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 12 years of age and older.

**Dosing & Administration**

**Dosing Schedule**

<table>
<thead>
<tr>
<th>Primary Series</th>
<th>Booster Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible individuals ≥12 years of age</td>
<td>Eligible individuals ≥18 years of age*</td>
</tr>
<tr>
<td>Number of doses in primary series</td>
<td>Number of booster doses</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Interval between doses</td>
<td>Interval between primary series &amp; booster dose</td>
</tr>
<tr>
<td>4 weeks between dose 1 &amp; 2</td>
<td>≥6 months</td>
</tr>
<tr>
<td>Volume administered per dose</td>
<td>Volume administered per dose</td>
</tr>
<tr>
<td>0.5 mL (100 mcg)</td>
<td>0.25 mL (50 mcg)</td>
</tr>
</tbody>
</table>

SPIKEVAX is administered intramuscularly as a primary series of two doses of 0.5 mL each (100 mcg) 4 weeks apart in individuals 12 years of age and older.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. In these individuals, a third dose (0.5 mL, 100 mcg) may be considered as part of the primary series.

*A booster dose of 0.25 mL (50 mcg) may be administered intramuscularly at least 6 months after completion of the primary series in individuals 18 years of age or older.

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 vial more than 20 times.

Dosing & Administration

Administration

Swirl vial gently after thawing and between each withdrawal. The vaccine comes ready to use once thawed. Do not shake or dilute.

Prior to injection, inspect each dose to:

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

- Verify syringe volume of 0.5 mL (100 mcg) for primary series dose or 0.25 mL (50 mcg) for booster dose.
  - If the amount of SPIKEVAX remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, 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.

- Administer SPIKEVAX by intramuscular (IM) injection only.
  - The preferred site is the deltoid muscle of the upper arm.

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)

Drug Identification Number (DIN):
02510014

Please see the Product Monograph at
**Frozen Storage**

Can be stored frozen until expiration date

-25° to -15°C (-13° to 5°F)

Do not store on dry ice or below -40ºC (-40°F)

Store in the original carton to protect from light.

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**Thaw Each Vial Before Use**

Vial images for illustrative purposes only

- **2 hours and 30 minutes in refrigerator**
  - 2° to 8°C (36° to 46°F)
  - Let vial sit at room temperature for 15 minutes before administering

- **1 hour at room temperature**
  - 15° to 25°C (59° to 77°F)

**Thawed Shelf Life**

- **Unpunctured Vial**
  - Maximum times
    - 30 days
      - Refrigerator: 2° to 8°C (36° to 46°F)
    - 24 hours
      - Cool storage up to room temperature: 8° to 25°C (46° to 77°F)

- **After first dose has been withdrawn**
  - Maximum time
    - 24 hours
      - Refrigerator or room temperature

Vial should be held between 2° to 25°C (36° to 77°F). 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

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**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 12 years of age and older. The safety and efficacy in individuals under 12 years 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 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).