

 ACCEDA a la página de Información Médica de la vacuna contra COVID-19 de Pfizer-BioNTech.

Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® Receives Full U.S. FDA Approval for Individuals 16 Years and Older

Learn more 

The Pfizer-BioNTech COVID-19 Vaccine is now known as COMIRNATY (COVID-19 Vaccine, mRNA). Comirnaty is U.S. Food and Drug Administration (FDA)-approved in individuals 16 years of age and older. Comirnaty is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS CoV 2) in individuals 16 years of age and older.

In individuals 12-15 years of age, the Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19). The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. The products are legally distinct with certain differences that do not impact safety or effectiveness.

Comirnaty (COVID-19 Vaccine, mRNA) WHAT IS COVID-19?

(Pfizer-BioNTech COVID-19 Vaccine)

Find Comirnaty (COVID-19 Vaccine, mRNA) medical information:

Our medical information is accurate, up to date, and scientifically balanced.

Comirnaty (COVID-19 Vaccine, mRNA) Quick Finder

Interact with the Medical Information Digital Assistant 

Ingredient & Allergen Checker 

Comirnaty Prescribing Information 

Comirnaty and Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Fact Sheet for Recipients and Caregivers 

Resources 

**Emergency Use Authorization
Fact Sheet for Recipients and
Caregivers**

**Emergency Use Authorization (EUA) Fact Sheet for Healthcare
Providers Administering Vaccines including the Full EUA
Prescribing Information**

Show All

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

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).

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.⁸

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 be administered to:
 - prevent COVID-19 in individuals 12 through 15 years, and
 - provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

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

- prevent COVID-19 in individuals 12 years of age and older, and
- provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

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.

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine are administered as a 2-dose series, 3 weeks apart, into the muscle.

Under EUA for individuals who are determined to have certain kinds of immunocompromise, a third dose may be administered at least 4 weeks after the second dose.

COMIRNATY (COVID-19 Vaccine, mRNA) and 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. 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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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 have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. What is an Emergency Use Authorization (EUA)?" section at the end of this Fact Sheet.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

WHO SHOULD GET THE VACCINE?

FDA has approved COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 16 years of age and older and has authorized it for emergency use in individuals 12 through 15 years.

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

WHO SHOULD NOT GET THE VACCINE?

NOT

You should not get the COMIRNATY (COVID-19 Vaccine, mRNA) or 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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

WHAT ARE THE INGREDIENTS IN COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine include 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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

HOW IS THE VACCINE GIVEN?

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

The vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the vaccine, you should receive a second dose of the vaccine 3 weeks later to complete the vaccination series.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

HAVE COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

WHAT ARE THE BENEFITS OF COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?

The 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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

WHAT ARE THE RISKS OF COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 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 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 the Pfizer-BioNTech COVID-19 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 COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine include:

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)
- 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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE?

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

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

WHAT IF I AM PREGNANT OR BREASTFEEDING?

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

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

WILL COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?

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

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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 or if you have certain kinds of immunocompromise, your third dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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>www.cvdvaccine.com</p>  | <p>1-877-829-2619 (1-877-VAX-CO19)</p> |

Did you find an answer to your question? **Yes** | **No**

[Read less](#)

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-...>

[Read more](#)

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...

[Read more](#)

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,...

[Read more](#)

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...

[Read more](#)

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...

[Read more](#)

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...

[Read more](#)

Full Emergency Use Authorization Fact Sheet for Recipients and Caregivers

...

[Read more](#)

[Show All](#)

Did you find an answer to your question? [Yes](#) | [No](#)

Resources

WEBSITE

[Pfizer-BioNTech COVID-19 Global Vaccine Site](#)

WEBSITE

[Pfizer COVID-19 Resources](#)

WEBSITE

[WHO: Information on COVID-19](#)

WEBSITE

[U.S. CDC Information on COVID-19 Disease](#)

WEBSITE

[U.S. FDA Information on EUA](#)

Didn't find what you were looking for? Contact us.

MI Digital Assistant

To interact with the Medical Information Digital Assistant click here.

Call (800) 438-1985

Contact **Pfizer Medical Information** to speak with a professional regarding your medical question on a Pfizer **prescription** product: (800) 438-1985

Report Adverse Event

Pfizer Safety

To report an adverse event related to the Pfizer-BioNTech COVID-19 Vaccine, and you are not part of a clinical trial* for this product, click the link below to submit your information:

[Pfizer Safety Reporting Site](#)

*If you are involved in a clinical trial for this product, adverse events should be reported to your coordinating study site.

If you cannot use the above website, or would like to report an adverse event related to a different Pfizer product, please call Pfizer Safety at (800) 438-1985.

FDA Medwatch

You may also contact the **U.S. Food and Drug Administration (FDA)** directly to report adverse events or product quality concerns at 1-800-FDA-1088 or www.fda.gov/MedWatch

Terms of Use
Privacy Policy
Pfizer.com

©2021 Pfizer. The product information provided by this site is intended only for health care professionals, patients, consumers and caregivers in the United States. The products discussed herein may have different product labeling in different countries.

Not a patient or caregiver?

Go to the healthcare professional homepage.

End session