Intended for U.S. Healthcare Professionals

COMIRNATY®
(COVID-19 Vaccine, mRNA)

Vaccine Presentation Guide

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.

SELECTED 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 additional Important Safety Information on page 4.

Please click for COMIRNATY Full Prescribing Information and Patient Information.

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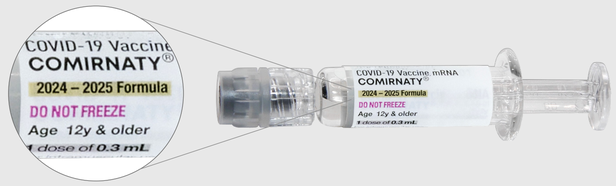
Identifying 2024-2025 Formula of COMIRNATY

Verify the single dose glass prefilled syringes (including labels) prior to preparation for administration to help avoid vaccine administration errors

	2024-2025 Formula of COMIRNATY SINGLE DOSE GLASS PREFILLED SYRINGE DO NOT FREEZE
Composition	Each 0.3 mL dose is formulated to contain 30 mcg of modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 Omicron variant lineage KP.2
Age group	12 years and older
Verify syringe label states “2024-2025 Formula”	
NDC codes	Single Dose Glass Prefilled Syringe: 00069-2432-01 Carton of 10 Single Dose Glass Prefilled Syringes: 00069-2432-10
CPT® code	91320
CVX code	309

Important Reminder

Previous COVID-19 vaccines are no longer available for use in the United States.

FDA and CDC guidance is to check inventory and dispose of previous COVID-19 vaccines according to state and local regulations.

Confirm syringe label states “2024-2025 Formula”

Please see following page for dosage and storage information for individuals 12 years of age and older.

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SELECTED SAFETY INFORMATION

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).

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Vaccine Presentation Guide

For eligible individuals **12 years of age and older**

▶ 2024-2025 Formula

COMIRNATY® (COVID-19 Vaccine, mRNA)

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	2024-2025 Formula of COMIRNATY SINGLE DOSE GLASS PREFILLED SYRINGE DO NOT FREEZE
Age group	12 years and older
Verify syringe label states “2024-2025 Formula” Confirm NDC	
Dose	30 mcg
Dose volume	0.3 mL
Storage Conditions*†	
Room temperature [8°C to 25°C (46°F to 77°F)]	Must not exceed 12 hours‡
Refrigerator [2°C to 8°C (35°F to 46°F)]	Refrigerator-stable for **up to 8 months** from date of manufacture to the expiration date printed on the carton and on the syringe labels
Freezer [-25°C to -15°C (-13°F to 5°F)]	**DO NOT STORE**
Ultra-Low-Temperature (ULT) freezer [-90°C to -60°C (-130°F to -76°F)]	**DO NOT STORE**

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Confirm syringe label states “2024-2025 Formula”

GLASS PREFILLED SYRINGES
DO NOT FREEZE. If glass prefilled syringes have been frozen, discard.

*Regardless of storage condition, the vaccine should not be used after the expiration date printed on the glass prefilled syringes and cartons.
†Regardless of presentation, during storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
‡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.

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Important Safety Information & Indication for COMIRNATY® (COVID-19 Vaccine, mRNA)

IMPORTANT SAFETY INFORMATION

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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

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Reference: COMIRNATY® Prescribing Information. BioNTech Manufacturing GmbH and Pfizer Inc.; 2024.

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.

COMIRNATY®

(COVID-19 Vaccine, mRNA)

Find out more at
www.comirnatyhcp.com

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