Intended for U.S. Healthcare Professionals

COMIRNATY®
(COVID-19 Vaccine, mRNA)

2025-2026 Formula

COMIRNATY Vaccine Presentation Guide

INDICATION

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.

IMPORTANT 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.

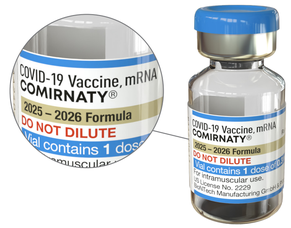
Please see additional Important Safety Information on page 5.

Please click for COMIRNATY Full Prescribing Information and Patient Information.

BIONTECH Pfizer

Identifying the 2025-2026 Formula of COMIRNATY

Verify the single-dose vials or single-dose glass prefilled syringes (including labels) prior to preparation for administration to help avoid vaccine administration errors.[1]

	2025-2026 Formula of COMIRNATY[1] SINGLE-DOSE GLASS PREFILLED SYRINGE DO NOT FREEZE. If glass prefilled syringes have been frozen, discard.	2025-2026 Formula of COMIRNATY[1] SINGLE-DOSE VIAL DO NOT REFREEZE THAWED VIALS. Refer to product labeling for detailed thawing instructions and information related to product handling.
Approved use[1]	• 65 years of age and older • 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19	• 5 years through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19
Composition[1]	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 sublineage LP.8.1	Each 0.3 mL dose is formulated to contain 10 mcg of modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 Omicron variant sublineage LP.8.1
Verify that labels state "2025-2026 Formula"[1]	 Labeled with gray borders on prefilled syringe	 Blue cap and labeled with blue borders on vial
Dose[1]	30 mcg	10 mcg
Dose volume[1]	0.3 mL	0.3 mL

Please see the following page for Storage Conditions for the 2025-2026 Formula of COMIRNATY.

IMPORTANT SAFETY INFORMATION (Cont'd)

Myocarditis and Pericarditis

Postmarketing data from use of authorized or approved mRNA COVID-19 vaccines, including COMIRNATY, have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.

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2025-2026 Formula of COMIRNATY Storage Conditions*

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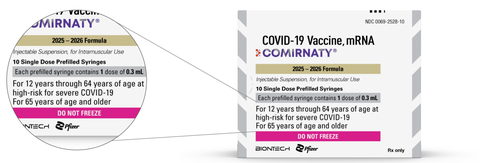
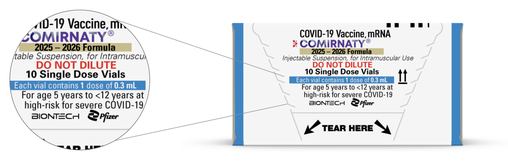
Total time out of refrigeration (at temperatures between 8°C and 25°C [46°F and 77°F])[1]	Must not exceed 12 hours*	Must not exceed 12 hours*
Refrigerator (2°C to 8°C [35°F to 46°F])	Refrigerator stable for **up to 12 months** from date of manufacture to the expiration date printed on the carton and on the syringe labels[1,2]	10 weeks[1] • The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer • Once thawed, the vials should not be refrozen
Ultra-low temperature (ULT) freezer (-90°C to -60°C [-130°F to -76°F])	**DO NOT STORE**[1]	18 months[3]
Carton images[1]		

*Regardless of presentation, during storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.[1]

IMPORTANT SAFETY INFORMATION (Cont'd)

Syncope

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

Please see additional Important Safety Information on page 5.

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2025-2026 Formula of COMIRNATY Stocking and Procedural Codes

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NDC[1]	Single-dose glass prefilled syringe: 0069-2528-01 Carton of 10 single-dose glass prefilled syringes: 0069-2528-10	Single-dose vial: 0069-2501-01 Carton of 10 single-dose vials: 0069-2501-10
CPT® code[4]	91320	91319
CVX code[4]	309	310

CPT=Current Procedural Terminology; CVX=vaccine administered; NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (Cont'd)

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.

Please see additional Important Safety Information on page 5.

Please click for COMIRNATY Full Prescribing Information and Patient Information.

IMPORTANT SAFETY INFORMATION and INDICATION for COMIRNATY

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Adverse Reactions

Most commonly reported adverse reactions after a dose:

- **12 years of age and older** (≥10%) 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%).
- **5 years through 11 years of age** (≥5%) were pain at the injection site (up to 83.8%), fatigue (up to 51.9%), headache (up to 38.4%), injection site redness (up to 25.9%), injection site swelling (up to 20%), muscle pain (up to 18.1%), chills (up to 13.3%), fever (up to 7.8%), and joint pain (up to 7.6%).

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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References: 1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. BioNTech Manufacturing GmbH and Pfizer Inc.; August 27, 2025. **2.** Data on file. BioNTech Manufacturing GmbH and Pfizer Inc.; April 18, 2025. **3.** Data on file. BioNTech Manufacturing GmbH and Pfizer Inc.; June 7, 2025. **4.** Data on file. Pfizer Inc.; August 20, 2025.

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 10001

COMIRNATY® (COVID-19 Vaccine, mRNA)

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

PP-CVV-USA-5373 August 2025