Frozen Storage

Can be stored frozen until expiration date

–25°C to –15°C (–13°F to 5°F)
Do not store on dry ice or below -40°C (-40°F)
Store in the original carton to protect from light.

Thaw Each Vial Before Use

Vial images for illustrative purposes only

2 hours and 30 minutes in refrigerator

2°C to 8°C (36°F to 46°F)

Let vial sit at room temperature for 15 minutes before administering

OR

1 hour at room temperature

15°C to 25°C (59°F to 77°F)

Thawed Shelf Life

Unpunctured Vial

Maximum times

30 days Refrigerator
2°C to 8°C (36°F to 46°F)

24 hours Cool storage up to room temperature
8°C to 25°C (46°F to 77°F)

After first dose has been withdrawn

Maximum time

24 hours Refrigerator or room temperature
Vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the vial label. Discard punctured vial after 6 hours.

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

NEVER refreeze thawed vaccine

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.

SPIKEVAX™ (elasomeran mRNA vaccine)

Dosing & Administration

Dosing and Schedule

SPIKEVAX is administered intramuscularly as a series of two doses (0.5 mL each) 28 days apart.

There are no data available on the interchangeability of the SPIKEVAX with other COVID-19 vaccines to complete the vaccination series. Patients who have received one dose of SPIKEVAX should receive a second dose of SPIKEVAX to complete the vaccination series.

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 colour in both vial and syringe
- Verify syringe volume of 0.5 mL
- Administer SPIKEVAX intramuscularly (IM) only. The deltoid muscle of the upper arm is the preferred site.

SPIKEVAX may contain white or translucent product-related particulates.

If dosage is incorrect, or discolouration and other particulate matter is present, do not administer the vaccine.

Provide a vaccination card to the patient or their caregiver with the date the patient needs to return for the SECOND DOSE of SPIKEVAX.

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

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
• Patients may not be optimally protected until after receiving the second dose

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).