VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH COVID-19 VACCINE, AND THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) 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), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, 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 the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, and also includes information about the U.S. Food and Drug Administration (FDA)-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older[1].

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine authorized under Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.[2]

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 12 years of age and older. It is also authorized under EUA to provide:

- **a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.**

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

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

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; and**
- **a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.**

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

- **a single booster dose to individuals 12 years of age and older at least 2 months after completion of primary vaccination with any authorized or approved monovalent[3] COVID-19 vaccine; or**
- **a single booster dose to individuals 12 years of age and older at least 2 months after receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, 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 ANY OF THESE VACCINES

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.

HOW ARE COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH COVID-19 VACCINE, AND THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT RELATED?

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. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is made in the same way as COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine but it also

[3] Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

contains an Omicron component to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2.

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 ANY OF THESE VACCINES?

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 ARE THESE VACCINES GIVEN?

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

Primary Series: The Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) are given for the 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 with certain kinds of immunocompromise.

Booster Dose: Pfizer-BioNTech COVID-19 Vaccine, Bivalent is administered as a single booster dose at least 2 months after:

- completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine; or
- receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine

The vaccine may not protect everyone.

WHO SHOULD <u>NOT</u> GET COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH COVID-19 VACCINE, OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

You should not get any of these vaccines if you:

- had a severe allergic reaction after a previous dose of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine
- had a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THESE VACCINES?

COMIRNATY (COVID-19 Vaccine, mRNA), Pfizer-BioNTech COVID-19 Vaccine, and Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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 Vaccine for individuals 12 years of age and older contains 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

Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 12 years of age and older contains the following additional ingredients:

- tromethamine, tromethamine hydrochloride, and sucrose

COMIRNATY (COVID-19 Vaccine, mRNA) contains 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

HAVE THESE VACCINES BEEN USED BEFORE?

In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. Millions of individuals have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020.

In a clinical trial, approximately 300 individuals greater than 55 years of age received one dose of a bivalent vaccine that differs from the Pfizer-BioNTech COVID-19 Vaccine, Bivalent in that it contains a different Omicron component.

WHAT ARE THE BENEFITS OF THESE VACCINES?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine have been shown to prevent COVID-19. FDA has authorized Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide better protection against COVID-19 caused by the Omicron variant of SARS-CoV-2.

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

WHAT ARE THE RISKS OF THESE VACCINES?

There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose. 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 COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine, more commonly in adolescent males and adult males under 40 years of age than among females and older males. 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 these vaccines include:

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain
- 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 these vaccines. Serious and unexpected side effects may occur. The possible side effects of these vaccines are still being studied.

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)", "Pfizer-BioNTech COVID-19 Vaccine EUA", or "Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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 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), THE PFIZER-BIONTECH COVID-19 VACCINE, OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
Under the EUA, it is your choice to receive or not receive any of these vaccines. Should you decide not to receive any of these vaccines, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH COVID-19 VACCINE, OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
For primary vaccination, another choice for preventing COVID-19 is SPIKEVAX (COVID-19 Vaccine, mRNA), an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under EUA, including bivalent vaccines that contain an Omicron component of SARS-CoV-2.

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

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

WHAT IF I AM IMMUNOCOMPROMISED?

If you are immunocompromised, you may receive a third primary series dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA). Individuals 12 years of age and older may receive a booster dose with Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Vaccinations may 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. 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 THESE VACCINES GIVE ME COVID-19?

No. These vaccines do not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you get your first COVID-19 vaccine, you will get a vaccination card. 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 of the primary series. 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 THESE COVID-19 VACCINES?

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 these vaccines. 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 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. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

An EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

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

Pfizer
Manufactured by
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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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Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you or your dependent feel after getting a COVID-19 vaccine. It takes just a few minutes to enroll and your participation in **v-safe** helps us monitor the safety of COVID-19 vaccines for everyone.

V-safe features:

- **Enroll your dependents** and complete check-ins on their behalf
- **Enter** and report how you feel after **first, second, additional, and booster doses**

How can I enroll and how does it work?

You can enroll in **v-safe** after any dose of COVID-19 vaccine by using your smartphone and going to vsafe.cdc.gov.

During the first week after each vaccination, **v-safe** will send you a text message each day to ask how you are feeling. After that, you will receive occasional check-ins, which you can opt out of at any time. Depending on your answers, someone from CDC may call to get more information. Your personal information in **v-safe** is protected so it's safe and private*.

How can I enroll my child or dependent?

You can enroll any family member (or friend) who is eligible to be vaccinated in **v-safe.** Children under 16 years old must be enrolled using a parent or guardian's **v-safe** account. You can add a dependent to your existing account or create a new account if you don't have one yet. Creating an account to enroll a dependent does not require that you enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: www.cdc.gov/vsafe

v-safe℠
after vaccination health checker

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

*v-safe uses existing information systems managed by CDC, FDA, and other federal agencies. These systems use strict security measures to keep information confidential. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

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