individuals 16

It is also authorized under EUA to provide:

o a two-dose primary series in individuals

individuals 12 years of age and older who have been determined to have

certain kinds of immunocompromise

18 through 64 years of age at high

18 through 64 years of age whose

occupational exposure to SARS-

serious complications of COVID-19

CoV-2 puts them at high risk of

a single booster dose in individuals:

65 years of age and older

risk of severe COVID-19

frequent institutional or

including severe COVID-19

a two-dose primary series in individuals 12

a third primary series dose for individuals
 12 years of age and older who have been

determined to have certain kinds of

a single booster dose in individuals:

18 through 64 years of age whose

IMPORTANT SAFETY INFORMATION

had a severe allergic reaction after a

had a severe allergic reaction to any

Tell the vaccination provider about all of your

have had myocarditis (inflammation of the

have a bleeding disorder or are on a blood

medicine that affects your immune system are pregnant, plan to become pregnant, or

have received another COVID-19 vaccine have ever fainted in association with an

Side effects reported with the vaccine include:

There is a remote chance that the vaccine

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

could cause a severe allergic reaction.

you received your vaccine for monitoring after vaccination

and weakness

hospital

o chest pain

o shortness of breath

the vaccine include:

the vaccine

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,

reaction, call 9-1-1 or go to the nearest

If you experience a severe allergic

Myocarditis (inflammation of the heart

in some people who have received the

symptoms after receiving the vaccine:

feelings of having a fast-beating,

Side effects that have been reported with

severe allergic reactions; non-severe

allergic reactions such as rash, itching,

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

fluttering, or pounding heart

hives, or swelling of the face;

 These may not be all the possible side effects of the vaccine. Serious and

unexpected side effects may occur. The

being studied in clinical trials. Call the

Data on administration of this vaccine at the

submitted to FDA, If you are considering

provider.

receiving this vaccine with other vaccines, discuss your options with your healthcare

Patients should always ask their healthcare providers for medical advice about adverse

events, Report negative side effects of

Administration (FDA) and the Centers for

Disease Control and Prevention (CDC), Visit

1-800-822-7967, In addition, you can report side

www.pfizersafetyreporting.com or by calling

Click here for full <u>Prescribing Information</u> (16+ years of age), EUA Fact Sheet for Vaccination

<u>Providers</u> (12+ years of age), and <u>Recipients</u> and <u>Caregivers Fact Sheet</u> (12+ years of age).

Vaccine Authenticity: What You

Need to Know

Around the world, Pfizer and BioNTech are working in partnership with government

agencies to safely and efficiently distribute

legitimate COVID-19 vaccines produced by

We urge everyone to be wary of any offers for COVID-19 vaccinations that do not come

from an authorized source – meaning, from anyone other than a healthcare provider or

from online pharmacies, are not

· Cannot be purchased in individual

Is not taken by mouth and is not

healthcare professionals

locations, and hospitals,

For more

information

General Product Inquiries

PfizerMedicalInformation.com

Call 1-877-829-2619.

Medical Information

or call 1-800-438-1985.

VISIT CDC.GOV*

Learn more about COVID-19

Prevention (CDC) website,

Disease Control and

vaccination on the Centers for

*This website is neither owned nor controlled

responsible for the content or services of this

The Pfizer-BioNTech COVID-19 Vaccine, which is based

© 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0430

This site is intended only for US residents. The

different product labeling in different countries.

FDA-CBER-2021-5683-0951896

products discussed in this site may have

discussions with a healthcare provider.

The information provided is for educational purposes only and is not intended to replace

on BioNTech proprietary mRNA technology, was

developed by both BioNTech and Pfizer.

Pfizer

Manufactured by

New York, NY 10017

Pfizer Inc.

by Pfizer, Pfizer does not endorse and is not

Visit

site

GmbH

Holder

Terms of Use

Privacy Policy

Contact Us

BIONTECH

BioNTech Manufacturing

Manufactured for

An der Goldgrube 12 55131 Mainz, Germany Marketing Authorization

available in a capsule or tablet form

Can only be administered by licensed

centers – such as doctors' offices, authorized pharmacies, outpatient

clinics, community vaccination

at government-authorized vaccination

Is NOT sold online. Any sales of COVID-19 vaccines over the Internet, including

any manufacturer that are available for

the vaccine, There are currently no

local government health agency.

purchase by individuals.

legitimate

doses

vaccines to the US Food and Drug

https://www.vaers.hhs.gov or call

effects to Pfizer Inc. at

1-800-438-1985.

same time as other vaccines have not yet been

bother you or do not go away

vaccination provider or your healthcare provider if you have any side effects that

possible side effects of the vaccine are still

vaccine, in most of these people, symptoms began within a few days

muscle) and pericarditis (inflammation of the lining outside the heart) have occurred

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

heart muscle) or pericarditis (inflammation

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

previous dose of this vaccine

medical conditions, including if you:

of the lining outside the heart)

are immunocompromised or are on a

The vaccine may not protect everyone.

ingredient of this vaccine

have any allergies

are breastfeeding

have a fever

thinner

injection

18 through 64 years of age at high risk 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

o 65 years of age and older

The Pfizer-BioNTech COVID-19 Vaccine has

received EUA from FDA to provide:

years of age and older

immunocompromise

severe COVID-19

FDA-approved COVID-19 vaccine made by

It is approved as a 2-dose series for

o a third primary series dose in

The FDA-approved COMIRNATY® (COVID-19)

Vaccine, mRNA) and the FDA-authorized
Pfizer-BioNTech COVID-19 Vaccine under

interchangeably to provide the COVID-19

same formulation and can be used

vaccination series.

Pfizer for BioNTech.

years of age and older

12 through 15 years

serious complications of COVID-19

Booster Dose: A single booster dose of the vaccine may be administered to individuals:

65 years of age and older

including severe COVID-19

severe COVID-19

USE?

a 2-dose series, 3 weeks apart, A third dose

dose of the vaccine?