



To our Incredible Patients and Residents, their Families and Loved Ones, and our Dedicated Team Members,

We've all been encouraged by news of the development, successful testing, and approval of the first effective vaccines against COVID-19. We are pleased that our state has placed a top priority on distributing and administering the vaccine to skilled nursing centers.

We are very excited of this opportunity, as the health, safety, and wellness of our residents, patients, and staff is our top priority. In an effort of full transparency, we are doing everything we can to help facilitate the vaccination process.

We are grateful for our partnership with **SpecialityRx Pharmacy** as this vaccination process will be both convenient and efficient for our residents, patients, and team members. An immunization clinic will be on-site at our community, where a team of pharmacy representatives will help us manage the immunization process. As always, we will continue to maintain our COVID-19 precautionary measures throughout this process.

Our incredible clinical team and frontline heroes continue to go above and beyond to ensure the safety and well-being of those that we care for and serve each and every day.

By receiving the COVID-19 vaccination, we will be protecting not only our own health and safety, but also the health, safety, and wellness of our loved ones, those who we serve, and our fellow neighbors in our local community.

As shared by the CDC (Centers for Disease Control and Prevention), here are several key facts regarding the COVID-19 vaccination:

- Getting vaccinated can help prevent you and others from getting sick with COVID-19. If you get sick, you may spread the disease to friends, family, and others around you while you're sick, but a COVID-19 vaccination helps protect you by creating an antibody response without having to experience sickness.
- COVID-19 vaccines will not give you COVID-19.
- COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests.
- People who have gotten sick with COVID-19 may still benefit from getting vaccinated- experts aren't sure how long someone who has recovered from COVID-19 is protected from getting sick again.

Preliminary Vaccination Clinic Dates: December 27, 2020 (Subject to change)

Pending date of: December 28, 2020

We've all been in this together since the pandemic erupted in March, and it has forced us to consistently consider how to best protect ourselves and each other. This long-awaited COVID-19 vaccine provides us all with a great chance to move forward and stop the spread of the virus. Let's come together again and continue to look out for one another by getting vaccinated as soon as possible.

Sincerely,
Administration



COVID VACCINE CONSENT FORM (1.4)

FACILITY INFORMATION:

FACILITY NAME

TELEPHONE

ADDRESS

CITY

STATE

ZIP

PATIENT INFORMATION:

LAST NAME

FIRST NAME

DATE OF BIRTH

GENDER

ADDRESS

CITY

STATE

ZIP

RACE
*REQUIRED

☐ White ☐ Black ☐ Asian ☐ Native Hawaiian or Other Pacific Islander
☐ American Indian/Alaska Native ☐ Other ☐ Unknown

ETHNICITY
*REQUIRED

☐ Hispanic or Latino ☐ Not Hispanic or Latino

MOTHER'S NAME

MOTHER'S MAIDEN NAME

PRIMARY CARE PROVIDER (PCP) NAME

PCP PHONE NUMBER

PCP FAX NUMBER

PCP ADDRESS

CITY

STATE

ZIP

ARE YOU A RESIDENT OR EMPLOYEE OF THE FACILITY?☐

RESIDENT

☐

EMPLOYEE

IS THIS THE PATIENT'S FIRST OR SECOND DOSE OF THE COVID-19 VACCINATION?☐

FIRST DOSE

☐

SECOND DOSE

INSURANCE INFORMATION:

A COPY OF YOUR INSURANCE
CARD (FRONT & BACK) IS
REQUIRED:

ARE YOU THE
PRIMARY
CARDHOLDER?☐

YES

☐

NO

IF NO, PLEASE PROVIDE THE PRIMARY CARDHOLDER'S NAME BELOW:

INSURANCE CARRIER NAME

INSURANCE/MEDICARE ID #

IF UNINSURED, YOU MUST CHECK THE BOX BELOW TO ATTEST THAT THE FOLLOWING INFORMATION IS TRUE AND ACCURATE

☐ I attest that I do not have any insurance, including but not limited to Medicaid, Medicare, or any other government-funded or private health benefit plan.

In order to have your vaccine administration fee paid for by the United States Health Resources & Services Administration's COVID-19 Program for uninsured patients, either (a) a valid Social Security number, **OR** (b) state identification number & state issuance, **OR** (c) a driver's license number & state of issuance must be provided.

(a) SOCIAL SECURITY NUMBER

OR (b) STATE IDENTIFICATION NUMBER & STATE**OR** (c) DRIVER'S LICENSE NUMBER & STATE

COVID-19 SCREENING QUESTIONS

YES

NO

I DON'T
KNOW

1. In the past two weeks, have you tested positive for COVID-19 or are you currently being monitored for COVID-19?

☐☐☐

2. In the past two weeks, have you had contact with anyone who tested positive for COVID-19?

☐☐☐

3. Have you had the new onset of fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, nausea, vomiting, or diarrhea?

☐☐☐

Patient Temperature:

(To be filled out by the VACCINATOR)

Date:

LAST NAME

DATE OF BIRTH

IMMUNIZATION SCREENING QUESTIONS

YES NO I DON'T KNOW

1. Are you sick today? For example: cold, fever, acute illness?

☐ ☐ ☐

2. Do you any allergies/reactions to any medications, vaccines, food or latex? (For example: eggs, gelatin, neomycin, thimerosal, etc.)

☐ ☐ ☐Have you ever had a serious reaction after receiving a vaccination? Have you ever fainted, particularly with vaccines? Have you
3. ever been cautioned or warned about receiving certain vaccines or receiving vaccines outside of a medical setting by a doctor or
other healthcare professional?☐ ☐ ☐

4. Do you take anticoagulation medication? For example: Coumadin/warfarin or other blood thinner?

☐ ☐ ☐

5. Have you had a seizure or a brain or other nervous system problem or Gillian Barre?

☐ ☐ ☐6. Do you have a long-term health problem such as heart disease, lung disease, liver disease, asthma, kidney disease, metabolic
disease (e.g. Diabetes), anemia, or other blood disorder?☐ ☐ ☐7. Do you have cancer, leukemia, rheumatoid arthritis, HIV/AIDS, ankylosing spondylitis, Crohn's disease or any other immune system
problem?☐ ☐ ☐8. Do you have a weakened immune system or in past 3 months, taken medication that weaken it such as cortisone, prednisone,
other steroids, anticancer drugs, or radiation treatments?☐ ☐ ☐9. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an
antiviral drug?☐ ☐ ☐

10. For WOMEN, are you pregnant or is there a chance you could become pregnant during the next month?

☐ ☐ ☐

11. Have you received any vaccination or TB skin test in the past 4 weeks?

☐ ☐ ☐

I have read the Vaccine Information Sheet or fact sheet about the corresponding vaccine(s) I am receiving. I have had a chance to ask questions to my satisfaction. I understand the benefits and risks of the vaccine and request that the vaccine be given to me or to the person named above for whom I am authorized to make the request. I authorize the release of any medical information or other information necessary to process an insurance claim. I understand that if applicable, Specialty RX (Citywide RX LLC) will submit my claim to insurances they contract with. I certify that all Medicare information given to Specialty RX (Citywide RX LLC) Pharmacy is true. Specialty Rx (Citywide RX LLC) has made their "Notice of Privacy Practices" available to me. I authorized the release of any medical or other information with respect to this vaccine to my healthcare providers, Medicare, Medicaid, the HRSA COVID-19 program for the uninsured, or other third party payer as needed and request payment of authorized benefits to be made on my behalf to Specialty RX (Citywide RX LLC) Pharmacy. I acknowledge that my vaccination record may be shared with federal or state or city agencies for registry reporting. I agree to stay in the general area for at least fifteen (15) minutes after receiving my vaccination for any potential adverse reactions. I understand if I experience side effects that I should contact a doctor, pharmacy, call 911 if an emergency.

SIGNATURE OF PATIENT TO RECEIVE VACCINE (OR PARENT, GUARDIAN, OR AUTHORIZED REPRESENTATIVE
If signing on behalf of the patient, you affirm that you are authorized to provide the required consents on behalf of the patient

DATE

NAME OF PARENT, GUARDIAN, OR AUTHORIZED REPRESENTATIVE

RELATIONSHIP

PHONE NUMBER

OFFICIAL USE ONLY:

☐ L ☐ R

VACCINE MANUFACTURER

INJECTION SITE

LOT# EXP. DATE

ADMINISTRATION DATE

ROUTE SITE VOLUME (mL)

ADMINISTERED BY:

LICENSE#

SIGNATURE OF VACCINATOR
WHO ADMINISTERED VACCINE(S) AND PROVIDED VIS

Vaccines & Immunizations

Answering Patients' Questions

Some patients won't have questions about coronavirus disease 2019 (COVID-19) vaccination when you give your strong recommendation and use language that assumes patients will get vaccinated when doses are widely available. If a patient questions your recommendation about COVID-19 vaccination, this does not necessarily mean they will not accept a COVID-19 vaccine. This is a new vaccine, and some questions are to be expected. Your patients consider you their most trusted source of information when it comes to vaccines, and sometimes they simply want *your* answers to their questions.

This page outlines some topics patients ask about most vaccines and tips for how to answer their questions.



Questions about Vaccine Safety and the Speed of Vaccine Development

The federal government, under the umbrella of [Operation Warp Speed](#), has been working since the start of the pandemic to make a COVID-19 vaccine available as soon as possible. This accelerated timeline is unprecedented and has raised concerns for some people that safety may be sacrificed in favor of speed. However, as with all vaccines, safety is a top priority.

Patients may ask: How do we really know if COVID-19 vaccines are safe? To respond, you can explain how:

- The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and an authorizes emergency vaccine use only when the expected benefits outweigh potential risks.
- The Advisory Committee on Immunization Practices (ACIP) reviews all safety data before recommending any COVID-19 vaccine for use. [Learn how ACIP makes vaccine recommendations.](#)
- FDA and CDC will continue to monitor the safety of COVID-19 vaccines, to make sure even very rare side effects are identified.

Example:

COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offers protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.



Questions about Whether It Is Better to Get Natural Immunity Rather than Immunity from Vaccines

Because some people with COVID-19 can have very mild symptoms, some may see natural infection as preferable to receiving a new vaccine. Others may be concerned that getting a COVID-19 vaccine could make a later illness worse. Help your patients understand the risks and benefits so they can be confident choosing to get vaccinated.

Patients may ask: Is the vaccine that helpful? I heard getting COVID-19 gives you better and longer immunity than the protection a vaccine can give. Can it actually make my illness worse if I do end up getting COVID-19? **To respond, you can:**

- Explain the potential serious risk COVID-19 infection poses to them and their loved ones if they get the illness or spread it to others. Remind them of the potential for long-term health issues after recovery from COVID-19 disease.
- Explain that scientists are still learning more about the virus that causes COVID-19. And it is not known whether getting COVID-19 disease will protect everyone against getting it again, or, if it does, how long that protection might last.

- Describe how the vaccine was tested in large clinical trials and what is currently known about its safety and effectiveness.

Be transparent that the vaccine is not a perfect fix. Patients will still need to practice other precautions like wearing a mask, social distancing, handwashing and other hygiene measures until public health officials say otherwise.

Example:

"Both this disease and the vaccine are new. We don't know how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice."



Questions about Known Side Effects

Some COVID-19 vaccines may be more reactogenic than vaccines that people are familiar with. Information about specific side effects of the COVID-19 vaccine will be available when it is approved. It is important to set this expectation with your patient, in case they experience a strong reaction.

Patients may ask: How much will the shot hurt? Can it cause you to get very sick? ***To respond, you can:***

- Explain what the most common side effects from vaccination are and how severe they may be.
- Provide a comparison if it is appropriate for the patient (for example, pain after receiving Shingrix for older adults who have received it).
- Make sure patients know that a fever is a potential side effect and when they should seek medical care.
- Let them know that symptoms typically go away on their own within a week. Also let them know when they should seek medical care if their symptoms don't go away.
- Explain that the vaccine cannot give someone COVID-19.
- Explain that side effects are a sign that the immune system is working.

Example:

"Most people do not have serious problems after being vaccinated. We will understand more about mild side effects of the COVID-19 vaccine before we start to use it. However, your arm may be sore, red, or warm to the touch. These symptoms usually go away on their own within a week. Some people report getting a headache or fever when getting a vaccine. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease."



Questions about Unknown, Serious, Long-term Side Effects

Due to the relative speed with which these vaccines were developed, patients' concerns about long-term side effects are reasonable and to be expected.

Patients may ask: How do we know that these vaccines are safe when they are so new? Couldn't they cause problems that we don't know about yet? What about long-term problems? ***To respond, you can:***

- Explain how FDA and CDC are continuing to monitor safety, to make sure even long-term side effects are identified.

- Reassure patients that COVID-19 vaccines will be continuously monitored for safety after authorization, and ACIP will take action to address any safety problems detected.
- Compare the potential serious risk of COVID-19 infection to what is currently known about the safety of COVID-19 vaccines.

Example:

COVID-19 vaccines are being tested in large clinical trials to assess their safety. However, it does take time, and more people getting vaccinated before we learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as it comes in and provides regular safety updates. If a safety issue is detected, immediate action will take place to determine if the issue is related to the COVID-19 vaccine and determine the best course of action.



How Many Doses Are Needed and Why?

All but one of the COVID-19 vaccines currently in phase 3 clinical trials use two shots. The same vaccine brand must be used for both shots.

Patients may ask: How many shots am I going to need? To respond, you can:

- Explain that two shots are generally needed to provide the best protection against COVID-19 and that the shots are given several weeks apart. The first shot primes the immune system, helping it recognize the virus, and the second shot strengthens the immune response.
- When applicable, explain the dosing options available in your office and advise the patient that they can set up an appointment before they leave to come back for a second dose.

Example:

Nearly all COVID-19 vaccines being studied in the United States require two shots. The first shot starts building protection, but everyone has to come back a few weeks later for the second one to get the most protection the vaccine can offer.

Other Questions Patients May Have about COVID-19 Vaccination

If you have additional questions from patients, reference [Frequently Asked Questions about COVID-19 Vaccination](#) for regularly updated answers to common questions.

Page last reviewed: November 2, 2020

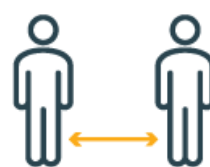
COVID-19 (Coronavirus Disease)

[MENU >](#)

CASES ARE RISING.
ACT NOW!



WEAR A MASK



STAY 6 FEET APART



AVOID CROWDS

Importance of COVID-19 Vaccination for Residents of Long-term Care Facilities

Updated Dec. 13, 2020

[Print](#)

Based on [recommendations](#) from the [Advisory Committee on Immunization Practices \(ACIP\)](#), an independent panel of medical and public health experts, CDC recommends residents of long-term care facilities be included among those offered the first supply of COVID-19 vaccines.

Vaccinating LTCF residents will save lives

Making sure LTCF residents can receive COVID-19 vaccination as soon as vaccines are available will help save the lives of those who are most at risk of dying from COVID-19. According to ACIP's recommendations, long-term care facility residents include adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. The communal nature of LTCFs and the population served (generally older adults often with underlying medical conditions) puts facility residents at increased risk of infection and severe illness from COVID-19. By November 6, 2020, [approximately 569,000–616,000 COVID-19 cases and 91,500 deaths](#) were reported among LTCF residents and staff members in the United States, accounting for 39% of deaths nationwide.

Benefits of vaccination believed to outweigh possible risks

All COVID-19 vaccines were tested in clinical trials involving tens of thousands of people to make sure they meet safety standards and protect adults of different races, ethnicities, and ages, including adults over the age of 65. There were no serious safety concerns. The most common side effects were pain at the injection site and signs and symptoms like fever and chills. After a review of all the available information, ACIP and CDC agreed the lifesaving benefits of COVID-19 vaccination for LTCF residents outweigh the risks of possible side effects.

The safety of COVID-19 vaccines is a top priority

To help make important unapproved medical products, including vaccines, available quickly during the [COVID-19](#) pandemic, the US Food and Drug Administration (FDA) can use what is known as an [Emergency Use Authorization \(EUA\)](#) [↗](#). Before any vaccine can be authorized for use under an EUA, FDA must determine that the vaccine's benefits outweigh possible risks.

Once people begin receiving COVID-19 vaccinations, CDC and FDA will monitor vaccine safety closely. The United States will use existing robust systems and data sources to conduct ongoing safety monitoring. An additional layer of safety monitoring has also been added that allows CDC and FDA to evaluate COVID-19 vaccine safety almost immediately. [Learn more about COVID-19 vaccine safety monitoring.](#)

For LTCFs in particular, CDC will work with pharmacies and other partners to report possible side effects (called adverse events) to the [Vaccine Adverse Event Reporting System \(VAERS\)](#) [↗](#). Facility staff and residents' families are encouraged to also report any adverse events immediately.

CDC will work with pharmacies and other partners to provide communication materials to help LTCFs educate residents and their families about the vaccine, answer their questions about vaccine safety and other issues, and prepare them for vaccination clinics. For some COVID-19 vaccines, two shots are needed to provide the best protection, and the shots are given several weeks apart. Each recipient or caregiver will receive a vaccination record card to ensure they receive the correct vaccine for the second dose.

Risks and benefits will be explained to everyone offered a COVID-19 vaccination

Explaining the risks and benefits of any treatments to a patient in a way that they understand is the standard of care. In LTCFs, consent or assent for vaccination should be obtained from residents (or the person appointed to make medical decisions on their behalf) and documented in the resident's chart per standard practice.

For LTCFs participating in the [Federal Pharmacy Partnership for Long-term Care Program](#), pharmacies will work directly with LTCFs to ensure staff and residents who receive the vaccine also receive an EUA fact sheet before vaccination. The EUA fact sheet explains the risks and benefits of the COVID-19 vaccine they are receiving and what to expect. Each LTCF resident's medical chart must note that this information was provided to the resident. If a resident is unable to make medical decisions due to decreased mental capacity or illness, the EUA fact sheet will be provided to the person appointed to make medical decisions on their behalf (the medical proxy or power of attorney).

Last Updated Dec. 13, 2020

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)
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- severe allergic reactions

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.

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 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).



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