REG 174 INFORMATION FOR UK RECIPIENTS

Package leaflet: Information for the recipient

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

This medicinal product has been given authorisation for temporary supply by the UK Department of Health and Social Care and the Medicines & Healthcare products Regulatory Agency. It does not have a marketing authorisation, but this temporary authorisation grants permission for the medicine to be used as a booster dose for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

Reporting of side effects

As with any new medicine in the UK, this product will be closely monitored to 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 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 Orginal / Omicron is given
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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 caused by SARS-CoV-2. It is given as a booster injection to individuals aged 18 years and older. The active substance in the vaccine is ribonucleic acid (RNA) encoding the SARS-CoV-2 Spike protein. The RNA 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 bivalent Original / Omicron 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. The vaccine contains mRNA. This carries 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 or Spikevax bivalent Original / Omicron 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

Myocarditis/pericarditis
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 bivalent Original / Omicron (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 of Spikevax (original), 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.

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.

Duration of protection
As with any vaccine, a booster dose of Spikevax bivalent Orginal / Omicron 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 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 Orginal / Omicron may affect the way other medicines work, and other medicines may affect how Spikevax bivalent Orginal / Omicron works.

Immunocompromised individuals

A booster dose of Spikevax bivalent Orginal / Omicron may not provide full immunity to COVID-19 in people who are immunocompromised, and 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
Spikevax bivalent Original / Omicron can be used during pregnancy. A large amount of information from pregnant women vaccinated with Spikevax during the second and third trimester has 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 change to the risk for miscarriage has been seen.

Spikevax bivalent Original / Omicron can be given during breastfeeding. A large amount of information from breastfeeding women vaccinated with Spikevax has not shown negative effects in breastfed babies.

If you are pregnant or think you may be pregnant, and have any questions or concerns, tell your doctor, nurse or pharmacist before you receive this vaccine.

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
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

Individuals 18 years of age and older
A booster dose will be given to you as a single 0.5 mL (50 microgram) injection. This should be at least 3 months after a second dose or a booster dose of a COVID-19 vaccine.

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 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.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. Most side effects go away within a few days of appearing. If side effects such as pain and/or fever are troublesome, they can be treated by medicines for pain and fever such as paracetamol.

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, tongue 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 of the underarm glands
- 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

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)

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. If you are concerned about a side effect it can be reported directly via the Coronavirus Yellow Card reporting site 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. By reporting side effects you can help provide more information on the safety of this vaccine.

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

This is a multidose vial that contains 5 doses of 0.5 mL each.

One dose (0.5 mL) contains 25 micrograms of elasomeran, 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).

This vaccine contains polyethylene glycol/macrogol (PEG) as part of PEG2000-DMG.

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 a single-stranded 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 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 looks like and contents of the pack

Multidose vial

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

Pack size: 10 multidose vials

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

Moderna Biotech Spain S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

For any information about this medicine, please contact the local representative of the Manufacturer

United Kingdom (Northern Ireland)
Tel: 0800 085 7562

This leaflet was last revised on 12-08-2022.

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.

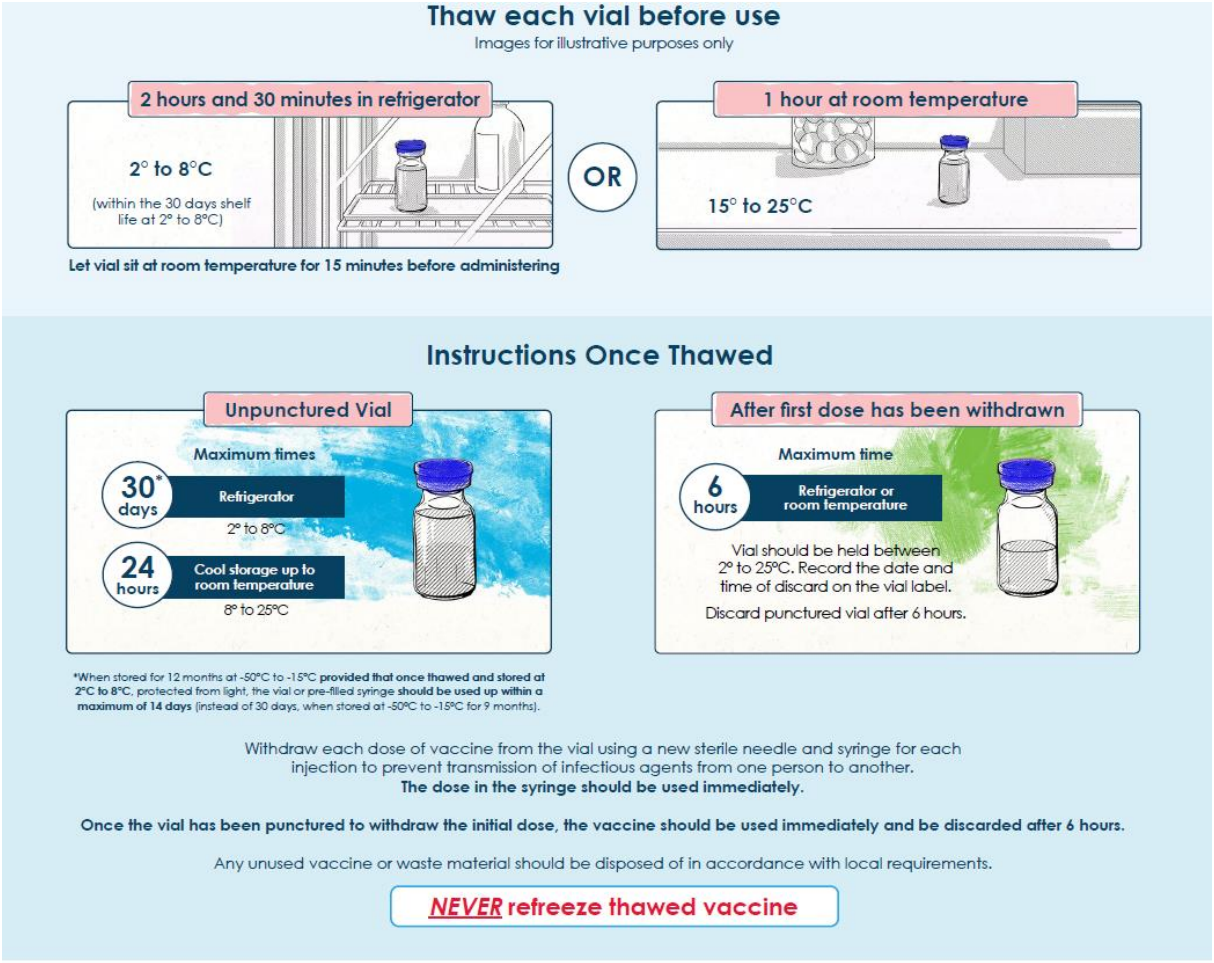
Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

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.

Multidose vials

Spikevax bivalent Original / Omicron vials are multidose.

Pierce the stopper preferably at a different site each time. Do not puncture the vial more than 5 times.



After thawing, do not refreeze.

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

Dosing and schedule

A booster dose of Spikevax bivalent Original / Omicron (0.5 mL, containing 50 micrograms mRNA) should be given intramuscularly to individuals 18 years of age and older at least 3 months after completion of a primary series or booster with a COVID-19 mRNA vaccine or adenoviral vector 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. 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 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.