

## **Package leaflet: Information for the user**

### **Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) elasomeran/davesomeran**

**Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Spikevax bivalent Original/Omicron BA.4-5 is and what it is used for
2. What you need to know before you are given Spikevax bivalent Original/Omicron BA.4-5
3. How Spikevax bivalent Original/Omicron BA.4-5 is given
4. Possible side effects
5. How to store Spikevax bivalent Original/Omicron BA.4-5
6. Contents of the pack and other information

#### **1. What Spikevax bivalent Original/Omicron BA.4-5 is and what it is used for**

Spikevax bivalent Original/Omicron BA.4-5 is a vaccine used to prevent COVID-19 caused by SARS-CoV-2. It is given to individuals aged 12 years and older. The active substance in Spikevax bivalent Original/Omicron BA.4-5 is mRNA encoding the SARS-CoV-2 Spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

Spikevax bivalent Original/Omicron BA.4-5 is only for individuals who have previously received at least a primary vaccination course against COVID-19.

As Spikevax bivalent Original/Omicron BA.4-5 does not contain the virus, it cannot give you COVID-19.

#### **How the vaccine works**

Spikevax bivalent Original/Omicron BA.4-5 stimulates the body's natural defences (immune system). The vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19. Spikevax bivalent Original/Omicron BA.4-5 uses a substance called messenger ribonucleic acid (mRNA) to carry instructions that cells in the body can use to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus. This will help to protect you against COVID-19.

#### **2. What you need to know before you are given Spikevax bivalent Original/Omicron BA.4-5**

**The vaccine must not be given if you are allergic** to the active substance or any of the other ingredients of this vaccine (listed in section 6).

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before you are given Spikevax bivalent Original/Omicron BA.4-5 if:

- you have previously had a severe, life-threatening **allergic** reaction after any other vaccine

- injection or after you were given Spikevax (original) in the past.
- you have a very weak or compromised immune system
- you have ever fainted following any needle injection.
- you have a bleeding disorder
- you have a high fever or severe infection; however, you can have your vaccination if you have a mild fever or upper airway infection like a cold
- you have any serious illness
- if you have anxiety related to injections

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Spikevax (original) (see section 4).

These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second dose compared to the first dose, and more often in younger males.

You should avoid strenuous activity for two weeks after vaccination.

Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Spikevax bivalent Original/Omicron BA.4-5.

### **Capillary leak syndrome (CLS) flare-ups**

A few cases of capillary leak syndrome flare-ups (causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint, low blood pressure) have been reported following vaccination with Spikevax (original). If you have previously had episodes of CLS, talk to a doctor before you are given Spikevax bivalent Original/Omicron BA.4-5.

### **Duration of protection**

As with any vaccine, the third dose of Spikevax bivalent Original/Omicron BA.4-5 may not fully protect all those who receive it and it is not known how long you will be protected.

### **Children**

Spikevax bivalent Original/Omicron BA.4-5 is not recommended for children aged under 12 years.

### **Other medicines and Spikevax bivalent Original/Omicron BA.4-5**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Spikevax bivalent Original/Omicron BA.4-5 may affect the way other medicines work, and other medicines may affect how Spikevax bivalent Original/Omicron BA.4-5 works.

### **Immunocompromised individuals**

The efficacy of Spikevax bivalent Original/Omicron BA.4-5 may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

### **Pregnancy and breast-feeding**

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine. No data are available yet regarding the use of Spikevax bivalent Original/Omicron BA.4-5 during pregnancy. However, a large amount of information from pregnant women vaccinated with Spikevax (original) during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or

the newborn baby after vaccination during the first trimester is limited, no increased risk for miscarriage has been seen.

No data are available yet regarding the use of Spikevax bivalent Original/Omicron BA.4-5 during breast feeding.

However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breastfeeding after vaccination with Spikevax (original) have not shown a risk for adverse effects in breastfed newborns/infants.

### **Driving and using machines**

Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

### **Spikevax bivalent Original/Omicron BA.4-5 contains sodium**

This medicine contains less than 1 mmol (23 mg) sodium per dose and, that is to say, essentially 'sodium-free'.

## **3. How you will be given Spikevax bivalent Original/Omicron BA.4-5**

The dose of Spikevax bivalent Original/Omicron BA.4-5 is 0.5 mL.

Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm.

**After** each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for at least **15 minutes** to monitor for signs of an allergic reaction.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

Spikevax bivalent Original/Omicron BA.4-5 is only for individuals who have previously received at least a primary vaccination course against COVID-19.

## **4. Possible side effects**

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Get **urgent** medical attention if you get any of the following signs and symptoms of an allergic reaction:

- feeling faint or light-headed;
- changes in your heartbeat;
- shortness of breath;
- wheezing;
- swelling of your lips, face, or throat;
- hives or rash;
- nausea or vomiting;
- stomach pain.

Talk to your doctor or nurse if you develop any other side effects. These can include:

**Very common** (may affect more than 1 in 10 people):

- swelling/tenderness in the underarm
- headache
- nausea
- vomiting
- muscle ache, joint aches, and stiffness

- pain or swelling at the injection site
- redness at the injection site (some of which may occur approximately 9 to 11 days after the injection)
- feeling very tired
- chills
- fever

**Common** (may affect up to 1 in 10 people):

- diarrhoea
- rash
- rash or hives at the injection site (some of which may occur approximately 9 to 11 days after the injection)

**Uncommon** (may affect up to 1 in 100 people):

- itchiness at the injection site
- dizziness
- stomach pain
- raised, itchy rash (urticaria) (which may occur from the time of injection and up to approximately two weeks after the injection)

**Rare** (may affect up to 1 in 1 000 people)

- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in patients who have had facial cosmetic injections.)
- decreased sense of touch or sensation
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)

**Very rare** (may affect up to 1 in 10 000 people)

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

**Frequency unknown**

- severe allergic reactions with breathing difficulties (anaphylaxis)
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)
- a skin reaction that causes red spots or patches on the skin that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- extensive swelling of the vaccinated limb
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this vaccine.

## **5. How to store Spikevax bivalent Original/Omicron BA.4-5**

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Information about storage, expiry, and use and handling are described in the section intended for healthcare professionals at the end of the package leaflet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Spikevax bivalent Original/Omicron BA.4-5 contains

Table 1. Composition by container type

Strength	Container	Dose(s)	Composition
<b>Spikevax bivalent Original/Omicron BA.4-5 (50 mcg/50 mcg)/mL dispersion for injection</b>	Multidose 2.5 mL vial	5 doses of 0.5 mL each	One dose (0.5 mL) contains 25 micrograms of elasomeran and 25 micrograms of davesomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).

Elasomeran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Original).

Davesomeran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 Omicron variant lineages BA.4 and BA.5. The S proteins of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 are identical.

The other ingredients are SM-102 (heptadecan-9-yl 8-[(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino]octanoate), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.

### What Spikevax bivalent Original/Omicron BA.4-5 looks like and contents of the pack

Spikevax bivalent Original/Omicron BA.4-5 is a white to off white dispersion supplied in a glass multidose vial with a rubber stopper and blue flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials. Each vial contains 2.5 mL.

### Product Owner

MODERNA BIOTECH SPAIN, S.L.  
Calle del Príncipe de Vergara 132 Plt 12  
Madrid 28002  
Spain

### Manufacturer

Rovi Pharma Industrial Services, S.A.  
Paseo de Europa, 50  
28703. San Sebastián de los Reyes  
Madrid, Spain

**This leaflet was last revised in 08/2023.**

Scan the code with a mobile device to get the package leaflet.



Or visit the URL <https://www.ModernaCovid19Global.com>

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**The following information is intended for healthcare professionals only:**

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection (multidose vials with a blue flip-off cap)

Spikevax bivalent Original/Omicron BA.4-5 should be administered by a trained healthcare professional.

The vaccine comes ready to use once thawed.

Do not shake or dilute.

The vaccine should be inspected visually for particulate matter and discolouration prior to administration.

Spikevax bivalent Original/Omicron BA.4-5 is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.

Vials are stored frozen between -50°C to -15°C.

Five (5) doses (of 0.5 mL each) can be withdrawn from each multidose vial.

Verify that the vial has a blue flip-off cap and the product name is Spikevax bivalent Original/Omicron BA.4-5.

Pierce the stopper preferably at a different site each time.

Thaw each multidose vial before use following the instructions below (Table 2). When the vial is thawed in the refrigerator, let it sit at room temperature for 15 minutes before administering.

**Table 2. Thawing instructions for multidose vials before use**


Configuration	Thaw instructions and duration
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	Thaw temperature (in a refrigerator)	Thaw duration	Thaw temperature (at room temperature)	Thaw duration
Multidose vial	2° – 8°C	2 hours and 30 minutes	15°C – 25°C	1 hour

**Thaw each vial before use**  
Images for illustrative purposes only

**2 hours and 30 minutes in refrigerator**

2° to 8°C  
(within the 30 days shelf life at 2° to 8°C)

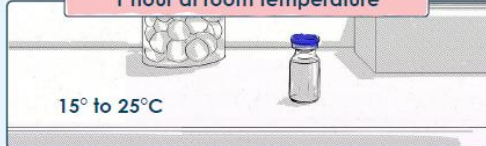


Let vial sit at room temperature for 15 minutes before administering

OR

**1 hour at room temperature**

15° to 25°C



**Instructions Once Thawed**

**Unpunctured Vial**


Maximum times

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**

Maximum time

19 hours

Refrigerator or room temperature

Vial should be held between 2° to 25°C. Record the date and time of discard on the vial label.  
Discard punctured vial after 19 hours.



Withdraw each dose of vaccine from the vial using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another.  
**The dose in the syringe should be used immediately.**

Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately and be discarded after 19 hours.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

**NEVER refreeze thawed vaccine**

## Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## Dosing and schedule

The dose of Spikevax bivalent Original/Omicron BA.4-5 is 0.5 mL.

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of Spikevax bivalent Original/Omicron BA.4-5.

Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.

There are no data to assess the concomitant administration of Spikevax bivalent Original/Omicron BA.4-5 with other vaccines. Spikevax bivalent Original/Omicron BA.4-5 must not be mixed with other vaccines or medicinal products in the same syringe.

## Administration

The vaccine must be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

#### *Multidose vials*

**Administration**

Swirl vial gently after thawing and before each withdrawal.  
The vaccine comes ready to use once thawed. **Do not shake or dilute.**

**Prior to injection, inspect each dose to:**

Confirm liquid is **white to off-white** in colour in both vial and syringe.

Verify syringe volume.

The vaccine may contain white or translucent product-related particulates.

If dosage is incorrect, or discolouration and other particulate matter is present, do not administer the vaccine.

