

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. 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 Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. 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.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

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).

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

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?

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

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

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.

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 an unapproved vaccine. 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.

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?

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. 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
- 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.

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.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967. 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 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: www.cdc.gov/vsafe.

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

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

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

Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

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.

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 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>.

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 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.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-1.1

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

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What to Expect after Getting a COVID-19 Vaccine

Accessible version: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

Common side effects

On the arm where you got the shot:

- Pain
- Swelling

Throughout the rest of your body:

- Fever
- Chills
- Tiredness
- Headache

Helpful tips

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot: **To reduce discomfort from fever:**

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.
- Drink plenty of fluids.
- Dress lightly.

When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

Remember

- Side effects may feel like flu and even affect your ability to do daily activities, but they should go away in a few days.
- With most COVID-19 vaccines, you will need 2 shots in order for them to work. Get the second shot even if you have side effects after the first one, unless a vaccination provider or your doctor tells you not to get a second shot.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until a week or two after your second shot.
- It's important for everyone to continue using all the tools available to help stop this pandemic as we learn more about how COVID-19 vaccines work in real-world conditions. Cover your mouth and nose with a mask when around others, stay at least 6 feet away from others, avoid crowds, and wash your hands often.



Ask your healthcare provider about getting started with v-safe

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second dose

Learn more about v-safe.

www.cdc.gov/vsafe



cdc.gov/coronavirus



STATE OF TENNESSEE DEPARTMENT OF HEALTH

NOTICE OF PRIVACY PRACTICES

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION

PLEASE REVIEW THIS CAREFULLY

OUR DUTY TO SAFEGUARD YOUR PROTECTED HEALTH INFORMATION

The Department of Health's workforce is required by the federal law entitled Health Insurance Portability and Accountability Act (HIPAA) to safeguard your Protected Health Information (PHI). PHI is individually identifiable information about your past, present or future health or condition; the provision of health care to you; and payment for health care. We are required to give you a notice of our privacy practices for the information we collect and keep about you.

OUR PLEDGE REGARDING YOUR PROTECTED HEALTH INFORMATION

We understand health information about you is personal and we are committed to protecting this information. This Privacy Notice applies to all of your health information, including (1) records relating to your care at a health department clinic (2) health care records received by the Department of Health from another source and (3) genetic information.

We are required by law to: (1) keep your PHI confidential; (2) give you this Privacy Notice; and (3) follow the terms of the current Privacy Notice.

HOW WE MAY USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION FOR TREATMENT, PAYMENT AND OPERATIONS

The following categories describe different ways we may use and disclose your PHI.

- **For Treatment.** We may use or disclose your PHI to doctors, nurses, nutritionists, technicians or other health department personnel who are involved in taking care of you. We may disclose your PHI to people outside the health department who may be involved in your medical care such as prescriptions, lab work and x-rays.
- **For Payment.** We may use or disclose your PHI to get payment or to pay for health services you receive. For example, we may need to tell your health insurance about a treatment you need to obtain prior approval or to determine whether your insurance will pay for the treatment.
- **For Health Care Operations.** We may use or disclose your PHI for Department of Health's operations. This is necessary to manage the Department's programs and activities. For example, we may use PHI to review our services, programs and/or the quality of care we provide you.
- **Appointment Reminders.** We may use your PHI to contact you as a reminder that you have an appointment for treatment or services.

HOW WE MAY USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION WITHOUT YOUR PERMISSION

The law provides that we may use or disclose your PHI from our records (even after your death) without your permission in the following circumstances:

- **As Required By Law.** We will disclose medical information about you when required to do so by law, to investigate reports of abuse or neglect, and to report the incident to the appropriate enforcement agency.
- **Health Oversight Activities.** We may disclose PHI to a health oversight agency for activities authorized by law. These oversight activities may include audits, investigations, inspections and licensure. These activities are necessary for the state and federal government to monitor the health care delivery system in Tennessee.
- **As Public Health Risks.** We may disclose PHI about you for public health activities. These activities may include the reporting of births and deaths and the tracking, prevention, or control of certain diseases, injuries and disabilities.

- **Research.** In certain circumstances, and under supervision of an institutional review board, we may disclose PHI to assist medical research.
- **To Avert a Serious Threat to Health or Safety.** We may use or disclose your PHI if necessary to prevent a serious threat to you or the health and safety of the public or another person. Any disclosure, however, would only be to someone able to help prevent the threat.
- **For Specific Government Functions.** We may disclose PHI to law enforcement, to government benefit programs relating to eligibility and enrollment, and for the interest of national security.

YOUR RIGHTS REGARDING HEALTH INFORMATION ABOUT YOU

You have the following rights regarding medical information we maintain about you:

- **Right to Inspect and Copy.** In most cases, you have the right to look at or get copies of your paper records and your electronic records. You must make the request in writing. You may be charged a fee for the cost of copying your records.
- **Right to Amend.** If you believe there is a mistake or missing information in our record of your PHI, you may ask us to correct or add to your record. Your request must be made in writing and you must provide a reason that supports your request. We may deny your request under certain circumstances. Any denial will state the reasons for denial and explain your rights to have the request and denial, along with any statement in response you provide, appended to your PHI.
- **Right to Know What Health Information We Have Released.** You have the right to ask for a list of disclosures made of your PHI made on or after April 14, 2003 for purposes other than those listed in the Privacy Notice. You must request this list in writing and state the period of time the list should cover for a period of no longer than six (6) years. The first list you request within a twelve (12) month period will be free.
- **Right to Request Restrictions.** You have the right to ask us to limit how your PHI is used or disclosed. You must make the request in writing and tell us what information you want to limit and to whom the limits apply. You have the right to restrict disclosure to a health plan for services which you fully paid for out of pocket.
- **Right to Confidential Communications.** You have the right to ask that we communicate with you in a certain way or at a certain place. For example, you may ask us to send information to your work address instead of your home address. You must make your request in writing. You will not have to explain the reason for your request. We will honor all reasonable requests.
- **Right to Authorize Release of Information.** Other releases of your PHI can be made only if you request it and you can change your authorization at any time.
- **Right to Be Notified of Information.** You have a right to be notified in the event of a breach of unsecured PHI.
- **Right to a Paper Copy of This Notice.** You have a right to a paper copy of this notice at any time, even if you have agreed to receive this notice electronically. You may obtain a copy of this notice at our website listed below. To obtain a paper copy of this notice, contact the TDH Privacy Officer listed below. We reserve the right to change our privacy practices and this notice at any time. We will post a copy of the current notice in all our offices and at the department's website.

HOW TO GET MORE INFORMATION OR FILE A COMPLAINT ABOUT OUR PRIVACY PRACTICES

If you have any questions about this notice, please contact the HIPAA PRIVACY OFFICER listed below. If you believe we have violated your privacy rights, you may file a written complaint with either of the agencies listed below. You will not be affected by filing a complaint.

HIPAA Privacy Officer
TN Department of Health
Compliance Office
5th Floor, Andrew Johnson Tower
710 James Robertson Parkway
Nashville, TN 37243
(615) 253-5637
877-280-0054 Fax: (615) 253-3926
email: privacy.health@tn.gov

Secretary
U.S. Department of Health & Human Services
200 Independence Ave. SW
HHH Building, Room 509H
Washington, DC 20201
TTY 886-788-4989
877-696-6775



Department of Health Authorization No. 343513.
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