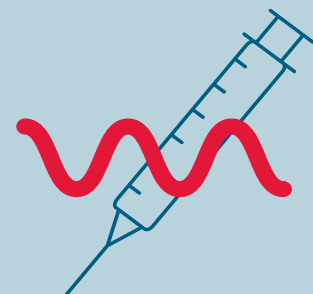


# Dosing, Administration & Storage



For healthcare professionals in Northern Ireland only.

Links to prescribing information can be found on the last page

spikevax bivalent Original/Omicron BA.1 and spikevax bivalent Original/Omicron BA.4-5 have a similar presentation. Pay careful attention to the vial label during administration:



**Green stripe on vial with blue cap**  
 spikevax bivalent Original/Omicron BA.1  
 elasomeran/imelasomeran  
 (50 mcg/50 mcg)/mL  
 Multidose vial 2.5 mL









**Grey stripe on vial with blue cap**  
 spikevax bivalent Original/Omicron BA.4-5  
 elasomeran/davesomeran  
 (50 mcg/50 mcg)/mL  
 Multidose vial 2.5 mL

## Dosing schedule

### Booster dose<sup>1-4</sup>

spikevax bivalent BA.1 and spikevax bivalent BA.4-5 (individuals aged  $\geq 6$  years) are indicated as booster doses. They may be administered as **1 dose** at least **3 months after** completion of the primary series or last booster dose. Use in accordance with official recommendations.

Age range	Dose	Vial presentation	Dose volume
 $\geq 12$ years	50 mcg		<b>0.50 mL</b>
			<b>0.50 mL</b>
 6–11 years	25 mcg		<b>0.25 mL</b>
			<b>0.25 mL</b>

## Administration<sup>2,3,5,6</sup>

Swirl vial gently after thawing and before each withdrawal.

The vaccine comes ready to use once thawed. **Do not shake or dilute.**

Administration method is the same for both spikevax bivalent vaccines.



spikevax bivalent Original/Omicron BA.1  
elasomeran/imelasomeran  
(50 mcg/50 mcg)/mL  
Multidose vial (2.5 mL)



spikevax bivalent Original/Omicron BA.4-5  
elasomeran/davesomeran  
(50 mcg/50 mcg)/mL  
Multidose vial (2.5 mL)

### Follow these steps:

1

#### Confirm liquid is white to off-white once thawed

- Confirm liquid is white to off-white in colour in both vial and syringe
  - The vaccine 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 Summary of Product Characteristics

2

#### Verify syringe volume

- Verify syringe volume based on recommended dose and dose volume (refer to the dosing information on the previous page)
  - If the amount of product remaining in the vial cannot provide a full dose, discard the vial and contents. Do not pool excess product from multiple vials
  - Pierce the stopper preferably at a different site each time

3

#### Administer the vaccine

- Administer the vaccine by intramuscular (IM) injection only
  - The preferred site is the deltoid muscle of the upper arm
- The dose in the syringe should be used immediately



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 for each injection. Pierce the stopper preferably at a different site each time.



Provide a vaccination card to the recipient or their caregiver with the date the recipient needs to return for any **ADDITIONAL DOSES** or for a **BOOSTER DOSE**.

For any questions, contact Moderna Medical Information at:

**0800 085 7562 or [EMEAMedinfo@modernatx.com](mailto:EMEAMedinfo@modernatx.com)**

## Storage & handling<sup>2,3,5,6</sup>

For spikevax bivalent Original/Omicron BA.1 and spikevax bivalent Original/Omicron BA.4-5



### Frozen storage

Can be stored frozen until expiration date  
• Store in the original carton to protect from light

### Thaw each vial before use

Images for illustrative purposes only

**In the refrigerator: 2° to 8°C**



**2 hours and 30 minutes**

OR

**At room temperature: 15° to 25°C**



**1 hour**

Once removed from the refrigerator and thawed, let vial sit at room temperature for 15 minutes before administering

### Thawed shelf life

Within the 9 or 12 month frozen period

#### Unpunctured vial

BA.1 & BA.4-5 (9 months)

**30 days**

Refrigerator  
2° to 8°C

**14 days**

Refrigerator  
2°C to 8°C

**24 hours**

Cool storage up to  
room temperature  
8° to 25°C

**24 hours**

Cool storage up to  
room temperature  
8°C to 25°C



#### After first dose has been withdrawn

**BA.1 & BA.4-5**

**Refrigerator or room temperature**

Vial should be stored between **2° and 25°C**. Record the date and time of discard on the vial label.


Use the vial as soon as practically possible, in accordance with the official recommendations.


Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately. The punctured vial should be discarded after it has exceeded the maximum time. Any unused vaccine or waste material should be disposed of in accordance with local requirements.

If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user.

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

**NEVER refreeze thawed vaccine.**

 **spikevax™ bivalent**  
original / omicron BA.1  
(50 micrograms/50 micrograms)/mL  
dispersion for injection  
elasomeran/imelasomeran  
Intramuscular use.

 **spikevax™ bivalent**  
original / omicron BA.4-5  
(50 micrograms/50 micrograms)/mL  
dispersion for injection  
elasomeran/davesomeran  
Intramuscular use.

Scan here for **NI** prescribing information and adverse event reporting



**spikevax bivalent Original/Omicron BA.1**  
(elasomeran/imelasomeran)  
(50 mcg/50 mcg)/mL dispersion  
for injection

**NI SmPC**  
<https://www.emcpi.com/pi/ni/921>



**spikevax bivalent Original/Omicron BA.4-5**  
(elasomeran/davesomeran)  
(50 mcg/50 mcg)/mL dispersion  
for injection

**NI SmPC**  
<https://www.emcpi.com/pi/ni/1048>

**Other presentations of spikevax bivalent are licensed but not currently supplied to the UK market.**

spikevax bivalent Original/Omicron BA.1 is indicated as a booster dose for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 years of age and older, who have previously received at least a primary vaccination course against COVID-19. The use of this vaccine should be in accordance with official recommendations.<sup>2</sup>

spikevax bivalent Original/Omicron BA.4-5 is indicated as a booster dose for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 years of age and older, who have previously received at least a primary vaccination course against COVID-19. The use of this vaccine should be in accordance with official recommendations.<sup>3</sup>

▼ This medicinal product is subject to additional monitoring

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and include the vaccine brand and batch/Lot number if available. They can also be reported to Moderna using the Adverse Event Intake Portal or by calling 0800 085 7562. To report a product quality complaint or for general medical information inquiries, please contact Moderna on 0800 085 7562 or at [EMEAMedinfo@modernatx.com](mailto:EMEAMedinfo@modernatx.com)

#### References:

**1.** Product Specifications Summary. Moderna; 2023. **2.** spikevax bivalent Original/Omicron BA.1 Summary of Product Characteristics. Northern Ireland. Moderna; 2023. Available at: <https://www.emcpi.com/pi/ni/921> Accessed June 2023. **3.** spikevax bivalent Original/Omicron BA.4-5 Summary of Product Characteristics. Northern Ireland. Moderna; 2023. Available at: <https://www.emcpi.com/pi/ni/1048> Accessed June 2023. **4.** UK Health Security Agency. COVID-19 Chapter 14a. In: The Green Book – Immunisation against infectious disease; 2023. p.32–35. **5.** Preparation of Spikevax Bivalent 0.5 mL (Booster Dose) Syringes for Administration. Specialist Pharmacy Services. Available at: <https://www.sps.nhs.uk/wp-content/uploads/2022/08/SOP-PCV-5-Preparation-of-Spikevax-Bivalent-COVID-19-Vaccine-0.5mL-V1.1-27.09.2022-.docx> Accessed June 2023. **6.** Preparation of Spikevax Original/Omicron BA.4-5 0.1mg/mL Syringes for Administration. Specialist Pharmacy Services. Available at: <https://www.sps.nhs.uk/articles/preparing-spikevax-original-omicron-ba-4-5/> Accessed June 2023.