

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

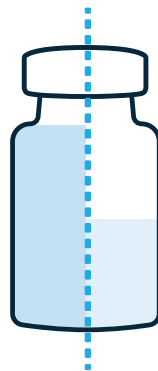
Unpunctured vial

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)**.