

FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 6 MONTHS THROUGH 4 YEARS OF AGE

FOR 6 MONTHS THROUGH 4 YEARS OF AGE

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

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide a 3-dose primary series to individuals 6 months through 4 years of age.¹

This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a 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 leading to death. 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.

For more information on EUA, see the "What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

¹ You may receive this Fact Sheet even if your child is 5 years old. Children who will turn from 4 years to 5 years of age between any doses in the primary series, and who received a first dose with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age, may also receive this vaccine for doses 2 and/or 3 of the primary series.

WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to your child as an injection into the muscle.

The vaccine is administered as a 3-dose series. The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose.

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?

Your child should not get the vaccine if your child:

- 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 VACCINE?

The 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), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAS THE VACCINE BEEN USED BEFORE?

Millions of individuals 5 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 1,200 individuals 6 months through 23 months of age, approximately 1,800 individuals 2 through 4 years of age, and approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In another clinical trial, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

The vaccine that is authorized for use in children 6 months through 4 years of age includes the same mRNA and lipids but different inactive ingredients compared to the

vaccine that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures.

WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?

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 child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

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 vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

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/tenderness
- 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
- Irritability

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.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child 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 the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a 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: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child's standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?

For children 6 months through 4 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

WILL THE VACCINE GIVE MY CHILD COVID-19?

No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.


KEEP YOUR CHILD'S VACCINATION CARD

When your child gets the first dose, you will get a vaccination card to show when to return for your child's next dose of the vaccine. Remember to bring the card when your child returns.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

WHERE WILL MY CHILD'S VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns for the second dose. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF 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, Health Resources & Services Administration [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 <https://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 (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An EUA is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An 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. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the 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 during the COVID-19 pandemic.

An EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: 0886983000486



Flu Shot Form

Patient Name: _____ Date of Birth: _____ Age _____

Mailing Address: _____

Home Phone: _____

Parent/Guardian (if minor): _____

Do you have health insurance? ☐ Yes ☐ No

Have you ever received the flu vaccine before? ☐ Yes ☐ No

We have a limited supply of high dose flu shots this season, if you are 65 years old or older, are you interested in receiving one? ☐ Yes ☐ No

****If you answer yes to any of the questions below please contact your Family Doctor before receiving the Flu Vaccine. ****

Do you have an allergy to eggs? ☐ Yes ☐ No

Have you ever had a reaction to an influenza vaccine? ☐ Yes ☐ No

Have you ever had Guillain-Barre Syndrome? ☐ Yes ☐ No

Have you ever had a febrile seizure? ☐ Yes ☐ No

Have you had a fever or been ill in the last 24 hours? ☐ Yes ☐ No

I have received a copy of the 2022-2023 influenza vaccination information sheet and understand the risks and benefits of receiving a flu shot.

I agree to allow Health Access Network clinical staff to administer an influenza vaccine to me (or patient listed above).

Signature Patient/Guardian: _____

Date: _____

Dose: _____ Route: _____ State: _____ Private: _____

Manufacturer: _____

Lot#: _____ Expiration Date: _____

Given by: _____

Medicare Mainecare Commercial Uninsured

Documented into eCW _____
Entered on Roster _____
Revised 8/31/2022 SL

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent influenza (flu).

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine does not cause flu.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call 1-800-338-2382 to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/flu.

