

Package leaflet: Information for the user

Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) elasomeran/imelasomeran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

1. What Spikevax bivalent Original/Omicron BA.1 is and what it is used for

Spikevax bivalent Original/Omicron BA.1 is a vaccine used as a 50 microgram booster dose to prevent COVID-19 caused by SARS-CoV-2. It is given to adults. The active substance in Spikevax bivalent Original/Omicron BA.1 is mRNA encoding the SARS-CoV-2 Spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

Spikevax bivalent Original/Omicron BA.1 is only for individuals who previously received the primary vaccination or a primary vaccination with first booster dose of an original monovalent vaccine.

As Spikevax bivalent Original/Omicron BA.1 does not contain the virus, it cannot give you COVID-19.

How the vaccine works

Spikevax bivalent Original/Omicron BA.1 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.1 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.1

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.1 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.

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.1.

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. If you have previously had episodes of CLS, talk to a doctor before you are given Spikevax bivalent Original/Omicron BA.1.

Duration of protection

As with any vaccine, the third dose of Spikevax bivalent Original/Omicron BA.1 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.1 is not recommended for children aged under 12 years.

Other medicines and Spikevax bivalent Original/Omicron BA.1

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Spikevax bivalent Original/Omicron BA.1 may affect the way other medicines work, and other medicines may affect how Spikevax bivalent Original/Omicron BA.1 works.

Immunocompromised individuals

The efficacy of Spikevax bivalent Original/Omicron BA.1 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.1 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. Since differences between the two products are only related to the spike protein in the vaccine, and there are no clinically meaningful differences, Spikevax bivalent Original/Omicron BA.1 can be used during pregnancy.

No data are available yet regarding the use of Spikevax bivalent Original/Omicron BA.1 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. Spikevax bivalent Original/Omicron BA.1 can be given during breastfeeding.

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 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.1

The dose of Spikevax bivalent Original/Omicron BA.1 is 0.5 mL, given at least 3 months after the last prior dose of a COVID-19 vaccine.

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.1 is only for individuals who have previously received at least a primary vaccination course against COVID-19.

For details on the primary vaccination course in individuals 12 years of age and older, see the Package Leaflet for Spikevax 0.2 mg/mL.

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):

- 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

Rare (may affect up to 1 in 1000 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)
- raised, itchy rash (urticaria) (some of which may occur approximately 7 to 13 days after the injection)

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)

Call for reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Please report adverse drug events to:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>

You can also report any suspected adverse reactions to:

Pharmacovigilance department in Tabuk Pharmaceuticals:
E-mail: pv.info@tabukpharmaceuticals.com
Tel: +966 4774946; Ext 233

5. How to store Spikevax bivalent Original/Omicron BA.1

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.1 contains

Table 1. Composition by container type

Strength	Container	Dose(s)	Composition
Spikevax bivalent Original/Omicron BA.1 (50 mcg/50 mcg)/mL dispersion for injection	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 imelasomeran, 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.

Imelasomeran is mRNA, 5'-capped, encoding a full-length, codon-optimised pre-fusion stabilised conformation variant (K983P and V984P) of the SARS-CoV-2 spike (S) glycoprotein (Omicron variant, B.1.1.529).

The other ingredients are lipid SM-102, 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.1 looks like and contents of the pack

Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection

Spikevax bivalent Original/Omicron BA.1 is a white to off white dispersion supplied in a 2.5 mL glass multi-dose vial with a rubber stopper and and blue flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials

Marketing Authorisation Holder in Saudi Arabia:

Tabuk Pharmaceutical Manufacturing Co.

Address: 2nd Industrial City

Postal code: 31421

City: Dammam

Country: Saudi Arabia

Manufacturer:

Rovi Pharma Industrial Services, S.A.

Paseo de Europa, 50

28703. San Sebastián de los Reyes

Madrid, Spain

Recipharm Monts

18 Rue de Montbazou

Monts, France 37260

Moderna Biotech Spain S.L.

Calle del Príncipe de Vergara 132 Plt 12

Madrid 28002

Spain

This leaflet was last revised in October 2022.

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



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

Detailed information on this vaccine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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.1 (50 mcg/50 mcg)/mL dispersion for injection (multidose vials with a blue flip-off cap)

Spikevax bivalent Original/Omicron BA.1 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 discoloration prior to administration.

Spikevax bivalent Original/Omicron 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) or ten (10) doses (of 0.5 mL each) can be withdrawn from each multidose vial, depending on vial size.


Verify that the vial has a blue flip-off cap and the product name is Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection. If the vial has a blue flip-off cap and the product name is Spikevax 0.1 mg/mL dispersion for injection, please make reference to the Summary of Product Characteristics for this formulation.

Pierce the stopper preferably at a different site each time.

Thaw each vial before use
Images for illustrative purposes only

2 hours and 30 minutes in refrigerator

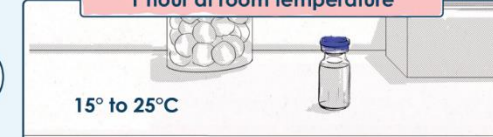
2° to 8°C
(within the 30 days shelf life at 2° to 8°C)



OR

1 hour at room temperature

15° to 25°C



Let vial sit at room temperature for 15 minutes before administering

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.



*When stored for 12 months at -50°C to -15°C provided that once thawed and stored at 2°C to 8°C, protected from light, the vial should be used up within a maximum of 14 days (instead of 30 days, when stored at -50°C to -15°C for 9 months).

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

Dosing and schedule

The dose of Spikevax bivalent Original/Omicron BA.1 is 0.5 mL, given at least 3 months after the last prior dose of a COVID-19 vaccine.

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.1.

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.1 with other vaccines. Spikevax bivalent Original/Omicron BA.1 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.

An illustration of a person's head and shoulders, wearing a blue surgical mask. To the right of the person, a syringe is shown horizontally. The background is a light blue gradient.