

## Patient Package Insert

### INFORMATION FOR RECIPIENTS AND CAREGIVERS COMIRNATY (Cuh-mir'-na-tee) (COVID-19 VACCINE, mRNA) (2023-2024 Formula)

This summary is not intended to take the place of talking with your healthcare provider. If you have questions or would like more information, please talk with your healthcare provider.

#### What is COMIRNATY?

COMIRNATY is a vaccine for use in people 12 years of age and older to protect against COVID-19.

COMIRNATY may not protect all people who receive the vaccine.

COMIRNATY does not contain SARS-CoV-2, the virus that causes COVID-19. COMIRNATY cannot give you COVID-19.

#### Who should not get COMIRNATY?

You should not get COMIRNATY if you had:

- a severe allergic reaction after a previous dose of COMIRNATY or any Pfizer-BioNTech COVID-19 vaccine\*
- a severe allergic reaction to any ingredient in these vaccines (see [What are the ingredients in COMIRNATY?](#)).

#### Before getting COMIRNATY, tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- 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 COMIRNATY given?

COMIRNATY is given as an injection into the muscle.

#### What are the possible risks of COMIRNATY?

There is a remote chance that COMIRNATY 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
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\* COMIRNATY (2023-2024 Formula) is made the same way as Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

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 mRNA COVID-19 vaccines, including COMIRNATY and Pfizer-BioNTech COVID-19 vaccines. Myocarditis and pericarditis following COMIRNATY have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of 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 or Pfizer-BioNTech COVID-19 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 reactions: pain, swelling, redness, arm pain
- General side effects: tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell, swollen lymph nodes (lymphadenopathy), decreased appetite, diarrhea, vomiting, dizziness
- Fainting in association with injection of the vaccine

These may not be all the possible side effects of COMIRNATY. Ask your healthcare provider about any side effects that concern you.

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>.

In addition, you can report side effects to Pfizer Inc. at 1-800-438-1985 or [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com).

### **What if you are pregnant or breastfeeding?**

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

### **What are the ingredients in COMIRNATY?**

COMIRNATY contains the following ingredients:

- messenger ribonucleic acid (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

COMIRNATY does not contain preservatives.

This Information for Recipients and Caregivers may have been updated. For the most recent Information for Recipients and Caregivers, please visit <https://dailymed.nlm.nih.gov/dailymed/>.

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If you have questions, talk to your healthcare provider or visit [www.COMIRNATY.com](http://www.COMIRNATY.com) or call 1-877-VAX-CO19 (1-877-829-2619).

**BIONTECH**

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Manufactured by  
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