2024–25 Formula Moderna COVID-19 Vaccine At-A-Glance



Guidance below summarizes basic storage, preparation, scheduling, administration, and dosage for all 2024–25 Moderna COVID-19 vaccine products.

Distributed in:

Ages: 6 months through 11 years

Manufacturer-filled syringe

Storage and Handling

Find additional guidance on storing vaccine properly at:

- <u>CDC Vaccine Storage and Handling Toolkit</u>
- Spikevax | FDA

Ages: 12 years and older

- Manufacturer-filled syringe
- Moderna COVID-19 FACT SHEET
- Moderna COVID-19 Vaccines | Modernatx.com

Ages	6 months through 11 years	12 Years and Older			
Supplied in:	Manufacturer-filled syringe (MFS)	Manufacturer-filled syringe (MFS)*			
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 60 days. 8°C and 25°C (46°F and 77°F) for a total of 12 hours. During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed syringes can be handled in room light conditions. Do NOT refreeze once thawed. NOTE: The beyond-use date (60 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): One syringe: Thaw for 1 hour. Carton of 10 syringes: Thaw for 2 hours and 30 minutes. OR Between 15°C and 25°C (59°F and 77°F): One syringe: Thaw for 45 minutes. Carton of 10 syringes: Thaw for 2 hours and 15 minutes. Do NOT refreeze once thawed. 				

* Single-dose vials for people 12 years and older are not available in the U.S., but may be available in other countries

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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
- COVID-19 Vaccines | FDA

Preparation

- Check that vial or syringe states 2024-25 Formula.
- If the vaccine is frozen, thaw before use.
- Do not refreeze frozen vaccine.
- Check syringe label to ensure the expiration date or beyond-use date/time (if applicable) has not passed.
- Use Moderna expiration date tool at <u>https://</u> modernacovid19global.com/vial-lookup

- Package Insert SPIKEVAX (fda.gov)
- Spikevax[®] (COVID-19 Vaccine, MRNA) 2024-2025 Formula (modernatx.com)
- Do NOT shake.
- 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.
- 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 inch [*]	 6 months-2 years of age: Vastus lateralis muscle in the anterolateral thigh[†] 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 inch ^{*§}	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.

§ See <u>Vaccine Administration: Needle Gauge and Length</u> chart for more details

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Scheduling Doses

The number of recommended 2024–25 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review <u>CDC's Interim Clinical Considerations for Use of</u> <u>COVID-19 Vaccines in the United States</u> for detailed clinical guidance when scheduling doses, and the <u>Interim COVID-19</u> <u>Immunization Schedule</u> 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
- Current 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

Reporting of Vaccine Adverse Events

For licensed Moderna COVID-19 vaccines (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 <u>VAERS</u>:

- Vaccine administration errors whether or not associated with an adverse event(AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
 - 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
- 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 <u>https://vaers.hhs.gov</u> or by calling 1-800-822-7967.

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