

Dosing & Administration

SPIKEVAX™ (elasomeran 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 two presentations. Dose volume will be different based on which presentation is being administered. Pay careful attention to the vial cap colour and the corresponding dose volume:



Red cap vial
SPIKEVAX
0.20 mg/mL
Multidose vial 5 mL










Royal blue cap vial
SPIKEVAX
0.10 mg/mL
Multidose vial 2.5 mL

Dosing Schedule




1 Primary Series

SPIKEVAX is administered as a series of **2 doses*** each **4 weeks apart** in eligible individuals ≥ 6 months of age.

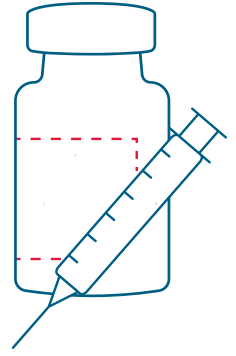
Age Range	Dose	Vial Presentation	Dose Volume
 ≥ 12 years	100 mcg		0.50 mL
 6 to 11 years	50 mcg	 OR 	0.25 mL OR 0.50 mL
 ≥ 6 months to 5 years	25 mcg		0.25 mL

2 Booster Dose

A booster dose may be administered as **1 dose** at least **4 months after** completion of the primary series in eligible individuals ≥ 12 years of age.

 ≥ 12 years	50 mcg	 OR 	0.25 mL OR 0.50 mL
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* Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. In these individuals, a third dose may be considered as part of the primary series.



Administration

Swirl vial gently after thawing and between each withdrawal.

The vaccine comes ready to use once thawed. **Do not shake or dilute.**



Drug Identification Number (DIN): **02510014**
0.20 mg/mL | multidose vial (5 mL)



Drug Identification Number (DIN): **02527685**
0.10 mg/mL | multidose vial (2.5 mL)

Prior to injection, inspect each dose to:

1

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
 - The vaccine does not contain a preservative
 - For detailed information regarding storage and handling, see the Product Monograph

2

Verify syringe volume

- Verify syringe volume based on recommended dose and dose volume (refer to the dosing information on the previous page)
 - 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 after first puncture, even if vaccine remains in the vial

3

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. Pierce the stopper preferably at a different site each time.

- **Do not puncture the red cap vial (SPIKEVAX 0.20 mg/mL) more than 20 times.**
- **Do not puncture the royal blue cap vial (SPIKEVAX 0.10 mg/mL) more than 10 times.**



Provide a vaccination card to the recipient or their caregiver with the date the recipient needs to return for any **ADDITIONAL DOSES** or for a **BOOSTER DOSE of SPIKEVAX**.

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

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 images for illustrative purposes only

In the refrigerator: 2° to 8°C

At room temperature: 15° to 25°C



2 hours and
30 minutes



2 hours

OR



1 hour



45 minutes

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

Thawed Shelf Life

Maximum times are the same for both presentations of SPIKEVAX

Unpunctured vial

30
days

Refrigerator
2° to 8°C

24
hours

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



After first dose has been withdrawn

24
hours

Refrigerator or room
temperature

Vial should be stored
between 2° and 25°C.
Record the date and time
of first use on the vial label.

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

NEVER refreeze thawed vaccine.



Indication and clinical use

SPIKEVAX™ (elasomeran mRNA vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals 6 months of age and older. The safety and efficacy in individuals under 6 months of age has not been established.

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 with SPIKEVAX may not protect all recipients

For more information

Please consult the Product Monograph at <http://spikevax.com/en-ca/pm.pdf> 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)**.