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AUTHORIZED USE
12 Years & Up

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for 16 year

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August 23, 2021,

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Label Update Effective: 10/20/21

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

Updated information is in purple.

HOW IS THE VACCINE GIVEN?

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

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

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID–19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose

The vaccine may not protect everyone.

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

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

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EMERGENCY USE AUTHORIZATION INFORMATION

The emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

CONTINUE

Indication & Authorized Use

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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 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

COMIRNATY® (COVID-19 Vaccine, mRNA)

Indication & Authorized Use

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FDA-CBER-2021-5683-0950677

Indication & Authorized Use

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WHAT IS THE INDICATION AND AUTHORIZED USE?

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

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

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- 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
- 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. FDA-CBER-2021-5683-0950678

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).

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under EUA to provide:
  - a two-dose primary series to individuals 12 through 15 years
  - a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
  - a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
    - 65 years of age and older
    - 18 through 64 years of age at high risk of severe COVID-19
    - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
  - a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series

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

- a two-dose primary series to individuals 12 years of age and older
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  - 65 years of age and older
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COMIRNATY® (COVID-19 Vaccine, mRNA) is

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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.

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STAY INFORMED | CDC VACCINE FINDER* | SHARE THE NEWS

COMIRNATY® (COVID-19 Vaccine, mRNA)

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 at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose

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

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.
- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
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  - a two-dose primary series to individuals 12 through 15 years
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    - 65 years of age and older
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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:

- 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
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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 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.

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.

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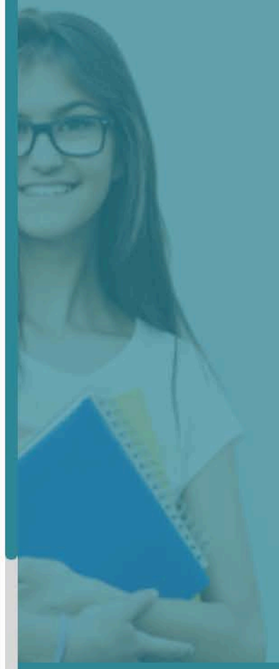

What you ne

Frequently Asked Questions

Label Update Effective: 10/20/21

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

Updated information is in teal.

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Indication & Authorized Use

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Indication & Authorized Use

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The Vaccine is Authorized for Ages 12 Years & Up

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CDC VACCINE FINDER*

What you need to know about the vaccine

Frequently Asked Questions

Indication & Authorized Use

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  - 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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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. FDA-CBER-2021-5683-0950684

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).

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under EUA to provide:
  - a two-dose primary series to individuals 12 through 15 years
  - a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
  - a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
    - 65 years of age and older
    - 18 through 64 years of age at high risk of severe COVID-19
    - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
  - a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series

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

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

The emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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.

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 at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine, Please check with your healthcare provider regarding eligibility for and timing of the booster dose

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

COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech,
- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
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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:
- 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
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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

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 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.

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.

Label Update Effective: 10/20/21

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

Updated information is in purple.

HOW IS THE VACCINE GIVEN?

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

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

Important Safety Information

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

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

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID–19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose

Important Safety Information

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

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

the booster dose

The vaccine may not protect everyone.

EMERGENCY USE AUTHORIZATION INFORMATION

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CONTINUE

Important Safety Information

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

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- had a severe allergic reaction to any

BIONTECH Pfizer

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

COMIRNATY®
(COVID-19 Vaccine, mRNA)

Important Safety Information

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

Important Safety Information

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

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

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

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

The vaccine may not protect everyone.

Side effects reported with the vaccine include:

Important Safety Information

- There is a remote chance that the vaccine could cause a severe allergic reaction.
    - A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination
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    - If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital
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Important Safety Information

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

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

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Important Safety Information

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FDA-CBER-2021-5683-0950694

Indication & Authorized Use

Important Safety Information

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 at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine.

Important Safety Information

WHAT IS THE INDICATION AND AUTHORIZED USE?

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

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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
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  - a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:

Important Safety Information

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

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Important Safety Information

information of the vaccine used for the primary series

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BIONTECH Pfizer

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

COMIRNATY® (COVID-19 Vaccine, mRNA) is

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STAY INFORMED

CDC VACCINE FINDER*

SHARE THE NEWS

COMIRNATY® (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

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

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- 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.

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BIONTECH Pfizer

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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.

Label Update Effective: 10/20/21

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

Updated information is in teal.

HOW IS THE VACCINE GIVEN?

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

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

Important Safety Information

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

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

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID–19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose

Important Safety Information

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

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

the booster dose

The vaccine may not protect everyone.

EMERGENCY USE AUTHORIZATION INFORMATION

The emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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

BIONTECH Pfizer

FDA APPROVED 16 Years & Up

AUTHORIZED USE 12 Years & Up

The Vaccine is Authorized for Ages 12 Years & Up

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

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

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

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

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

The vaccine may not protect everyone.

Side effects reported with the vaccine include:

Important Safety Information

- There is a remote chance that the vaccine could cause a severe allergic reaction.
  - A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination
  - Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness
  - If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after

Important Safety Information

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

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

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

Important Safety Information

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).

Authorized Use & Indication

Important Safety Information

Authorized Use & Indication

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

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

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose

Important Safety Information

WHAT IS THE INDICATION AND AUTHORIZED USE?

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

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

- It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
- It is also authorized under EUA to provide:
  - a two-dose primary series to individuals 12 through 15 years
  - a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
  - a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®:
    - 65 years of age and older

Important Safety Information

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

- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series

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

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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.

INDICATION & AUTHORIZED USE

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- have any allergies
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- 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

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 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.

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