# Help protect eligible patients 12 years of age & older against COVID-19 with COMIRNATY

COMIRNATY® (COVID-19 Vaccine, mRNA)

BIONTECH Pfizer

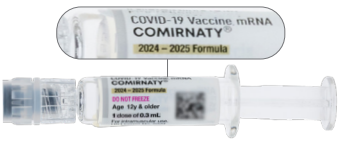
- The first and only mRNA COVID-19 vaccine that has never been frozen and is stored at refrigerated temperature
- Available in a single dose glass prefilled syringe
- May be stored for up to 8 months from date of manufacture

## The 2024-2025 Formula of COMIRNATY, a monovalent Omicron KP.2-adapted vaccine

COMIRNATY is FDA-approved to be administered as a single dose (0.3 mL) to eligible individuals 12 years of age and older whether or not they have been previously vaccinated with a COVID-19 vaccine, to help prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). According to the COMIRNATY USPI, for individuals previously vaccinated with any COVID-19 vaccine, administer the dose of COMIRNATY at least 2 months after the last dose of COVID-19 vaccine.

**Presentation[1]**

**SINGLE DOSE GLASS PREFILLED SYRINGE**




**DO NOT FREEZE**

**Eligible healthcare providers can order their office's supply of the 2024-2025 Formula of COMIRNATY by:**

Scanning the QR code **OR** Visiting: www.pfi.sr/Order **OR** Contacting a wholesaler

Store in refrigerator 2°C to 8°C (35°F to 46°F) up to 8 months from date of manufacture. DO NOT FREEZE.[1]
Regardless of storage condition, vaccine should not be used after the expiration date printed on the prefilled syringes and cartons.
Do not shake. Remove tip cap by slowly turning the cap counterclockwise while holding the Luer lock and attach a sterile needle. Use immediately. If COMIRNATY cannot be used immediately, it must be used within 4 hours.

For detailed information regarding storage, handling, preparation and administration, please refer to the full **Prescribing Information**.

### CDC recommendation

ACIP recommendations include vaccination with an updated 2024-2025 Formula COVID-19 vaccine for eligible individuals 12 years of age and older[2,3]

According to CDC, individuals who have previously had COVID-19 also should be vaccinated. Please see CDC's Interim Clinical Considerations for the use of COVID-19 Vaccines.

### Coadministration of COVID-19 and other vaccines

Per CDC, coadministration of age-appropriate vaccines is recommended if there are no contraindications at time of healthcare visit[4*]

### Your recommendation matters

Discussing COVID-19 vaccination with patients can be an important step in helping to protect them against COVID-19[5]

*There are additional considerations for simultaneous administration of an orthopoxvirus vaccine and COVID-19 vaccine.
For best practices for administering multiple injections, see ACIP General Best Practice Guidelines for Immunization.[4]

The Centers for Disease Control and Prevention has published considerations related to COVID-19 vaccination for individuals who are moderately to severely immunocompromised (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html).

## SELECT SAFETY INFORMATION

Do not administer COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

### Management of Acute Allergic Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of COMIRNATY.

**Please see Important Safety Information and Indication on next page.**
**Please click for COMIRNATY Full Prescribing Information and Patient Information.**

Visit **cvdvaccine-us.com** for more information

## IMPORTANT SAFETY INFORMATION

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### Myocarditis and Pericarditis

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For COMIRNATY, the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

The Centers for Disease Control and Prevention (CDC) has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

### Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including COMIRNATY. Procedures should be in place to avoid injury from fainting.

### Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to COMIRNATY.

### Limitation of Vaccine Effectiveness

COMIRNATY may not protect all vaccine recipients.

### Adverse Reactions

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%).

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or https://www.pfizersafetyreporting.com or VAERS at 1-800-822-7967 or https://vaers.hhs.gov

## INDICATION

COMIRNATY® (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.

**Please click for COMIRNATY Full Prescribing Information and Patient Information.**

ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention.

**References: 1.** COMIRNATY® (COVID-19 Vaccine, mRNA). Full Prescribing Information. BioNTech Manufacturing GmbH and Pfizer Inc. August 22, 2024. **2.** ACIP Recommendations. Centers for Disease Control and Prevention. Updated June 28, 2024. Accessed August 22, 2024. https://www.cdc.gov/vaccines/acip/recommendations.html **3.** CDC Recommends Updated 2024-2025 COVID-19 and Flu Vaccines for Fall/Winter Virus Season. Centers for Disease Control and Prevention. Updated June 27, 2024. Accessed August 22, 2024. https://www.cdc.gov/media/releases/2024/s-t0627-vaccine-recommendations.html **4.** Interim clinical considerations for use of COVID-19 vaccines in the United States. Centers for Disease Control and Prevention. Updated April 4, 2024. Accessed August 22, 2024. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html **5.** Talking with patients about COVID-19 vaccination. Centers for Disease Control and Prevention. Updated November 3, 2021. Accessed August 22, 2024. https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

BIONTECH Pfizer

COMIRNATY® (COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
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55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 10001

COVID-19 vaccines from BioNTech and Pfizer, which are based on BioNTech proprietary mRNA technology, were developed by both BioNTech and Pfizer.