




Moderna COVID-19 Vaccine (2023-2024 Formula) Product Information Quick Guide

Presentation

For children 6 months through 11 years of age

AUTHORIZED USE

- Moderna COVID-19 Vaccine (2023-2024 Formula) has not been approved or licensed by the FDA, but has been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 6 months through 11 years of age.
- The EUA for this product is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.
- For more information on the EUA authorized uses of the vaccine, refer to the Fact Sheet for Healthcare Providers Administering Vaccine.

Product Presentation ¹	
Age Group	6 months through 11 years of age
Dose Volume	0.25 mL
Doses Per Vial	Single dose
Vial Cap Color	Dark blue 
Vial Label	Green box NDC 80777-287-07 
Carton	Carton of 10 single-dose vials NDC 80777-287-92 

The CDC, AAP, and ACIP recommend COVID-19 vaccination for all children 6 months of age and older in the United States to help prevent COVID-19.²⁻⁴

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent.


moderna[®]




Storage and Handling¹

Storage

Stability and storage of Moderna COVID-19 Vaccine
(2023-2024 Formula) remains consistent

For children 6 months through 11 years of age

Item and Packing Information		
Single-Dose Vials Carton		<ul style="list-style-type: none">For children 6 months - 11 years of age0.25 mL single-dose vials*10-count cartonNDC: 80777-287-92 <p>*Volume beyond 0.25 mL is considered waste.</p>
		Carton weight: 0.21 lb Volume: 11.76 in ³ (3.68 in x 1.54 in x 2.20 in)

Storage Timeline		
 Frozen Storage	 Storage After Thawing	 Preparing to Use
Option to Store Frozen (until expiration date) -58°F to 5°F (-50°C to -15°C) Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.	Option to Store Refrigerated (up to 30 days or until expiration date, whichever comes first) 36°F to 46°F (2°C to 8°C) Thawed vials can be handled in room light conditions. DO NOT REFREEZE AFTER THAWING	Storage at Room Temperature (up to 24 hours) 46°F to 77°F (8°C to 25°C)

Thaw Instructions		
	Thaw in Refrigerator	Thaw at Room Temperature
0.25 mL Single-Dose Vial	Thaw between 36°F to 46°F (2°C to 8°C) for 45 minutes . Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 59°F to 77°F (15°C to 25°C) for 15 minutes .

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- Management of Acute Allergic Reactions:** Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine. Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

moderna[®]

Dosing Schedule¹

Dosing & Admin

For children 6 months through 11 years of age

Age Group	Number of Previous Doses of Moderna COVID-19 Vaccine*	Dosing Regimen, Dose, and Schedule [†]
6 months through 4 years	Unvaccinated [‡]	2 doses, [§] 0.25 mL each Dose 1: month 0 Dose 2: month 1
	1 previous dose	Single dose, 0.25 mL One month after receipt of previous Moderna COVID-19 Vaccine*
	≥2 previous doses	Single dose, 0.25 mL ≥2 months after receipt of last previous Moderna COVID-19 Vaccine*
5 years through 11 years	Irrespective of COVID-19 vaccination status	Single dose, 0.25 mL If previously vaccinated, ≥2 months after receipt of the last previous dose of COVID-19 vaccine

*Previous dose(s) of Moderna COVID-19 Vaccine(s) refers to Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.

[†]Individuals with certain kinds of immunocompromise 6 months through 11 years of age should complete at least a 3-dose series with a COVID-19 vaccine, each dose 1 month apart. At least 1 dose should be with a COVID-19 vaccine (2023-2024 Formula). "Certain kinds of immunocompromise" refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Please refer to the Fact Sheet for Healthcare Providers Administering Vaccine for additional dosing information in this patient population.

[‡]Not previously vaccinated with any COVID-19 vaccine.

[§]Individuals turning from 4 years to 5 years of age during the vaccination series should receive both doses with Moderna COVID-19 Vaccine (2023-2024 Formula).

^{||}COVID-19 vaccine refers to the monovalent COVID-19 vaccines (original) and the bivalent COVID-19 vaccines (original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.

Administration¹

Administer intramuscularly

Single-dose vial

Swirl vial gently after thawing. Each vial is **single use only**. **Administer** the entire dose intramuscularly.

Discard vial after single use.

For any questions, contact Moderna Medical Information at: **1-866-MODERNA (1-866-663-3762)**.

For more information on the Moderna COVID-19 Vaccine (2023-2024 Formula) under Emergency Use Authorization, visit <https://eua.modernatx.com/providers>.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **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. The observed risk is highest in males 18 years through 24 years of age. The 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>).

moderna[®]

Billing, Coding, and Ordering Information

Coding

For children 6 months through 11 years of age

Vaccine Type	Vaccine CPT Code*	Vaccine Administration CPT Code*	NDC 10/NDC 11 Labeler Product ID	CVX Code
Single-Dose Vial	91321 25 mcg/0.25 mL	90480 Admin SARSCOV2 Vacc 1 dose	80777-287-07; 80777-287-07; Carton 80777-287-92	311

CPT Copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
*The new COVID-19 CPT codes were posted August 14th, 2023. Check with your payer to determine coding and billing instructions. AMA CPT Assistant coding guidance can be found at <https://www.ama-assn.org/system/files/cpt-assistant-guide-coronavirus-august-2023.pdf>.



Order through modernadirect.com or an authorized wholesaler or distributor. Moderna COVID-19 Vaccines are also available to order through the Vaccines for Children (VFC) program.



Ready-to-use formulation, no need to reconstitute.¹

For questions related to billing, contact Moderna
Customer Care at: **1-866-MODERNA (1-866-663-3762)**
8:00AM - 8:00PM ET, Monday-Friday (excluding holidays)



IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to Moderna COVID-19 Vaccine.
- **Limitations of Vaccine Effectiveness:** The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

moderna[®]

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

Solicited adverse reactions included:

- **6 months through 36 months of age:** Injection site erythema, pain and swelling; axillary (or groin) swelling/tenderness, fever, irritability/crying, loss of appetite and sleepiness
- **37 months of age and older:** Injection site erythema, pain and swelling; arthralgia, axillary (or groin) swelling/tenderness, chills, fatigue, fever, headache, myalgia, nausea/vomiting, and rash

Reporting Adverse Events and Vaccine Administration Errors

Vaccination providers must report the listed events following administration of the Moderna COVID-19 Vaccine (2023-2024 Formula) to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events (irrespective of attribution to vaccination)
- cases of myocarditis
- cases of pericarditis
- cases of Multisystem Inflammatory Syndrome (MIS)
- cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967. Reports should include the words “Moderna COVID-19 Vaccine (2023-2024 Formula) EUA” in the description section of the report.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762) or by visiting <https://report.moderna.convergehealthsafety.com/>.

Please see the Moderna COVID-19 Vaccine (2023-2024 Formula) [Fact Sheet for Healthcare Providers Administering Vaccine](#) and [Letter of Authorization](#) for more information.

CO and CT prescribers and pharmacists may view the price disclosure at <https://modernadirect.com/wac-disclosure>.

References: **1.** Fact sheet for healthcare providers administering vaccine: Emergency Use Authorization of Moderna COVID-19 vaccine (2023-2024 formula), for individuals 6 months through 11 years of age. ModernaTX, Inc; 2023. **2.** Centers for Disease Control and Prevention. Interim clinical considerations for use of COVID-19 vaccines in the United States. Updated September 15, 2023. Accessed September 25, 2023. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html> **3.** American Academy of Pediatrics. Children and COVID-19 vaccination trends. Updated May 11, 2023. Accessed September 4, 2023. <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/> **4.** Centers for Disease Control and Prevention. ACIP vaccine recommendations and schedules. September 22, 2023. Accessed September 25, 2023. <https://www.cdc.gov/vaccines/acip/recommendations.html>