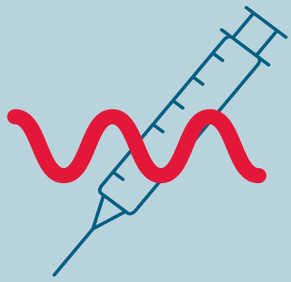
spikevax™ bivalent ▼
original / omicron BA.1
(50 micrograms/50 micrograms)/mL
dispersion for injection
elasomeran/imelasomeran
Intramuscular use.

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

Dosing, Administration & Storage



For healthcare professionals in Great Britain 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[1–4]

spikevax bivalent BA.1 (individuals aged ≥6 years) and spikevax bivalent BA.4-5 (individuals aged ≥12 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
 ≥12 years	50 mcg		**0.50 mL**
			**0.50 mL**
 6–11 years	25 mcg		**0.25 mL**

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moderna

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

Administration[2,3,5]

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

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(50 micrograms/50 micrograms)/mL
dispersion for injection
elasomeran/davesomeran
Intramuscular use.

Storage & handling[2,3,5]

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		**At room temperature:** 15˚ to 25˚C
 2 hours and 30 minutes	OR	 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)

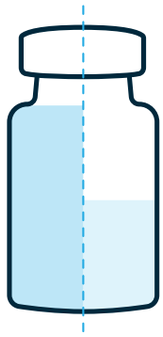
30 days Refrigerator 2˚ to 8˚C

24 hours Cool storage up to room temperature 8˚ to 25˚C

BA.1 (12 months)

14 days Refrigerator 2°C to 8 °C

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



After first dose has been withdrawn

6 hours
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.

Discard punctured vial after 6 hours.

Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately. The vial should be discarded after 6 hours for spikevax bivalent BA.1 and spikevax bivalent BA.4-5. 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.

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(50 micrograms/50 micrograms)/mL
dispersion for injection
elasomeran/davesomeran
Intramuscular use.

Scan here for GB prescribing information and adverse event reporting

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

GB PI
https://www.emcpi.com/pi/42055

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

GB PI
https://www.emcpi.com/pi/43037

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.[2]

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 12 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.[3]

▼ 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

References:
1. Product Specifications Summary. Moderna; 2022. **2.** spikevax bivalent Original/Omicron BA.1 Summary of Product Characteristics. Great Britain. Moderna; 2023. Available at: https://www.emcpi.com/pi/42055 Accessed April 2023. **3.** spikevax bivalent Original/Omicron BA.4-5 Summary of Product Characteristics. Great Britain. Moderna; 2023. Available at: https://www.emcpi.com/pi/43037 Accessed April 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 April 2023.

