spikevax™ XBB.1.5
andusomeran
mRNA Vaccine

Dosing & Administration

SPIKEVAX XBB.1.5 (andusomeran 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 6 months of age and older.

SPIKEVAX XBB.1.5 is available in one presentation:

Royal blue cap vial with coral blue label
SPIKEVAX XBB.1.5
0.10 mg/mL | multidose vial (2.5 mL)
Drug Identification Number (DIN): **XXXXXXXX**

Dosing Schedule

Age Range	COVID-19 Vaccination History	Dose Timing	Dose	Vial Presentation	Dose Volume
 **12 years of age and older**	Not previously vaccinated **OR** previously vaccinated	At least **6 months after** previous COVID-19 vaccine dose	50 mcg		**0.5 mL**
 **5 to 11 years**		At least **6 months after** previous COVID-19 vaccine dose	25 mcg		**0.25 mL**
 **6 months to 4 years of age**	Not previously vaccinated	A **two-dose series** may be given at least **4 weeks apart**	2 x 25 mcg		**0.25 mL**
	Previously vaccinated (1 or more previous doses)	At least **6 months after** previous COVID-19 vaccine dose	25 mcg		**0.25 mL**

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 XBB.1.5 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 XBB.1.5 remaining in the vial cannot provide a full dose, discard the vial and contents. Do not pool excess SPIKEVAX XBB.1.5 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 XBB.1.5

- Administer SPIKEVAX XBB.1.5 by intramuscular (IM) injection only
  - The preferred site is the deltoid muscle of the upper arm or, in infants and young children, the anterolateral aspect of the thigh

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)

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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

Vial image for illustrative purposes only

In the refrigerator: 2° to 8°C	**At room temperature:** 15° to 25°C
2 hours	45 minutes

OR

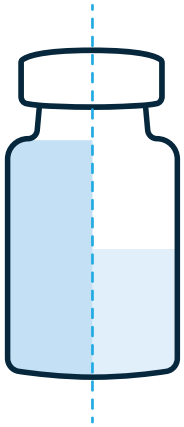
Let vial sit at room temperature for 15 minutes before administering.

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 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 XBB.1.5 (andusomeran 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 6 months of age and older.

SPIKEVAX XBB.1.5 has been issued marketing authorization with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety, and effectiveness of the vaccine.

Patients should be advised of the nature of the authorization.

Pediatrics: Safety and efficacy in individuals <6 months of age not yet established.

Geriatrics: Clinical studies of SPIKEVAX Bivalent (Original/Omicron BA.1) that included participants ≥65 years of age and their data contribute to the overall assessment of safety and effectiveness of SPIKEVAX XBB.1.5 (andusomeran) mRNA COVID-19 vaccine.

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 spikevax.com 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)**.

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