

COMIRNATY<sup>®</sup> (COVID-19 Vaccine, mRNA) 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) in individuals 12 years of age and older.

**COMIRNATY is administered as a single dose for people 12 years of age and older. For people previously vaccinated with any COVID-19 vaccine, administer the dose of COMIRNATY at least 2 months after the last dose of COVID-19 vaccine.**

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

*Vaccination with COMIRNATY may not protect everyone.*

### SELECTED SAFETY INFORMATION

You should **NOT** receive COMIRNATY (COVID-19 Vaccine, mRNA) if you have had a severe allergic reaction to any ingredient in COMIRNATY or Pfizer-BioNTech COVID-19 Vaccine.

**Don't delay. Find COVID-19 vaccines by Pfizer and BioNTech in your area.**

## Important Safety Information and Indication

### IMPORTANT SAFETY INFORMATION

- You should **NOT** receive COMIRNATY (COVID-19 Vaccine, mRNA) if you have had a severe allergic reaction to any ingredient of COMIRNATY or a previous dose of a Pfizer-BioNTech COVID-19 vaccine
- 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 of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. **If you or your pre-teen or teenager experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital.** 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
- Authorized or approved mRNA COVID-19 vaccines show increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart), particularly within the first week following vaccination. For COMIRNATY, the observed risk is highest in males 12 through 17 years of age. **Seek medical attention right away if you 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

Please see additional Important Safety Information on the following page.  
Please click here for Full Prescribing Information for [COMIRNATY](#).

# Important Safety Information and Indication (cont'd)

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 for 15 minutes after receiving the vaccine
  - People with weakened immune systems may have a reduced immune response to COMIRNATY
  - COMIRNATY may not protect all vaccine recipients
  - **Tell your 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 the 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
  - The **most commonly reported adverse reactions** (≥10%) after a dose of COMIRNATY were pain at the injection site (up to 90.5%), fatigue (up to 77.5%), headache (up to 75.5%), chills (up to 49.2%), muscle pain (up to 45.5%), joint pain (up to 27.5%), fever (up to 24.3%), injection site swelling (up to 11.8%), and injection site redness (up to 10.4%).

These may not be all the possible side effects of the vaccine. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

You should always ask your healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (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). You can also report side effects to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling 1-800-438-1985

## INDICATION

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