

Package leaflet: Information for the user

INTERIM AUTHORISATION

Spikevax bivalent Original / Omicron 0.1 mg/mL dispersion for injection

COVID-19 mRNA Vaccine (nucleoside modified)

elasomeran / imelasomeran

The HSA has granted interim authorisation of Spikevax bivalent Original / Omicron to prevent COVID-19 in individuals 18 years of age and older under the Pandemic Special Access Route (PSAR).

For more information on Interim Authorisation under PSAR, visit HSA at <https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/psar-emergency-therapeutic-product>.

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

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

Spikevax bivalent Original / Omicron is a vaccine used to prevent COVID-19 disease caused by SARS-CoV-2. It is given to adults aged 18 years and older. The active substance in Spikevax bivalent Original / Omicron is mRNA encoding the SARS-CoV-2 Spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

Spikevax bivalent Original / Omicron contains two different types of messenger ribonucleic acid (mRNA), elasomeran and imelasomeran. Elasomeran encodes the spike protein of the original strain of the virus whereas imelasomeran encodes the spike protein of the Omicron BA.1 variant of the virus. The original Spikevax vaccine contains elasomeran only.

As Spikevax does not contain the virus, it cannot give you COVID-19.

How the vaccine works

Spikevax bivalent Original / Omicron 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 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

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 if:

- you have previously had a severe, life-threatening **allergic** reaction after any other vaccine injection or after you were given Spikevax in the past.
- you have any allergies
- 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 fever
- you are pregnant or plan to be pregnant
- you are breastfeeding
- you have any serious illness
- you have received another COVID-19 vaccine
- 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 vaccination, and more often in younger males.

The chance of having this occur is very low. You should avoid strenuous physical activity for two weeks after vaccination. You should seek medical attention right away if you have any of the following symptoms after receiving Spikevax bivalent Original / Omicron:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

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.

As with any vaccine, a booster dose of Spikevax bivalent Original / Omicron may not fully protect all those who receive it and it is not known how long you will be protected.

Children and adolescents

Spikevax bivalent Original / Omicron is not recommended for children aged under 18 years.

Other medicines and Spikevax bivalent Original / Omicron

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

Immunocompromised individuals

If you are immunocompromised, you may receive a third dose of Spikevax. The efficacy of Spikevax even after a third dose 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.

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 contains sodium

Spikevax bivalent Original / Omicron 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

Table 1. Spikevax bivalent Original / Omicron dosing for booster doses

| | |
|--------------|--|
| Vaccination | Spikevax bivalent Original / Omicron 0.1 mg/mL |
| Booster dose | Adults 18 years of age and older: 0.5 mL |

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

During and after each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for around 30 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.

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 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

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)
- 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 (anaphylaxis)
- hypersensitivity

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.

5. How to store Spikevax bivalent Original / Omicron

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 contains

Table 2. Composition by container type

| Strength | Container | Dose(s) | Composition |
|-----------|----------------|---------------------------|---|
| 0.1 mg/mL | Multidose vial | 5 doses of 0.5 mL each | One dose (0.5 mL) contains 25 micrograms of elasmomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles), 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 looks like and contents of the pack

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

Pack size: 10 multidose vials

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

Recipharm Monts
18 Rue de Montbazon
Monts, France 37260

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in 10/2022.

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



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

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.

Storage and preparation for administration

Spikevax bivalent Original / Omicron 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 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.

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

Frozen Storage



**Store frozen between
-50° to -15°C**
Keep the vial and pre-filled syringe in the outer
carton to protect from light.

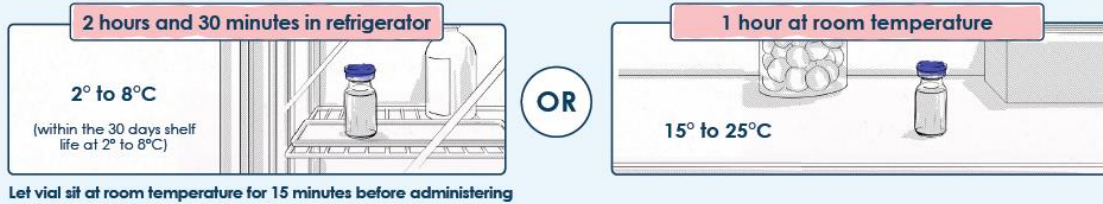
Multidose vials with a blue flip-off cap (0.1 mg/mL)

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

Pierce the stopper preferably at a different site each time.

Thaw each vial before use

Images for illustrative purposes only



Instructions Once Thawed



*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 or pre-filled syringe 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

Table 3. Spikevax bivalent Original / Omicron dosing for booster doses

| | |
|--------------|--|
| Vaccination | 0.1 mg/mL strength |
| Booster dose | Adults 18 years of age and older: 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.

Individuals should be observed by a healthcare professional for at least 30 minutes after vaccination.

There are no data to assess the concomitant administration of Spikevax bivalent Original / Omicron with other vaccines. Spikevax bivalent Original / Omicron 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.

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.

