



FDA APPROVED  
16 Years & Up

AUTHORIZED USE  
12 Years & Up

URL Flat annotations are provided at first mention

**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

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**INDICATION & AUTHORIZED USE**

**Indication & Authorized Use**

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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
- are immunocompromised or are on a medicine that affects your immune system



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.

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CDC VACCINE FINDER\*

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## INDICATION & AUTHORIZED USE

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(see  
following  
page)

### Indication & Authorized Use

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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:
  - a two-dose primary series in individuals 12 through 15 years
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The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

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- 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
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- 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](http://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).

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# 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 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.

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## INDICATION & AUTHORIZED USE

### HOW IS THE VACCINE GIVEN?

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**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.

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The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

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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
- 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:

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## 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](http://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.



FDA APPROVED  
16 Years & Up

AUTHORIZED USE  
12 Years & Up

## The Vaccine is Authorized

The emergency use of the product is authorized by FDA, under an Emergency Use Authorization (EUA) for COVID-19 (COVID-19) for use in individuals 16 years of age and older. The product is only authorized for the emergency use of the product unless the declaration is terminated.

CDC VACCINE FINDER\*

### 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.

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The vaccine may not protect everyone.

CONTINUE

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## What you need to know

### Frequently Asked Questions

#### What Is Emergency Use Authorization?

#### Indication & Authorized Use

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Report vaccine side effects to FDA/CDC  
Vaccine Adverse Event Reporting 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\\*](#)



## What you need to know about the vaccine

### Frequently Asked Questions

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[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? [+](#)

#### Getting Ready for Your Second Dose

[Open all](#)

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? [+](#)

Where can I learn more? [+](#)

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS) and Pfizer Inc.

[REPORT AN ADVERSE EVENT TO VAERS](#)

[REPORT AN ADVERSE EVENT TO PFIZER](#)

[FACT SHEET FOR RECIPIENTS AND CAREGIVERS](#)

- Patients should always ask their doctors for medical advice about adverse events.
- 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> or call 1-800-822-7967.

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

The Pfizer-BioNTech COVID-19 Vaccine has received 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 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](http://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).

### 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

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

**Medical Information**  
Visit [PfizerMedicalInformation.com](http://PfizerMedicalInformation.com)  
or call 1-800-438-1985.

[VISIT CDC.GOV\\*](#) Learn more about COVID-19 vaccination on the Centers for Disease Control and Prevention (CDC) website.

\*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.



All mobile content reflects a responsive design to desktop

All annotations for desktop apply to mobile

## 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.

## 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

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

## 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



**FDA APPROVED**  
16 Years & Up

**AUTHORIZED USE**  
12 Years & Up

COMIRNATY® (COVID-19 Vaccine, mRNA) is

**FDA APPROVED**  
for 16 years old & up

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[CDC VACCINE FINDER\\*](#)

[SHARE THE NEWS](#)

 **COMIRNATY**<sup>®</sup>  
(COVID-19 Vaccine, mRNA)

## Important Safety Information



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- 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:

- 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 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

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<https://www.vaers.hhs.gov> or call [1-800-822-7967](tel:1-800-822-7967). In addition, you can report side effects to Pfizer Inc. at

[www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling [1-800-438-1985](tel: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

### 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.

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- 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:
    - 65 years of age and older
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    - 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 APPROVED**  
16 Years & Up

**AUTHORIZED USE**  
12 Years & Up

COMIRNATY® (COVID-19 Vaccine, mRNA) is

## FDA APPROVED for 16 years old & up

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[CDC VACCINE FINDER\\*](#)

[SHARE THE NEWS](#)



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 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
- 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.

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  - a single booster dose in individuals:
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    - 18 through 64 years of age at high risk of severe COVID-19
    - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The Pfizer-BioNTech COVID-19 Vaccine has 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 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.

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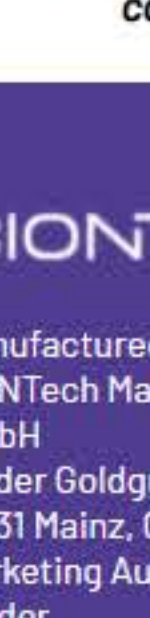
Click here for full [Prescribing Information](#) (16+ years of age), [EUA Fact Sheet for Vaccination Providers](#) (12+ years of age), and [Recipients and Caregivers Fact Sheet](#) (12+ years of age).

### Vaccine Authenticity: What You Need to Know

Around the world, Pfizer and BioNTech are working in partnership with 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](http://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 for BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany  
Marketing Authorization Holder

Manufactured by Pfizer Inc.  
New York, NY 10017

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

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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.

## 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

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



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

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

BIONTECH

FDA APPROVED  
16 Years & UpAUTHORIZED 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



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:

- 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
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  - 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
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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.

**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.

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- 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:
    - 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

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- a two-dose primary series in individuals 12 years of age and older
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- a single booster dose in individuals:
  - 65 years of age and older
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  - 18 through 64 years of age 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



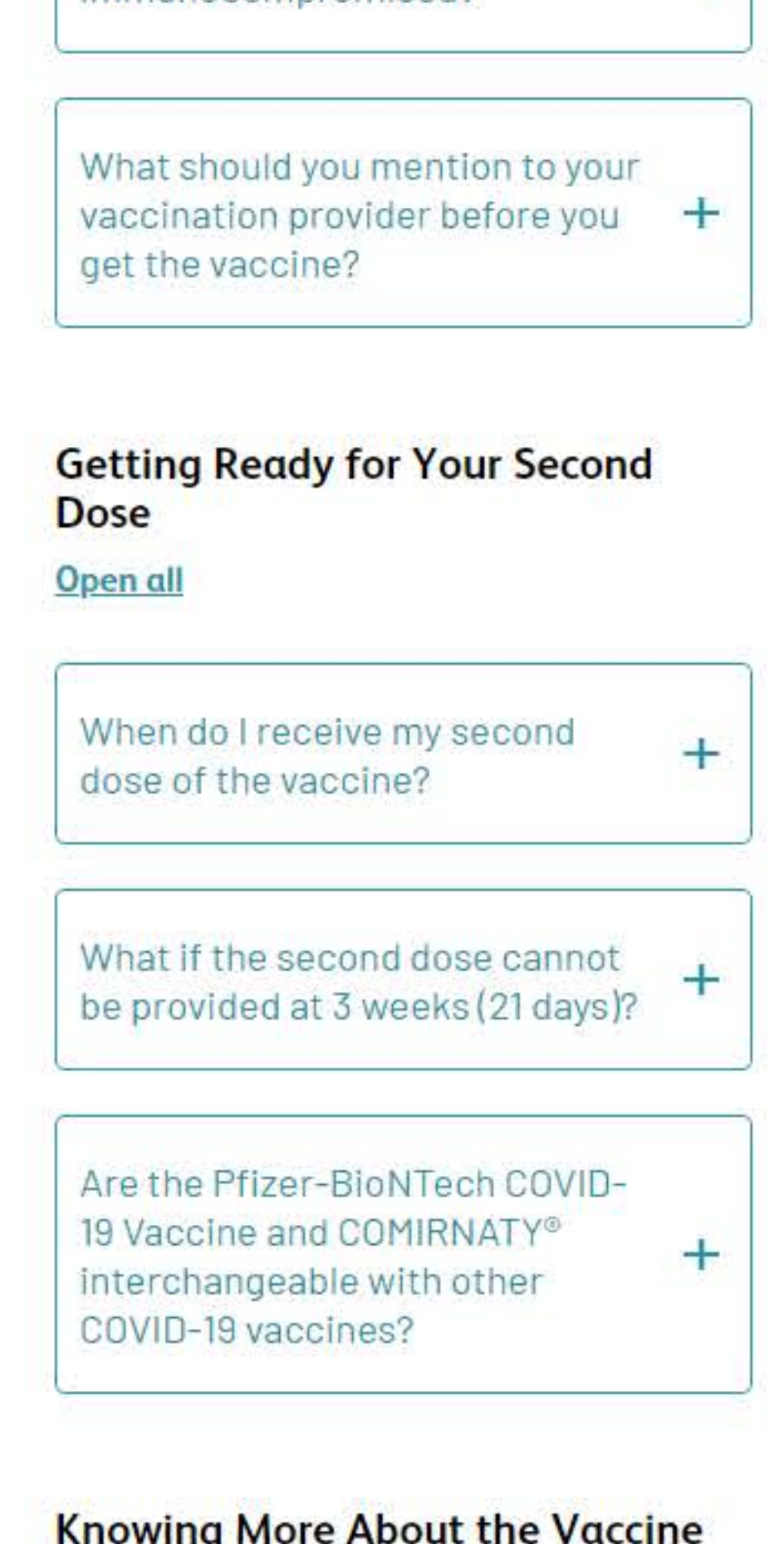
**FDA APPROVED**  
16 Years & Up

**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\***



## 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? +

#### Getting Ready for Your Second Dose

[Open all](#)

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

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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? +

Where can I learn more? +

#### Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS) and Pfizer Inc.

[REPORT AN ADVERSE EVENT TO VAERS](#)

[REPORT AN ADVERSE EVENT TO PFIZER](#)

[FACT SHEET FOR RECIPIENTS AND CAREGIVERS](#)

- Patients should always ask their doctors for medical advice about adverse events.
- 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> or call [1-800-822-7967](tel:1-800-822-7967).

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

The Pfizer-BioNTech COVID-19 Vaccine has received 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:
  - 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 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](tel:1-800-822-7967). In addition, you can report side effects to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling [1-800-438-1985](tel: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).

## 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**

**General Product Inquiries**  
Call [1-877-829-2619](tel:1-877-829-2619).

**Medical Information**  
Visit [PfizerMedicalInformation.com](http://PfizerMedicalInformation.com) or call [1-800-438-1985](tel:1-800-438-1985).

[VISIT CDC.GOV\\*](#)

Learn more about COVID-19 vaccination on the Centers for Disease Control and Prevention (CDC) website.

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Manufactured for BioNTech Manufacturing GmbH, Mainz, Germany. Marketing Authorization Holder. Manufactured by Pfizer Inc., New York, NY 10017.

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

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