

INFORMATION FOR RECIPIENTS AND CAREGIVERS
COMIRNATY (Cuh-mir'-na-tee)
(COVID-19 VACCINE, mRNA)
(2025-2026 Formula)

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

What is COMIRNATY?

COMIRNATY is a vaccine to protect against COVID-19. COMIRNATY is for people who are:

- 65 years of age and older, or
- 5 years through 64 years of age at high risk for severe COVID-19.

Vaccination with 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 or your child COVID-19.

Who should not get COMIRNATY?

You or your child should not get COMIRNATY if you or your child 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 the vaccination provider about all of your or your child's medical conditions, including if you or your child:

- 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 the 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 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, the vaccination provider may ask you or your child to stay at the place where you or 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 mRNA COVID-19 vaccines, including COMIRNATY and Pfizer-BioNTech COVID-19

vaccines. Myocarditis and pericarditis following administration of mRNA COVID-19 vaccines have occurred most commonly in males 12 years through 24 years of age. In most of these people, symptoms began within a week following vaccination. Based on available data, estimated rates of myocarditis and/or pericarditis from 1 through 7 days after getting a dose of the 2023-2024 Formula of mRNA COVID-19 vaccines were approximately 8 cases per million doses in people 6 months through 64 years of age and approximately 27 cases per million doses in males 12 years through 24 years of age.

In most people who have had myocarditis or pericarditis after receiving an mRNA COVID-19 vaccine, symptoms have gone away a few days after receiving treatment with medicines used to reduce inflammation.

In a study, follow-up information was collected on people who developed myocarditis after receiving the original formula of a COVID-19 vaccine; most people had received an mRNA COVID-19 vaccine. Some people in the study reported having heart symptoms approximately 3 months after developing myocarditis. Some people in the study had heart MRIs (scans that show detailed images of the heart muscle) initially after developing myocarditis and again approximately 5 months later. The initial and follow-up heart MRIs commonly showed signs of injury to the heart muscle, with improvement over time in most people. It is not known if these heart MRI findings might predict long-term heart effects of myocarditis. Studies are underway to find out if there are long-term heart effects in people who have had myocarditis after receiving an mRNA COVID-19 vaccine.

You should seek medical attention right away if you or your child have any of the following symptoms after receiving COMIRNATY, 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

These could be symptoms of myocarditis or pericarditis.

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

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
- Febrile seizures (convulsions during a fever) in children 5 through 11 years of age

These may not be all the possible side effects of COMIRNATY. Ask your or your child's 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.

What if you or your child are pregnant or breastfeeding?

If you or your child are pregnant or breastfeeding, discuss your options with the 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/>.

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

BIONTECH

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



Manufactured by
Pfizer Inc., New York, NY 10001
LAB-1587-7.0
US Govt. License No. 2229

Revised: 8/2025

Revised: 8/2025

Pfizer Laboratories Div Pfizer Inc