

Dosing & Administration



SPIKEVAX™ Bivalent (elasomeran / imelasomeran mRNA vaccine) is indicated as a booster dose for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 18 years of age or older.

SPIKEVAX Bivalent is available in one presentation:



Royal blue cap vial with green label
SPIKEVAX Bivalent Original / Omicron BA.1
0.10 mg/mL | multidose vial (2.5 mL)
Drug Identification Number (DIN): **02530252**

Dosing Schedule

Booster Dose	Age Range	Dose	Vial Presentation	Dose Volume
<p>A booster dose of 50 mcg may be administered intramuscularly at least 4 months after completion of a primary series and/or a previous booster dose in individuals 18 years of age or older.</p>	 ≥ 18 years	50 mcg		0.50 mL

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

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:

1

Confirm liquid is white to off-white

- Confirm liquid is white to off-white in color in both vial and syringe
 - SPIKEVAX Bivalent may contain white or translucent product-related particulates
 - Do not administer the vaccine if it is discolored or contains other particulate matter
 - 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 above)
 - If the amount of SPIKEVAX Bivalent remaining in the vial cannot provide a full dose, discard the vial and contents. Do not pool excess SPIKEVAX Bivalent 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 Bivalent

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



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)**

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

Royal blue cap vial with green label



In the refrigerator: 2° to 8°C
 2 hours

Let vial sit at room temperature for 15 minutes before administering

OR

At room temperature: 15° to 25°C
 45 minutes

Vial image for illustrative purposes only

Thawed Shelf Life

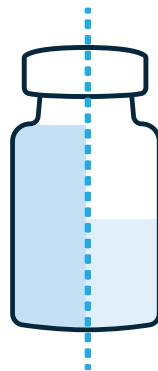
Unpunctured vial

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 discard time
 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™ Bivalent is indicated as a booster dose for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 18 years of age or older.

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://modernacovid19global.com/ca/spikevax-bivalent-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 (1-866-633-3762)**.