Fact sheet for recipients and caregivers of individuals receiving Pfizer-BioNTech COVID-19 vaccine

You are being offered the Pfizer-BioNTech COVID-19 vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This fact sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The U.S. Food and Drug Administration has granted an Emergency Use Authorization (EUA) that allows healthcare providers to administer the Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

This fact sheet may be updated. To ensure you have the most current version, visit www.cvdvaccine.com. For additional information, go to https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.

What you need to know before you receive a COVID-19 vaccine

WHAT IS COVID-19?
COVID-19 is a disease is caused by a new coronavirus called SARS-CoV-2. 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 was developed to help prevent COVID-19.

WHAT APPROVAL HAS THE VACCINE RECEIVED?
The FDA has issued an Emergency Use Authorization (EUA) allowing use of the Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19 in individuals 16 years of age and older.

WHAT IS AN EMERGENCY USE AUTHORIZATION?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.

Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Vaccines must meet specific standards for safety and effectiveness in order to receive an EUA. You can learn more about the EUA process for COVID-19 vaccine [here](#).

Guidance for recipients and caregivers

WHO IS ELIGIBLE?
FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 vaccine in individuals 16 years of age and older. The vaccine is not yet authorized for individuals younger than 16 or pregnant women.

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 INFORMATION DO I NEED TO GIVE THE VACCINE PROVIDER?
Tell the vaccination provider about all of your medical conditions, including if you:
   • have any allergies
   • 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 or plan to become pregnant
   • are breastfeeding
   • have received another COVID-19 vaccine

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer BioNTech COVID-19 vaccine includes the following ingredients:
Active Ingredient

- nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2

Lipids
- (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis (ALC-3015)
- (2- hexyldecanoate),2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
- 1,2-distearoyl-snglycero-3-phosphocholine (DPSC)
- cholesterol

Salts
- potassium chloride
- monobasic potassium phosphate
- sodium chloride
- basic sodium phosphate dihydrate

Other
- sucrose

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.
The Pfizer-BioNTech COVID-19 vaccine 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 weeks later to complete the vaccination series.

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
The Pfizer-BioNTech COVID-19 vaccine is a new vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least one dose of the Pfizer-BioNTech COVID-19 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 be approximately 95 percent effective at preventing COVID-19 following 2 doses given 3 weeks apart. How long that protection lasts is still being studied.

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
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling

• injection site redness
• nausea
• feeling unwell
• swollen lymph nodes (lymphadenopathy)

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

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 you can 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. by going to www.pfizersafetyreporting.com, by fax at 1-866-635-8337 or by phone at 1-800-438-1985.