

Updated (2023-24 Formula) Moderna COVID-19 Vaccine





At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2023–24 Moderna COVID-19 Vaccine products.

Distributed in:



Ages: 6 months through 11 years

Single-dose vial:

Dark blue cap and green label



Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Spikevax | FDA

■ <u>Moderna COVID-19 Vaccines | Modernatx.com</u>

Ages	6 months through 11 years	12 years and older				
Supplied in:	Single-dose vial (SDV)	Single-dose vial (SDV)	Manufacturer-filled syringe (MFS)			
Cap and/or label color:	Dark blue cap and green label	Dark blue cap and blue label	N/A			
Storage temperature before puncture	 Between: -50°C and -15°C (-58°F and 5°F) until the expiration date 2°C and 8°C (36°F and 46°F) for up to 30 days 8°C and 25°C (46°F and 77°F) for a total of 24 hours. Discard vial or syringe and unused vaccine after 24 hours. NOTE: The beyond-use date (30 days) replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date. 					
Thawing frozen vaccine	 Between: 2°C and 8°C (36°F and 46°F) for 45 minutes. Let stand at room temperature (between 15°C and 25°C [59°F and 77°F]) for 15 minutes. OR 15°C and 25°C (59°F and 77°F) for 15 minutes 	 Between: 2°C and 8°C (36°F and 46°F) for 45 minutes. Let stand at room temperature (between 15°C and 25°C [59°F and 77°F]) for 15 minutes. OR 15°C and 25°C (59°F and 77°F) for 15 minutes 	Between: 15°C and 25°C (59°F and 77°F) for 45 minutes.			



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Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Considerations for Use of COVID-19
 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- Moderna COVID-19 Vaccines | FDA
- Moderna COVID-19 Vaccine | cvdvaccine.com

Preparation

If the vaccine is frozen, allow to thaw. Before preparing the vaccine, let vaccine stand at room temperature for 15 minutes. Do NOT refreeze thawed vaccine.

- Check the vial label to ensure the expiration date has not passed.
 - Use Moderna expiration date tool at https://modernacovid19global.com/vial-lookup
- Do not shake.
- If using a SDV, gently swirl prior to withdrawing vaccine.
- Refer to <u>package insert</u> or <u>EUA Fact Sheet</u> for detailed instructions.

Administration

 COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.

- If using a SDV, withdraw 1 dose. After withdrawing the dose, discard the vial and any residual vaccine. Do NOT save used SDVs.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
6 months through 11 years of age	0.25 mL/25 <i>ug</i>	IM injection	22–25 gauge, 1"*	6 months-2 years of age: Vastus lateralis muscle in the anterolateral thigh [†]
i i years of age				3–11 years of age: Deltoid muscle in the upper arm [‡]
12 years of age and older	0.5 mL/50 <i>ug</i>	IM injection	22–25 gauge, 1–1.5"*	Deltoid muscle in the upper arm [‡]

^{*} A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched for children and adolescents ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

[†]The deltoid muscle in the upper arm may be used if the muscle mass is adequate in children ages 1–2 years.

[‡]The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.



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Scheduling Doses

The number of recommended 2023–24 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- 30 minutes for persons with:
 - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
 - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- 15 minutes: All other persons

Documentation

Document each recipient's vaccine administration information:

- Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- Vaccination record for recipient: Date of vaccination, product name/manufacturer, lot number, and name/ location of the administering clinic or health care professional
- Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

Reporting of Vaccine Adverse Events

<u>For licensed Moderna COVID-19 vaccines</u> (for people ages 12 years and older), healthcare providers are **strongly encouraged** to report to <u>VAERS</u>:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors, whether or not associated with an adverse event

For Moderna COVID-19 vaccines given under an Emergency Use Authorization (for persons 11 years of age and younger) Vaccination providers are **required** to report to VAERS:

- Vaccine administration errors whether or not associated with an adverse event(AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
 - o Death
 - A life-threatening AE
 - Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above



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- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also **encouraged** for other clinically significant adverse events, even if it is uncertain whether the vaccine caused the event.

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, anyone can register in <u>V-safe</u> after their COVID-19 vaccination to receive health check-ins via text messages or email.