# FACT SHEET FOR RECIPIENTS AND CAREGIVERS

**EMERGENCY USE AUTHORIZATION (EUA) OF**

**THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)**

**IN INDIVIDUALS 16 YEARS OF AGE AND OLDER**

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine. The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle. The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://www.cvdvaccine.com/).

**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 illness that can 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 or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

# WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

# WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech COVID-19 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.

# WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3- phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

# 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 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

# WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

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. 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, fast heartbeat, bad rash all over your body, Dizziness and weakness

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, injection site pain, tiredness, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, feeling unwell, swollen lymph nodes (lymphadenopathy), diarrhea, vomiting, arm pain.

#  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.

# WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

# 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.

# WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.



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