COMIRNATY®
(COVID-19 Vaccine, mRNA)

BIONTECH Pfizer

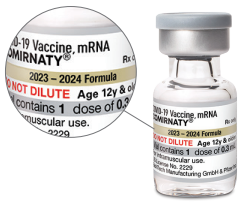
Help protect eligible patients 12 years & older against COVID-19

The 2023-2024 Formula of COMIRNATY is a vaccine administered as a single dose (0.3 mL), regardless of the number of previous COVID-19 vaccine doses, for people 12 years and older to help prevent coronavirus disease 2019 (COVID-19).[1]

Individuals previously vaccinated with any COVID-19 vaccine should receive the dose of COMIRNATY at least 2 months after the last dose.[1]

Currently available in 3 presentations[1]

SINGLE DOSE VIAL



SINGLE DOSE PLASTIC PREFILLED SYRINGE*

SINGLE DOSE GLASS PREFILLED SYRINGE*

DO NOT FREEZE

Regardless of storage condition, vaccine should not be used past the expiration date printed on the label.

*Some presentations may be available only in limited quantities.

Store in refrigerator (2-8 °C) up to 6 months or until the expiration date printed on carton and syringes[1]

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

CDC recommendation

ACIP recommendations include vaccination with an updated 2023–2024 Formula COVID-19 vaccine for eligible individuals 12 years of age and older[2,3]

Coadministration of COVID-19 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 eligible patients can be an important first step in helping to protect them against COVID-19

Complete recommendations and CDC Interim Clinical Considerations, including recommendations for immunocompromised individuals, may be viewed on the CDC website.

†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]

SELECT SAFETY INFORMATION

Do not administer COMIRNATY® (COVID-19 Vaccine, mRNA) to individuals with a 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 used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COMIRNATY.

Please see Important Safety Information and Indication on reverse side. Please see accompanying COMIRNATY Full Prescribing Information and Patient Information in pocket.

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 http://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 see accompanying COMIRNATY Full Prescribing Information and Patient Information in pocket.

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. October 17, 2023.
2. Recommended child and adolescent immunization schedule for ages 18 years or younger. Centers for Disease Control and Prevention. Accessed November 30, 2023. https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf **3.** Recommended adult immunization schedule for ages 19 or older. Centers for Disease Control and Prevention. Accessed November 30, 2023. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf
4. Interim clinical considerations for use of COVID-19 vaccines in the United States. Centers for Disease Control and Prevention. Updated November 3, 2023. Accessed November 30, 2023. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

BIONTECH Pfizer

COMIRNATY® (COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
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.

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