Rockville
SKILLED NURSING & REHABILITATION CENTER

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 **PharmScript, LLC**, 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 Date: January 6, 2021 (Subject to change)

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

PharmScript COVID-19 Vaccination Informed Consent Form Instruction Sheet

Please read below for instructions on how to complete the PharmScript COVID-19 Vaccination Informed Consent Form:

Sections 1–3 must be completed prior to Clinic Day.

SECTION 1

Patient Information

This section must be completed for any resident or facility staff that will receive the COVID-19 Vaccine. All fields are required.

SECTION 2

Healthcare Worker Information

This section must be completed for any facility staff that will receive the COVID-19 Vaccine. This section does not need to be completed for residents.

SECTION 3

Consent

This section must be completed for any resident or facility staff that will receive the COVID-19 Vaccine.

PHARMSCRIPT

SECTION 1: PATIENT INFORMATION

This section must be completed for residents/facility staff receiving the vaccine.

First Name:	Last Name:
Date of Birth:	Gender: ☐ Male ☐ Female
Allergies:	☐ No Known Drug Allergies
Facility Name & Address:	

Race/Ethnicity: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Hispanic or Latino American ☐ Pacific Islander ☐ White ☐ Other, specify:

Mother's First Name: ☐ Unavailable	Mother's Maiden Name: ☐ Unavailable

Patient Guardian Type (Please select from the options below):

☐ Aunt (AUN)	☐ Child (CHD)	☐ Guardian (GRD)	☐ Parent (PAR)	☐ Sister (SIS)	☐ Uncle (UNC)
☐ Brother (BRO)	☐ Foster Child (FCHI)	☐ Grandparent (GRP)	☐ Self (SEL)	☐ Spouse (SPO)	☐ Other (OTH):
☐ Caregiver (CGV)	☐ Father (FTH)	☐ Mother (MTH)	☐ Sibling (SIB)	☐ Stepchild (SCH)	☐ Unavailable

I consent to receive the following vaccination(s) [Vaccine]: SARS-CoV-2 Vaccine (2-dose series) ☐ **Yes** ☐ **No**

SECTION 2: HEALTHCARE WORKER INFORMATION

Facility Staff receiving the vaccine must complete section 2 below.

Medical Conditions:			
Mailing Address:			
Street:	City:	State:	Zip:
Personal Phone Number:	Personal Email Address:		
Primary Care Provider (PCP):	PCP Phone Number:		

Insurance Information (Please fill table below or check "No Insurance" if not insured)

☐ **No Insurance**	**Pharmacy/Medication**	**Medical**
Insurance Plan/Plan ID		
Member/Recipient ID Number		
RX BIN		N/A
RX PCN		N/A
Group Number		

Are you the cardholder? ☐ Yes ☐ No If no, please provide the Cardholder's name, date of birth and relationship below:

Cardholder Name:	Cardholder DoB:	Relationship to Cardholder:

SECTION 3: CONSENT

Please read the following statements and sign below on the signature line.

I have received, read and understand the COVID-19 Vaccine Information provided by PharmScript. I hereby authorize PharmScript and the practitioners employed by or contracted with PharmScript (each, a "Provider") to administer the Vaccine I have requested above as a two-dose regimen series administered 19 to 23 days apart (the "Services"). The scope of this consent includes discussion about the vaccine(s) and its administration between PharmScript and other health care professionals for purposes of care and treatment. I understand that I may withdraw this consent at any time by making a request in writing.

Continued on next page.

SECTION 3: CONSENT

Please read the following statements and sign below on the signature line.

I acknowledge that I have been informed about, the following:

- The goal of the Services is to administer the Vaccine I requested.
- The Provider(s) will provide me with additional information about any risks associated with the Services, which depend upon my specific diagnoses and health status.
- Administering Vaccines is not an exact science and there are no guarantees as to the results of the Services that may be provided to me.
- The nature and purpose of the Services, expected benefits, potential known and unknown complications, likelihood of achieving goals, and relative risks that may arise from the Services, along with the relevant risks and consequences of no treatment.

I understand the benefits and risks of the Vaccine and I expressly consent, request, and authorize the administration of the Vaccine. On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless PharmScript, each Provider and the applicable staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liability or claims, whether known or unknown, arising out of, in connection with, or in any way related to the Services.

I acknowledge that: (a) I understand the purposes/benefits of my state's vaccination registration ("State Registry") and my state's health information exchange ("State HIE"); and (b) the Provider may disclose my vaccination information to the State Registry, to the State HIE, or through the State HIE to the State Registry, for purposes of public health reporting, or to my healthcare providers enrolled in the State Registry and/or State HIE for purposes of care coordination.

I further authorize the applicable Provider to: (a) release my medical or other information, including my communicable disease (including HIV), mental health and drug/alcohol abuse information, to, or through, the State HIE to my healthcare professionals, Medicare, Medicaid, or other third-party payers as necessary to effectuate care or payment; (b) submit a claim to my insurer for the Services; and (c) request payment or authorized benefits be made on my behalf to the applicable Provider with respect to the Services.

I acknowledge that, depending upon my state's law, I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the Provider: (a) the disclosure of my vaccination information by the Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my vaccination information with any of my other healthcare providers enrolled in the State Registry and/or State HIE. The Provider will, if my state permits, provide me with an Opt-Out Form. I understand that I may need to consent, depending on my state's law, and to the extent so required, I hereby do consent by signing below to the Provider reporting my vaccination information to the State HIE, or through the State HIE and/or State Registry to the entities and for the purposes described in this Informed Consent Form. Unless I provide the Provider with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to the Provider and/or my State HIE, as applicable. I understand that even if I do not consent or if I withdraw my consent, my state's laws may permit certain disclosures of my vaccination information to or through the State HIE as required or permitted by law.

Photocopies/electronic transmissions/faxes of this consent and any signatures are to be considered as valid originals.

MY SIGNATURE BELOW INDICATES THAT I VOLUNTARILY AGREE TO ALL OF THE ABOVE AND THAT THE NATURE OF THIS CONSENT WAS EXPLAINED TO ME AND THAT I HAD THE OPPORTUNITY TO ASK ANY AND ALL QUESTIONS REGARDING THE ABOVE AND MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION. I UNDERSTAND THE BENEFITS AND RISKS OF THE VACCINE AND I EXPRESSLY CONSENT, REQUEST AND AUTHORIZE THE ADMINISTRATION OF THE VACCINE. I HAVE BEEN PROVIDED WITH THE CDC'S VACCINE INFORMATION SHEET(S) OR THE EMERGENCY USE AUTHORIZATION (EUA) PATIENT FACT SHEET CORRESPONDING TO THE VACCINE THAT I AM RECEIVING.

If signing on behalf of the patient, please provide the following information:

☐ I am the legal and authorized representative of the patient and am authorized to sign this consent on the patient's behalf.

☐ The patient verbally agreed to all of the above and provided verbal consent but is unable to physically sign this consent form. Patient has verbally provided me with authorization to sign this consent on patient's behalf.

☐ The legal and authorized representative of the patient verbally agreed to all of the above on behalf of patient and provided verbal consent on behalf of the patient and verbal authorization for this consent to be signed.

Print Name (Signatory):	Signature:	Date:

Guardian Name:

Relationship to Patient (if applicable): ☐ Spouse ☐ Power of Attorney ☐ Legal Guardian ☐ Other, Please Specify:
(If "Other", refer to witness section)

Witness (use for Relationship To Patient is "Other"): (optional)

Signature:	Print Name:

PHARMSCRIPT

Refusal to Consent to Vaccination

This is a tool for documentation in the patient's medical record. This is not a waiver form.

Name _____ **Date of Birth** _____

I have been advised about receiving the following vaccine(s):

- COVID-19 Vaccine, including all applicable doses of the SARS-CoV-2 Vaccine.

I understand and refuse the administration of the Vaccine, including any and all recommended doses. I acknowledge that I have received and reviewed the Centers for Disease Control and Prevention's (CDC) Vaccine Information Statement(s) or Emergency Use Authorization information explaining the Vaccine(s) and the disease(s) they prevent.

The following have been explained to me:

- The purpose of the Vaccine.
- The benefits of the Vaccine.
- The risks of not receiving the Vaccine, including, but not limited to the fact that I may contract the illness the Vaccine is intended to prevent, and may transmit such illness to others. There may be other unknown risks that cannot be identified at this time, and I fully accept and assume responsibility for these risks.

I also acknowledge that:

- I have had the opportunity to have all my questions related to the Vaccine answered and the answers are to my satisfaction.
- I may ask further questions, change my decision, consent to the Vaccine at any time and receive the Vaccine based on availability.
- I accept sole and complete responsibility for any consequences to my general health or to others as a result of the Vaccine that I declined, and do hereby release PharmScript and the skilled nursing facility where I reside from all responsibility for any ill effects that may result from my refusal of the administration of the Vaccine as identified in this form.

MY SIGNATURE BELOW ACKNOWLEDGES THAT I HAVE READ AND UNDERSTAND THIS DOCUMENT AND REFUSE THE VACCINE PROPOSED WITHIN.

Signature _____ **Date** _____

Resident signature OR Signature/Printed Name of Health POA OR Name of Health POA/verbally acknowledged by licensed staff (sign & print name & credentials)

_____ **Date** _____

Centers for Disease Control and Prevention

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

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

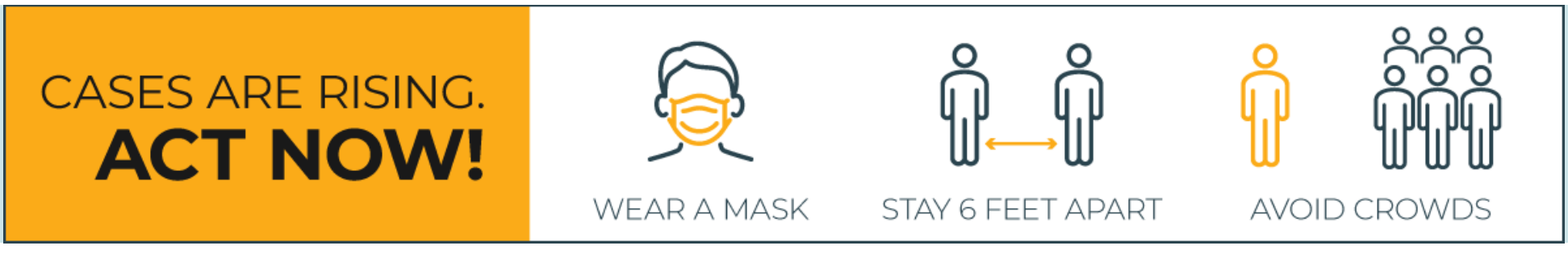
If you have additional questions from patients, reference Frequently Asked Questions about COVID-19 Vaccination for regularly updated answers to common questions.

Page last reviewed: November 2, 2020

Centers for Disease Control and Prevention

COVID-19 (Coronavirus Disease)

MENU >



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 <u>NOT</u> 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. 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

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. FDA may allow the emergency use of other vaccines to prevent COVID-19.

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

Manufactured for
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An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-1.0

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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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