



Vaccine Registry Data Collection Form

**PLEASE CARRY THIS FORM WITH YOU THROUGHOUT THE VACCINATION CLINIC
IT WILL BE COLLECTED FROM YOU AT CHECKOUT**

**REGISTRATION INFORMATION
To be completed by the Vaccine Recipient**

Vaccine Recipient Name (Last, First, MI): _____

Address: _____ **Town:** _____ **State:** ____ **Zip:** _____

Phone Number: _____ **Email address:** _____

Date of Birth (MM/DD/YYYY): _____

Gender:

- Male
- Female
- Other

Race:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

Ethnicity:

- Not Hispanic or Latino
- Hispanic or Latino

**VACCINE ADMINISTRATION INFORMATION
To be completed by Clinic Staff**

Vaccinator Name: _____

Vaccine Product: _____ **Dose #:** 1st 2nd 3rd Booster

Lot #: _____ **Expiration Date:** ____/____/____

Administration Date: _____ **Administration time (HH:MM):** _____

Administration Site: L Arm (LA) L Deltoid (LD) L Anterior Lateral Thigh (LALT)

R Arm (RA) R Deltoid (RD) R Anterior Lateral Thigh (RALT)



Bureau of Infectious Disease Control

Pre-Vaccination Screening Questions for Persons 5-17 Years of Age Receiving the Pfizer-BioNTech COVID-19 Vaccine

The following questions will help us determine if there is any reason your child should not get the COVID-19 vaccine. If you answer “yes” to any of the questions, it does not necessarily mean your child should not be vaccinated. It just means additional information may be needed. Please answer the questions below for your child who is receiving the vaccine.

Name of Person Receiving the Vaccine: _____

Date of Birth: _____ Age: _____

	Yes	No	Don't Know
1. Are you feeling sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you ever received a dose of a COVID-19 vaccine before? If yes , which COVID-19 vaccine product(s) were you previously given? <input type="checkbox"/> Pfizer-BioNTech <input type="checkbox"/> Moderna <input type="checkbox"/> Janssen (Johnson & Johnson)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Did you have an allergic reaction after a prior dose of any COVID-19 vaccine? (Allergic reactions can include symptoms like rash, hives, swelling of the face or mouth, wheezing and difficulty breathing, etc.) If yes , please specify the specific vaccine AND your allergic reaction: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you have a known allergy to an ingredient in the Pfizer-BioNTech COVID-19 vaccine? (See the provided age-appropriate FDA Fact Sheet for a list of vaccine ingredients)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you have a known allergy to polyethylene glycol (PEG)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Do you have a known allergy to polysorbate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Have you ever had any allergic reaction within 4 hours of receiving a non-COVID-19 vaccine or other injectable medication (including medications injected into a muscle, vein, or under the skin)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Have you ever had a severe allergic reaction (like anaphylaxis) due to any other cause, including to medications taken by mouth, food, or other substances?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Did you develop myocarditis or pericarditis after receiving a prior dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Do you have a bleeding disorder or are you taking blood thinners?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. In the last 90 days, have you been given a COVID-19 antibody therapy to either treat COVID-19, or to prevent COVID-19 from developing after you were exposed to another person with COVID-19? (Antibody therapies include monoclonal antibodies or a blood product called “convalescent plasma”)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please sign below to confirm that the information on this form is accurate to the best of your knowledge:

Signature of Parent/Legal Guardian: _____

Printed Name of Parent/Legal Guardian: _____

Date: _____



Bureau of Infectious Disease Control

Consent to Administer COVID-19 Vaccine to a Person Under the Age of 18 Years

INFORMATION AND INSTRUCTIONS:

The parent or legal guardian of the child or teenager being vaccinated should review the additional information below about the COVID-19 vaccine and follow the instructions.

You will be asked some medical questions about the health of your child to make sure they do not have any allergies that would prevent them from getting the COVID-19 vaccine. Right now, the only COVID-19 vaccine available for people under the age of 18 years is the Pfizer-BioNTech COVID-19 vaccine (sometimes just called the “Pfizer vaccine”). There are two different formulations of this vaccine – a lower-dose vaccine for children 5-11 years of age, and a higher-dose vaccine for people 12 years of age and older. The dose your child or teenager will receive is based on their age and NOT their size or weight. Both formulations of the Pfizer COVID-19 vaccine have been shown to be safe and effective when used within the intended age group. Regardless of age, however, this vaccine requires two doses to be given about 21 days apart in order for a person to be considered fully vaccinated and have the best protection against COVID-19. So if this is your child’s first COVID-19 vaccine, they will need to get a second shot about 21 days after the first shot. Also, people who have a weakened immune system may be able to get a third shot to improve their protection. This additional third shot is given at least 28 days after the second shot, but it’s only for people who are 12 years of age or older who have a moderately to severely compromised immune system. More information about who may benefit from this additional third shot can be found on CDC’s website: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>.

Before your child can be given the COVID-19 vaccine, you need to review the information in a FDA Fact Sheet which should have been provided to you already. There are different Fact Sheets for the different Pfizer vaccines, which can also be found online. The Fact Sheet for vaccinating children 5-11 years old can be found here: <https://www.fda.gov/media/153717/download>. The Fact Sheet for vaccinating people 12 years of age and older can be found here: <https://www.fda.gov/media/153716/download>.

If you agree to have your child vaccinated with the age-appropriate Pfizer COVID-19 vaccine and if there is not a medical reason why your child cannot get the vaccine, then please answer the questions on the next page and follow the instructions to agree (consent) to have your child vaccinated. Then sign and date the form and return the form to the vaccine clinic staff. If you do not want your child to be vaccinated, then do not sign or return the form, and your child will not be given the COVID-19 vaccine.

Name of Person Receiving the Vaccine: _____

Date of Birth: _____ Age: _____

➤ Check the box below for the COVID-19 vaccine dose number that is to be given to your child:

Dose #1

Dose #2

Dose #3 (a third dose is only for people 12 years of age and older who are moderately to severely immunocompromised)

➤ If your child is receiving a second or third dose of the COVID-19 vaccine, did your child experience any serious or severe side effects or allergic reactions after an earlier vaccine dose?

(If your child only experienced the normal mild side effects after an earlier vaccine dose like injection site pain, redness, or swelling; or body symptoms like fatigue/tiredness, headache, muscle aches, joint aches, fever, chills, etc. then please check the "no" box)

Question does not apply – this will be my child's first dose of the vaccine

No

Yes – Please specify the serious/severe reaction your child had after an earlier vaccine dose:

CONSENT FOR MY CHILD TO RECEIVE THE COVID-19 VACCINE:

I have been given and reviewed the age-appropriate FDA Fact Sheet for people receiving the Pfizer-BioNTech COVID-19 vaccine. I have also been given and reviewed the NH Department of Health and Human Services' Notice of Privacy Practices. By checking the box and signing below, I am acknowledging that I have received and reviewed the information provided, I **confirm that the information entered on this form is accurate, and I GIVE CONSENT** for my child named above to be vaccinated with the age-appropriate Pfizer-BioNTech COVID-19 vaccine.

Signature of Parent/Legal Guardian: _____

Printed Name of Parent/Legal Guardian: _____

Date: _____

Phone Number of Parent/Legal Guardian (Emergency Contact Number): _____

(Note: vaccine clinic staff may contact you at this number if there are questions about the information you provided on this form.)

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT
CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS
5 THROUGH 11 YEARS OF AGE**

FOR 5 THROUGH 11 YEARS OF AGE

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

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 through 11 years of age.¹

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 5 through 11 years of age.

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

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

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

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

¹ You may receive this Vaccine Information Fact Sheet even if your child is 12 years old. Children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older.

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

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

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

HOW IS THE VACCINE GIVEN?

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

The vaccine is administered as a 2-dose series, 3 weeks apart.

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?

Your child should not get the vaccine if your child:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE VACCINE?

The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAS THE VACCINE BEEN USED BEFORE?

Millions of individuals 12 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In other clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. The vaccine that is authorized for use in children 5 through 11 years of age includes the same mRNA and lipids but different inactive ingredients compared to the vaccine that has been used under EUA in individuals 12 years of age and older and that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be readily prepared to deliver appropriate doses to the 5 through 11 year-old population.

WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

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

WHAT ARE THE RISKS OF THE VACCINE?

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

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

Call the vaccination provider or your child’s healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Pfizer-BioNTech COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

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

You may also be given an option to enroll in v-safe. V-safe is a 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 HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

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

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

For children 5 through 11 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

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

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

WHAT ABOUT PREGNANCY OR BREASTFEEDING?

If your child is pregnant or breastfeeding, discuss the options with your healthcare provider.

WILL THE VACCINE GIVE MY CHILD COVID-19?

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


KEEP YOUR CHILD’S VACCINATION CARD

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

ADDITIONAL INFORMATION

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

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

Global website	Telephone number
<p data-bbox="315 1509 620 1539">www.cvdvaccine.com</p> 	<p data-bbox="948 1583 1221 1654">1-877-829-2619 (1-877-VAX-CO19)</p>

HOW CAN I LEARN MORE?

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

WHERE WILL MY CHILD'S VACCINATION INFORMATION BE RECORDED?

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

<https://www.cdc.gov/vaccines/programs/iis/about.html>.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The 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.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1486-0.3

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

Barcode Date: 09/30/2021

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA)
AND THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND
OLDER**

FOR 12 YEARS OF AGE AND OLDER

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for ages 12 years and older, when prepared according to their respective instructions for use, can be used interchangeably.¹

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- a 2-dose primary series to individuals 12 through 15 years;**
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:**
 - 65 years of age and older**
 - 18 through 64 years of age at high risk of severe COVID-19**

¹ When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of Pfizer-BioNTech COVID-19 Vaccine for ages 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. **Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.**

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- a 2-dose primary series to individuals 12 years of age and older;
- a third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose to the following individuals who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- a single booster dose to eligible individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. **Booster eligibility and schedule are based on the labeling information of the vaccine used for the primary series.**

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

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

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine when prepared according to their respective instructions for use, can be used interchangeably.

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 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- 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
- have ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose:

- A single booster dose of the vaccine may be administered at least 6 months after completion of a primary series to individuals:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2
- A single booster dose of the vaccine may be administered to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?

You should not get the 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 VACCINES?

COMIRNATY (COVID-19 Vaccine, mRNA) and the authorized formulations of the vaccine include the following ingredients:

- mRNA and 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).

Pfizer-BioNTech COVID-19 vaccines for individuals 12 years of age and older contain 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:

- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR

- tromethamine, tromethamine hydrochloride, and sucrose

COMIRNATY (COVID-19 Vaccine, mRNA) contains the following additional ingredients: potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HAS THE VACCINE BEEN USED BEFORE?

Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccines and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020. The vaccine that is authorized for use in individuals 12 years and older includes two formulations; one that was studied in clinical trials and used under EUA, and one with the same mRNA and lipids but different inactive ingredients. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be administered without dilution.

WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

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

WHAT ARE THE RISKS OF THE VACCINE?

There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the 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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If 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 either “COMIRNATY (COVID-19 Vaccine, mRNA)” or “Pfizer-BioNTech COVID-19 Vaccine EUA”, as appropriate, 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 COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, it is your choice to receive or not receive the 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 COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?

If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are

immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE VACCINE GIVE ME COVID-19?

No. The 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 next dose(s) of the 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
<p data-bbox="315 999 620 1029">www.cvdvaccine.com</p> 	<p data-bbox="951 1073 1221 1142">1-877-829-2619 (1-877-VAX-CO19)</p>

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>.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a

COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The 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.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.



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BIONTECH

Manufactured for
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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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