



COVID-19 mRNA vaccine
2024-2025, Omicron KP.2 variant

Dosing & Administration

SPIKEVAX (COVID-19 mRNA vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 months of age and older.

SPIKEVAX is available in one presentation:







Royal blue cap vial with coral blue label

0.1 mg/mL | multidose vial (2.5 mL)

Drug Identification Number (DIN): **02541270**

Dosing Schedule

Age Range	COVID-19 Vaccination History	Dose Timing	Dose	Vial Presentation	Dose Volume
 12 years of age and older	Not previously vaccinated OR previously vaccinated	At least 6 months after previous COVID-19 vaccine dose	50 mcg		0.5 mL
 5 to 11 years		At least 6 months after previous COVID-19 vaccine dose	25 mcg		0.25 mL
 6 months to 4 years of age	Not previously vaccinated	A two-dose series may be given at least 4 weeks apart	Dose 1: 25 mcg Dose 2: 25 mcg		0.25 mL
	Previously vaccinated (1 or more previous doses)	At least 6 months after previous COVID-19 vaccine dose	25 mcg		0.25 mL

Administration

Swirl vial gently after thawing and between each withdrawal. The vaccine comes ready to use once thawed.

Do not shake or dilute. The vaccine does not contain a preservative.

Prior to injection, inspect each dose to:

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Confirm liquid is white to off-white

- Confirm liquid is white to off-white in colour in both vial and syringe
 - SPIKEVAX may contain white or translucent product-related particulates
 - Do **not** administer the vaccine if it is discoloured or contains other particulate matter
 - For detailed information regarding storage and handling, see the Product Monograph

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Verify syringe volume

- Verify syringe volume based on recommended dose and dose volume (refer to the dosing information above)
 - If the amount of SPIKEVAX remaining in the vial cannot provide a full dose, discard the vial and contents. Do **not** pool excess SPIKEVAX from multiple vials
 - Pierce the stopper preferably at a different site each time
 - Discard vial 24 hours (if refrigerated) or 12 hours (if stored at room temperature) after first puncture, even if vaccine remains in the vial

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Administer SPIKEVAX

- Administer SPIKEVAX by intramuscular (IM) injection only
 - The preferred site is the deltoid muscle of the upper arm or, in infants and young children, the anterolateral aspect of the thigh



Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw each dose of vaccine from the vial using a new sterile needle and syringe (preferentially a low dead-volume syringe and/or needle) for each injection.



Provide a vaccination card to the recipient or their caregiver with the date the recipient received their dose.

For any questions, contact Moderna Medical Information at:

1-866-MODERNA (1-866-663-3762)



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Storage & Handling

Frozen Storage

- Can be stored frozen until expiration date
- Store in the original carton to protect from light



-50° to -15°C

Thaw Each Vial Before Use

Vial image for illustrative purposes only

In the refrigerator: 2° to 8°C



2 hours

OR



45 minutes

Let vial sit at room temperature for 15 minutes before administering.

Thawed Shelf Life

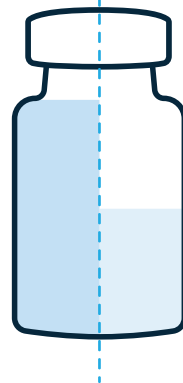
Unpunctured vial
(Prior to first use)

50
days

Refrigerator
2° to 8°C

12
hours

Cool storage up to
room temperature
8° to 25°C



Punctured vial
(After first dose has been withdrawn)

24
hours

Refrigerator
2° to 8°C

12
hours

Cool storage up to
room temperature
8° to 25°C

Record the date and time of discard on the vial label.

Thawed vials and filled syringes can be handled in room light conditions.

NEVER refreeze thawed vaccine.



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Indication and clinical use

SPIKEVAX (COVID-19 mRNA vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 months of age and older.

SPIKEVAX has been issued marketing authorization with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety, and effectiveness of the vaccine.

Patients should be advised of the nature of the authorization.

Pediatrics: Safety and efficacy in individuals <6 months of age not yet established.

Geriatrics: Clinical studies of SPIKEVAX Bivalent (Original/Omicron BA.1) that included participants ≥65 years of age and their data contribute to the overall assessment of safety and effectiveness of SPIKEVAX (COVID-19 mRNA vaccine).

Contraindications

Hypersensitivity to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.

Relevant warnings and precautions

- Hypersensitivity and anaphylaxis
- Myocarditis and pericarditis
- Patients with acute infection
- Patients with hematologic disorders or on anticoagulant therapy
- Patients who are immunocompromised
- Syncope
- Vaccination may not protect all recipients

For more information

Please consult the Product Monograph at <https://www.modernacovid19global.com/ca/> for important information relating to adverse reactions, drug interactions, and dosing information which has not been discussed in this piece. The Product Monograph is also available by calling us at **1-866-MODERNA (1-866-663-3762)**.



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