

## Dosing & Administration

SPIKEVAX™ Bivalent Original / Omicron BA.4/5 (elasomeran/davesomeran 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 6 years of age or older.

SPIKEVAX Bivalent Original / Omicron BA.4/5 is available in one presentation:







**Royal blue cap vial with grey label**

SPIKEVAX Bivalent Original / Omicron BA.4/5  
0.10 mg/mL | multidose vial (2.5 mL)

Drug Identification Number (DIN): **02532352**

## Dosing Schedule

	Age Range	Dose	Vial Presentation	Dose Volume
<b>Booster Dose</b> A booster dose may be administered intramuscularly at least <b>4 months after</b> completion of a primary series for individuals ≥12 years of age and at least <b>6 months after</b> completion of a primary series for individuals 6 to 11 years of age.	 <b>12 years of age and older</b>	50 mcg		<b>0.50 mL</b>
	 <b>6 to 11 years</b>	25 mcg		<b>0.25 mL</b>

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 colour in both vial and syringe
    - SPIKEVAX Bivalent Original / Omicron BA.4/5 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
- 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 Original / Omicron BA.4/5 remaining in the vial cannot provide a full dose, discard the vial and contents. Do not pool excess SPIKEVAX Bivalent Original / Omicron BA.4/5 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 Original / Omicron BA.4/5**
  - Administer SPIKEVAX Bivalent Original / Omicron BA.4/5 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 grey 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

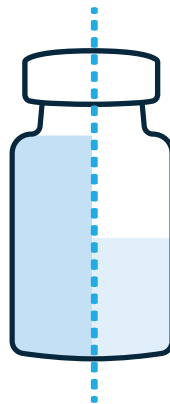
### Unpunctured vial

**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 Original / Omicron BA.4/5 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 6 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://spikevax.com/en-ca/bivalent45-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)**.