

Spikevax (COVID-19 Vaccine, mRNA) by Moderna 2023-2024 Formula Product Information Quick Guide

Product Presentations¹



Pre-filled syringe

- The pre-filled syringe presentation contains a single 0.5 mL dose



Single-dose vial

- The single-dose vial presentation comes in a 0.5 mL vial
- Cap color is dark blue

Two available presentations, no reconstitution, no need to deep freeze

INDICATION

SPIKEVAX (COVID-19 Vaccine, mRNA) 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) in individuals 12 years of age and older.


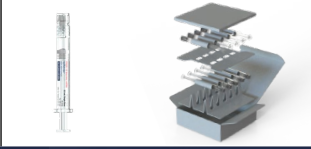

IMPORTANT SAFETY INFORMATION




Contraindications

Do not administer SPIKEVAX to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of SPIKEVAX.

Storage and Handling¹

Stability and storage of Spikevax remains consistent, whether administering by single-dose vial or pre-filled syringe.

Item and Packing Information			
Pre-filled Syringe Blister Pack		<ul style="list-style-type: none"> • 12+ years of age • 0.5 mL single-dose pre-filled syringes • 10-count carton (blister pack) • NDC: 80777-0102-93 	Carton Weight: 0.24 lbs Volume: 38.84 in ³ (2.25 in x 5.25 in x 3.43 in)
Pre-filled Syringe Paperboard Carton		<ul style="list-style-type: none"> • 12+ years of age • 0.5 mL single-dose pre-filled syringes • 10-count carton • NDC: 80777-0102-96 	Carton Weight: 0.20 lbs Volume: 24.10 in ³ (4.10 in x 4.14 in x 1.42 in)
Single-dose Vials Carton		<ul style="list-style-type: none"> • 12+ years of age • 0.5 mL single-dose vials • 10-count carton • NDC: 80777-0102-95 	Carton Weight: 0.21 lbs Volume: 11.76 in ³ (3.68 in x 1.54 in x 2.20 in)

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

Thaw Instructions		
	Thaw in Refrigerator	Thaw at Room Temperature
0.5 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 .
0.5 mL Pre-filled Syringe	Thaw between 36°F to 46°F (2°C to 8°C) for 1 hour . Let each syringe stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 59°F to 77°F (15°C to 25°C) for 45 minutes .

IMPORTANT SAFETY INFORMATION

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 SPIKEVAX.



Dosing Schedule¹

Age	Vaccination Status	Dose and Schedule
12 years of age and older	Unvaccinated	Single dose, 0.5 mL
	≥1 previous dose	Single dose, 0.5 mL ≥2 months after any COVID-19 vaccine

Administration¹

Administer Spikevax intramuscularly

Pre-filled syringe

Remove tip cap by twisting counterclockwise. See following page for additional instructions on pre-filled syringes.

Use a sterile needle of the appropriate size for intramuscular injection.

Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.

Administer the entire dose intramuscularly.

Discard syringe after use.

Single-dose vial

Swirl vial gently after thawing.

Each vial is **single use only**.

Administer the entire dose intramuscularly.

Discard vial after use.

Please see Prescribing Information for more information on Spikevax® (COVID-19 Vaccine, mRNA) available at [Spikevax.com/PI](https://www.spikevax.com/PI).

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

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

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. The observed risk is highest in males 18 through 24 years of age.



Guidance on Proper Preparation¹

Spikevax pre-filled syringes and single-dose vials must be thawed prior to administration



Pre-filled syringe

Thaw in refrigerator between 2°C to 8°C (36°F to 46°F) for 1 hour. Let each syringe stand at room temperature for 15 minutes before administering.

Alternatively, **thaw at room temperature** between 15°C to 25°C (59°F to 77°F) for 45 minutes.

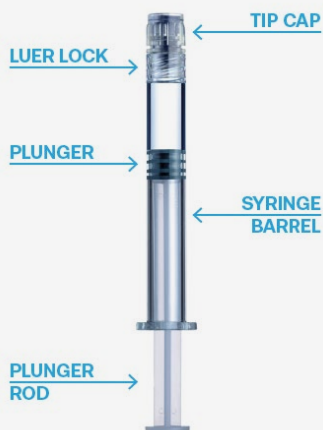
- After thawing, **do not refreeze. Do not shake. Do not dilute**
- Inspect each dose visually for particulate matter and discoloration prior to administration. Spikevax is a white to off-white suspension. It may contain white or translucent product-related particulates
- **Do not administer** if vaccine is discolored or contains other particulate matter



Single-dose vial

Thaw in refrigerator between 2°C to 8°C (36°F to 46°F) for 45 minutes. Let each vial stand at room temperature for 15 minutes before administering.

Alternatively, **thaw at room temperature** between 15°C to 25°C (59°F to 77°F) for 15 minutes.



Luer Lock Syringe Design: This pre-filled syringe (PFS) is suitable for frozen storage and may look and feel slightly different than a standard PFS. Please follow the preparation instructions outlined here when preparing this PFS for use.

EXPECT TO FEEL RESISTANCE WHILE TWISTING THE TIP CAP

Follow the steps below to properly remove the tip cap.

- 1 Grab the syringe with one hand and grip the tip cap with the other hand.
- 2 Hold the syringe vertically, with the tip cap facing upright.
- 3 Remove the tip cap by twisting counterclockwise until the tip cap releases. You may feel resistance.
- 4 Avoid pulling the tip cap while twisting. The tip cap can be removed in a slow, steady motion once it is released from the Luer Lock threads.
- 5 Do not apply pulling force while twisting.

- **Syringe may contain an air bubble²; however, priming is not required. Entire volume should be injected.**
- **Immunizer should select a sterile Luer lock needle of appropriate size and gauge for intramuscular injection.**

This resource is not intended to be a substitute for clinical judgment. Please refer to Spikevax Full Prescribing Information for additional guidance.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

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

Reimbursement, Ordering, and Reporting Codes

Vaccine Type	Vaccine CPT Code*	Vaccine Administration CPT Code*	NDC 10/NDC 11 Labeler Product ID	CVX Code
Pre-filled Syringe Blister Pack	91322 50 mcg/0.5 mL	90480 Admin SARSCOV2 Vacc 1 dose	80777-102-01 80777-0102-01 Carton 80777-102-93	312
Pre-filled Syringe	91322 50 mcg/0.5 mL	90480 Admin SARSCOV2 Vacc 1 dose	80777-102-01 80777-0102-01 Carton 80777-102-96	312
Single-dose Vial	91322 50 mcg/0.5 mL	90480 Admin SARSCOV2 Vacc 1 dose	80777-102-04 80777-0102-04 Carton 80777-102-95	312

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*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>.

To order Spikevax, go to modernadirect.com.
For simple, easy-to-follow directions on ordering,
please see the Moderna Direct Ordering Guide.



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

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most commonly reported ($\geq 10\%$) adverse reactions following any dose in any indicated patient population were pain at the injection site, headache, fatigue, myalgia, chills, arthralgia, axillary swelling/tenderness, nausea/vomiting, swelling at the injection site, erythema at the injection site, and fever.



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Important Safety Information

Contraindications

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Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event

The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at <https://vaers.hhs.gov> or by calling 1-800-822-7967.

Please click for [SPIKEVAX Full Prescribing Information](#).

References: 1. Spikevax Prescribing Information. Moderna; 2023.
2. Data on file, Moderna TX.