

COMIRNATY® is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

COMIRNATY is approved for use in individuals who are 65 years of age and older, or 5 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

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

**COMIRNATY is FDA approved to be administered as a single dose (0.3 mL) into the muscle for people 5 years of age and older. People previously vaccinated with any COVID-19 vaccine should receive the dose of COMIRNATY at least 2 months after the last dose of COVID-19 vaccine.**

If you or your child are immunocompromised, talk to your healthcare provider. Your or your child's immune response to COVID-19 vaccination may not be as strong as people who are not immunocompromised. Your or your child's healthcare provider may have different recommendations for COVID-19 vaccinations.

Updated formulas of COMIRNATY are made using a process similar to previous formulas, with the difference only in the mRNA, which encodes the viral spike protein of recently circulating strains.

*Vaccination with COMIRNATY may not protect everyone.*



## SELECTED SAFETY INFORMATION

You or your child should **NOT** get COMIRNATY® (COVID-19 Vaccine, mRNA) if you or your child had a severe allergic reaction after a previous dose of COMIRNATY or any Pfizer-BioNTech COVID-19 vaccine or to any ingredient in these vaccines.

**Don't delay. Find a vaccine near you today. | [VAXASSIST.COM](https://vaxassist.com)**

## Important Safety Information and Indication

- You or your child should **NOT** get COMIRNATY® (COVID-19 Vaccine, mRNA) if you or your child had a severe allergic reaction after a previous dose of COMIRNATY or any Pfizer-BioNTech COVID-19 vaccine or to any ingredient in these vaccines
- 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

Important Safety Information continues on the next page.

Please click here for full [Prescribing Information](#) and [Patient Information](#) for COMIRNATY.

## Important Safety Information (cont'd)

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

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
- Fainting can happen after getting injectable vaccines including COMIRNATY. Your vaccination provider may ask you to sit or lie down
  - People with weakened immune systems may have a reduced immune response to COMIRNATY
  - Vaccination with COMIRNATY may not protect all people who receive the vaccine

**Before getting COMIRNATY, tell your 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 your immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

Additional side effects that have been reported with COMIRNATY or Pfizer-BioNTech COVID-19 vaccines include:

- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- 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
- 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.

You may report 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 [www.vaers.hhs.gov/reportevent.html](http://www.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).

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