

COVID-19 Vaccine, mRNA (Pfizer-BioNTech)

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

IMPORTANT WARNING: Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine is currently being studied to prevent coronavirus disease 2019 caused by the SARS-CoV-2 virus. There is no FDA-approved vaccine to prevent COVID-19.

Some clinical trial information is available at this time to support the use of Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 vaccine. More information is needed to know how well Pfizer-BioNTech COVID-19 vaccine works to prevent COVID-19 and the possible adverse events from it.

Pfizer-BioNTech COVID-19 vaccine has not undergone the standard review to be approved by the FDA for use. However, the FDA has approved an Emergency Use Authorization (EUA) to allow people 16 years of age and older to receive it.

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. 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 in 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 weeks later to complete the vaccination series.



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.

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 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 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:

- injection site pain, swelling, and redness
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- nausea
- feeling unwell
- swollen lymph nodes

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

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>.

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 second 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 the second dose. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

How can I learn more?

- 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.



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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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