FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT PFIZER-BIONTECH COVID-19 VACCINE (2024-2025 FORMULA) WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)[1] to prevent coronavirus disease 2019 (COVID-19), which is caused by the virus SARS-CoV-2.[2] This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), hereafter referred to as 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 https://www.covidvaxoption.com/.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make the Pfizer-BioNTech COVID-19 Vaccine available during the COVID-19 pandemic (for more details about an EUA please see "**WHAT IS AN EMERGENCY USE AUTHORIZATION?**" at the end of this document). The Pfizer-BioNTech COVID-19 Vaccine is not an FDA-approved vaccine in the United States. Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine.

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close 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;

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[1] The Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) encodes the spike protein of SARS-CoV-2 Omicron variant lineage KP.2.

[2] If your child is immunocompromised and turning from 11 to 12 years of age during the vaccination series for immunocompromised individuals, you may receive this Fact Sheet because your child is being offered COMIRNATY (COVID-19 Vaccine, mRNA) (2024-2025 Formula) (hereafter referred to as COMIRNATY). COMIRNATY is an FDA-approved vaccine for prevention of COVID-19 in individuals 12 years of age and older that is authorized under EUA to complete the dosing schedule for immunocompromised individuals who turn from 11 years to 12 years of age during the vaccination series. Under the authorized dosing schedule, these individuals receive the Pfizer-BioNTech COVID−19 Vaccine before they turn 12 years old, and complete the vaccination series with COMIRNATY on or after the date the individual turns 12 years old. The dosing schedule is: Dose 1: Week 0; Dose 2: Week 3; Dose 3: ≥4 weeks after Dose 2. The information in this Fact Sheet about the Pfizer-BioNTech COVID-19 Vaccine, including information about the benefits, risks, and ingredients of that vaccine, also applies to your child's use of COMIRNATY, except with respect to the dosing schedule and the ages authorized for use.

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 a vaccine for use in individuals 6 months through 11 years of age to prevent COVID-19. The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine under an EUA.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

WHAT SHOULD YOU MENTION TO THE VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE PFIZER-BIONTECH COVID-19 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 the immune system
- is pregnant
- is breastfeeding
- 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 is given as an injection into the muscle.

<u>Individuals 6 months through 4 years of age</u>

- **Unvaccinated individuals:** Three doses of Pfizer-BioNTech COVID-19 Vaccine are administered over at least 11 weeks. The first 2 doses are administered 3 weeks apart. The third dose is administered at least 8 weeks after the second dose.
- **Individuals who have received 1 previous dose of the Pfizer-BioNTech COVID-19 Vaccine[3]:** Two doses of Pfizer-BioNTech COVID-19 Vaccine are administered. The first dose of Pfizer-BioNTech COVID-19 Vaccine is administered 3 weeks after the previous dose of a Pfizer-BioNTech COVID-19 Vaccine and the second dose at least 8 weeks later.
- **Individuals who have received 2 or more previous doses of the Pfizer-BioNTech COVID-19 Vaccine[3]:** A single dose of Pfizer-BioNTech COVID-19 Vaccine is administered at least 8 weeks after the last previous dose of a Pfizer-BioNTech COVID-19 Vaccine.

[3] Previous dose refers to a dose of any prior Pfizer-BioNTech COVID-19 Vaccine that is no longer authorized for use in the United States.

Individuals 5 through 11 years of age
A single dose of Pfizer-BioNTech COVID-19 Vaccine is administered to individuals who have not received a COVID-19 vaccine (2024-2025 Formula). You must wait at least 2 months since your last dose of any COVID-19 vaccine.

Immunocompromised individuals 6 months through 11 years of age
Additional doses of Pfizer-BioNTech COVID-19 Vaccine may be administered. For more information, talk to your child's healthcare provider.

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

Your child should not get Pfizer-BioNTech COVID-19 Vaccine if they had:

- a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine
- a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THIS VACCINE?

Pfizer-BioNTech COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (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, and sucrose. Pfizer-BioNTech COVID-19 Vaccine for use in individuals 6 months through 4 years of age also contains sodium chloride.

HAS THIS VACCINE BEEN USED BEFORE?

Millions of individuals 6 months of age and older have received a Pfizer-BioNTech COVID-19 vaccine under EUA.

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 the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent[4]). 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 (Original monovalent).

In clinical trials, 60 individuals 6 months through 4 years of age, 113 individuals 5 through 11 years of age, 107 individuals 12 through 17 years of age, 103 individuals 18 through 55 years of age, and 106 individuals greater than 55 years of age received a dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent[5].

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[4] Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) refers to Pfizer-BioNTech COVID-19 Vaccine that encodes the spike protein of only the Original SARS-CoV-2. This vaccine is no longer authorized for use in the United States.

[5] Pfizer-BioNTech COVID-19 Vaccine, Bivalent refers to Pfizer-BioNTech COVID-19 Vaccine that encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2. This vaccine is no longer authorized for use in the United States.

WHAT ARE THE BENEFITS OF PFIZER-BIONTECH COVID-19 VACCINE?
FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine to provide protection against COVID-19.

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

WHAT ARE THE RISKS OF PFIZER-BIONTECH COVID-19 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. For this reason, the 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 mRNA COVID-19 vaccines. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 Vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. 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

Additional symptoms, particularly in children, may include:

- 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 Pfizer-BioNTech COVID-19 Vaccines 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
- Dizziness
- Irritability
- Febrile seizures (convulsions during a fever)

These may not be all the possible side effects. Serious and unexpected side effects may occur. The possible side effects are still being studied.

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 (2024-2025 Formula) 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

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 this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care.

ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES THE PFIZER-BIONTECH COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under EUA, including vaccines that encode the spike protein of the SARS-CoV-2 Omicron variant lineage KP.2.

CAN MY CHILD RECEIVE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
If you are considering having your child receive Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?
Immunocompromised individuals 6 months through 11 years of age may receive additional doses of Pfizer-BioNTech COVID-19 Vaccine (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, your child should continue to maintain physical precautions to help prevent COVID-19. Your child's close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If your child is pregnant or breastfeeding, discuss the options with your child's healthcare provider.

WILL THIS VACCINE GIVE MY CHILD COVID-19?
No. This vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

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 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. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

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)?

The FDA has made Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. 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 under EUA during the COVID-19 pandemic.

The 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 under the EUA).

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