

COMIRNATY[®] (COVID-19 Vaccine, mRNA) 2026-2027 Formula*

*Product availability subject to FDA regulatory action.

FDA = U.S. Food and Drug Administration.



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Pfizer Prime

5-11 Years Presentation

12+ Years Presentation

Reservation Process

Frequently Asked
Questions

 **COMIRNATY[®]**
(COVID-19 Vaccine, mRNA)

Important Safety Information and Indication for COMIRNATY® (COVID-19 Vaccine, mRNA) 2025-2026 Formula

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.

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.

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.

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Important Safety Information and Indication for COMIRNATY® (COVID-19 Vaccine, mRNA) 2025-2026 Formula (cont.)

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>

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.

Please click for [COMIRNATY Full Prescribing Information and Patient Information](#).



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Anticipated 2026–2027 Formula COMIRNATY® (COVID-19 Vaccine, mRNA) Vaccine Presentations*

Provided for informational purposes only; 2026-2027 vaccine product(s) are anticipated to be available at a future date, subject to FDA regulatory action and commercial availability.

Name	2026-2027 Formula of COMIRNATY SINGLE-DOSE VIAL - DO NOT DILUTE
Variant composition	Each 0.3 mL dose is anticipated to be formulated to contain 10 mcg of modRNA encoding the strain(s) as directed by FDA
Age group	5 years through 11 years
Verify syringe label states “2026-2027 Formula”	
NDC codes	Single-dose vial: 0069-2609-01 Carton of 10 single-dose vials: 0069-2609-10
Important Product Information	<ul style="list-style-type: none"> • COMIRNATY single-dose vials may arrive frozen at ultra-cold conditions. Once received, frozen vials may be immediately transferred to the refrigerator at 2°C to 8°C (35°F to 46°F) and stored for up to 10 weeks. Once thawed, they should not be refrozen • Alternatively, single-dose vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F). Do not store vials at -25°C to -15°C (-13°F to 5°F) • Cartons of COMIRNATY single-dose vials may be received at 2°C to 8°C (35°F to 46°F), and they should be stored at 2°C to 8°C (35°F to 46°F). Check that the carton has been previously updated to reflect the 10-week refrigerated expiry date • Please review the expiry date on each carton to ensure product stability

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Please see Important Safety Information on pages 6-7.

Please click for [COMIRNATY Full Prescribing Information](#) and [Patient Information](#).



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Name	2026-2027 Formula of COMIRNATY SINGLE-DOSE GLASS PREFILLED SYRINGE (PFS)
Variant composition	Each 0.3 mL dose is anticipated to be formulated to contain 30 mcg of modRNA encoding the strain(s) as directed by FDA
Age group	12 years and older
Verify syringe label states "2026-2027 Formula"	
NDC codes	Single-dose glass prefilled syringe (unit of use): 0069-2631-01 Carton of 10 single-dose glass prefilled syringes (unit of sale): 0069-2631-10
Important Product Information	<ul style="list-style-type: none"> Product must never be frozen and should be stored refrigerated at 2°C to 8°C (35°F to 46°F). DO NOT FREEZE single-dose glass PFS. If single-dose glass PFS has been frozen, discard A single-dose glass PFS is refrigerator stable for up to 12 months from date of manufacture. Do not exceed the expiration date printed on the carton and syringe labels The barcode will have the expiry date, and there is no need for relabeling or updating expiry. Note, expiry could fall within a month. Please review the expiry date on each carton to ensure product stability

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Please see Important Safety Information on pages 6-7.

Please click for COMIRNATY Full [Prescribing Information](#) and [Patient Information](#).



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