

# COVID-19 Vaccine, mRNA (Pfizer-BioNTech)

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**Brand Name(s):** Comirnaty®

**Other Name(s):** BNT162b2 mRNA, mRNA COVID-19 vaccine , SARS-CoV-2 (COVID-19) vaccine, mRNA spike protein, Tozinameran

**Notification:** COVID-19 vaccine, mRNA (Pfizer-BioNTech; Comirnaty), is approved by the FDA as a primary (2-dose) series to prevent COVID-19 caused by the SARS-CoV-2 virus in people 16 years of age and older.

Information from clinical trials is available at this time to support the use of Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine. Millions of people 12 years of age and older have received the Pfizer-BioNTech COVID-19 vaccine under an Emergency Use Authorization (EUA) since December 11, 2020.

Pfizer-BioNTech COVID-19 vaccine has not undergone the standard review to be approved by the FDA for use in adolescents 12 through 15 years of age. However, the FDA has approved an Emergency Use Authorization (EUA) to allow adolescents 12 through 15 years of age and older to receive it.

The FDA has also approved an EUA for the Pfizer-BioNTech COVID-19 vaccine to allow:

- a third dose in certain people 12 years of age and older who are immunocompromised (have a weakened immune system).
- a single booster dose after completion of the primary series in people:
  - 65 years and older;
  - 18 to 64 years of age at high risk of severe COVID-19;
  - 18 to 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.

Talk to your doctor or vaccine provider about the risks and benefits of receiving this medication.

## What is COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory (lung) illness, but it can also affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever, chills, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, runny nose, nausea, vomiting, or diarrhea.

## How is the Pfizer-BioNTech COVID-19 vaccine given?

The Pfizer-BioNTech COVID-19 vaccine will be given to you as an injection into the muscle. For most individuals, the Pfizer-BioNTech COVID-19 vaccine primary vaccination series is 2 doses given 3 weeks apart. If you receive one dose of the Pfizer-BioNTech COVID-19 vaccine, you should receive a second dose of this *same* vaccine 3

This leaflet does not contain all the possible information about this drug. Your doctor or pharmacist can give you additional information to answer any questions you may have.

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weeks later. As authorized under an EUA, a third dose may be given 4 weeks after the second dose to people who are immunocompromised.

As authorized under an EUA, a single booster dose may be given at least 6 months after the primary series is completed in people:

- 65 years and older;
- 18 to 64 years of age at high risk of severe COVID-19;
- 18 to 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 should you tell the person who is giving the vaccine?**

Tell your vaccine 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 taking a blood thinner such as warfarin (Coumadin, Jantoven).
- have a weakened immune system or are on a medicine that affects your immune system.
- are pregnant or plan to become pregnant.
- are breast-feeding.
- have received another COVID-19 vaccine.
- have ever fainted in association with an injection.
- have had a severe allergic reaction after a previous dose of this vaccine.
- have had a serious allergic reaction to any ingredient in this vaccine.

**What are the benefits of the Pfizer-BioNTech COVID-19 vaccine?**

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 vaccine has been shown to prevent COVID-19 after getting 2 doses given 3 weeks apart. How long you are protected against COVID-19 is currently unknown.

**What are the risks of the Pfizer-BioNTech COVID-19 vaccine?**

Side effects that have been reported with the Pfizer-BioNTech COVID-19 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)

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- injection site pain, swelling, and redness
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- nausea
- feeling unwell
- swollen lymph nodes
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting at the time you receive your injection

There is a remote chance that the Pfizer-BioNTech COVID-19 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 Pfizer-BioNTech COVID-19 vaccine.

Signs of a severe allergic reaction can include:

- difficulty breathing
- swelling of your face and throat
- a fast heartbeat
- a bad rash all over your body
- dizziness and weakness

Myocarditis and pericarditis have occurred in some people who have received the Pfizer-BioNTech COVID-19 vaccine. In most of these people, symptoms began within 7 days after getting the second dose of the Pfizer-BioNTech COVID-19 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 Pfizer-BioNTech COVID-19 vaccine:

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

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 vaccine is still being studied in clinical trials.

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## What should I do about side effects?

- If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.
- Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.
- Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.
- In addition, you can report side effects to Pfizer Inc. at <http://www.pfizersafetyreporting.com> or at 1-800-438-1985.
- You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: <http://www.cdc.gov/vsafe>.

## What if I am immunocompromised?

Based on the EUA, if you are immunocompromised (have a weakened immune system), you may receive a third dose of the Pfizer-BioNTech COVID-19 vaccine 4 weeks after the second dose. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

## Will the Pfizer-BioNTech COVID-19 vaccine give me COVID-19?

No. The Pfizer-BioNTech COVID-19 vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

## Keep your vaccination card

When you get your first dose, you will get a vaccination card to show you when to return for your next dose of Pfizer-BioNTech COVID-19 vaccine. Remember to bring your card when you return.

## Where will my vaccination information be recorded?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for your next dose of Pfizer-BioNTech COVID-19 vaccine. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## How can I learn more?

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- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <http://bit.ly/3qI0njF>.
- Contact your local or state public health department.

**Can I be charged an administration fee for receiving the COVID-19 vaccine?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

**Where can I report cases of suspected fraud?**

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or [TIPS.HHS.GOV](http://TIPS.HHS.GOV).

**What is the Countermeasures Injury Compensation Program**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one year from the date of receiving the vaccine. To learn more about this program, visit <http://www.hrsa.gov/cicp/> or call 1-855-266-2427.

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