Package leaflet: Information for the user
Spikevax XBB.1.5
0.1 mg/mL dispersion for injection
Spikevax XBB.1.5
COVID-19 mRNA Vaccine (nucleoside modified)
andusomeran

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 XBB.1.5 is and what it is used for

Spikevax XBB.1.5 is a vaccine used to prevent COVID-19 disease caused by SARS-CoV-2. It is given to adults and children aged 6 months and older. The active substance in Spikevax XBB.1.5 is mRNA encoding the SARS-CoV-2 Spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

As Spikevax XBB.1.5 does not contain the virus, it cannot give you COVID-19.

How the vaccine works
Spikevax XBB.1.5 stimulates the body's natural defences (immune system). The vaccine works by causing thebody to produce protection (antibodies) against the virus that causes COVID-19. Spikevax XBB.1.5 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 XBB.1.5

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 XBB.1.5 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 (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:

- 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 XBB.1.5.

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 XBB.1.5.

Duration of protection
As with any vaccine, the additional dose of Spikevax XBB.1.5 may not fully protect all those who receive it and it is not known how long you will be protected.

Children
Spikevax XBB.1.5 is not recommended for children aged under 6 months old.

Other medicines and Spikevax XBB.1.5
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Spikevax XBB.1.5 may affect the way other medicines work, and other medicines may affect how Spikevax XBB.1.5 works.

Immunocompromised individuals
If you are immunocompromised, you may receive a third dose of Spikevax. The efficacy of Spikevax XBB.1.5 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.

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 XBB.1.5 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 XBB.1.5 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 XBB.1.5 contains sodium
Spikevax XBB.1.5 contains less than 1 mmol sodium (23 mg) per dose and, that is to say essentially 'sodium-free'.

3. How you will be given Spikevax XBB.1.5

Vaccination	**0.10 mg/mL concentration**
Primary series It is recommended to get the second dose 28 days after the first dose. If a child has received one prior dose of any Spikevax vaccine, one dose of Spikevax XBB.1.5 should be administered to complete the two-dose series.	*Children 6 months through 5 years of age* two 0.25 mL injections *Children 6 years through 11 years of age* two 0.50 mL injections
Booster dose	*Individuals 12 years of age and older* 0.5 mL

If you are immunocompromised, you may receive a third dose of Spikevax.

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 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
- decreased appetite (observed in 6 month to 5 year olds)
- irritability/crying (observed in 6 month to 5 year olds)
- headache
- sleepiness (observed in 6 month to 5 year olds)
- 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 1,000 people)
- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (Swelling of the face may occur in individuals who have had facial cosmeticinjections.)
- 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 not known
- 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 XBB.1.5

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 XBB.1.5 contains

Strength	**Container**	**Dose(s)**	**Composition**
Spikevax XBB.1.5 0.1 mg/mL dispersion for injection	Multidose vial 2.5 mL vial	5 doses of 0.5 mL each	One dose (0.5 mL) contains 50 micrograms of andusomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).
		10 doses of 0.25 mL each	One dose (0.25 mL) contains 25 micrograms of andusomeran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Andusomeran 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 XBB.1.5).

The other ingredients are 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 forinjections.

What Spikevax XBB.1.5 looks like and contents of the pack

Multidose vial
Spikevax XBB.1.5 is a white to off white dispersion supplied in a glass vial with a rubber stopper and 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

Manufacturers:

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

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

This leaflet was last revised in 09/2023.

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

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 XBB.1.5 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 XBB.1.5 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.

Multidose vials

Vials are stored in a freezer at -50ºC to -15ºC.

Five (5) doses (of 0.5 mL each) or a maximum of ten (10) doses (0.25 mL each) can be withdrawn from each multidose vial.

Pierce the stopper preferably at a different site each time.

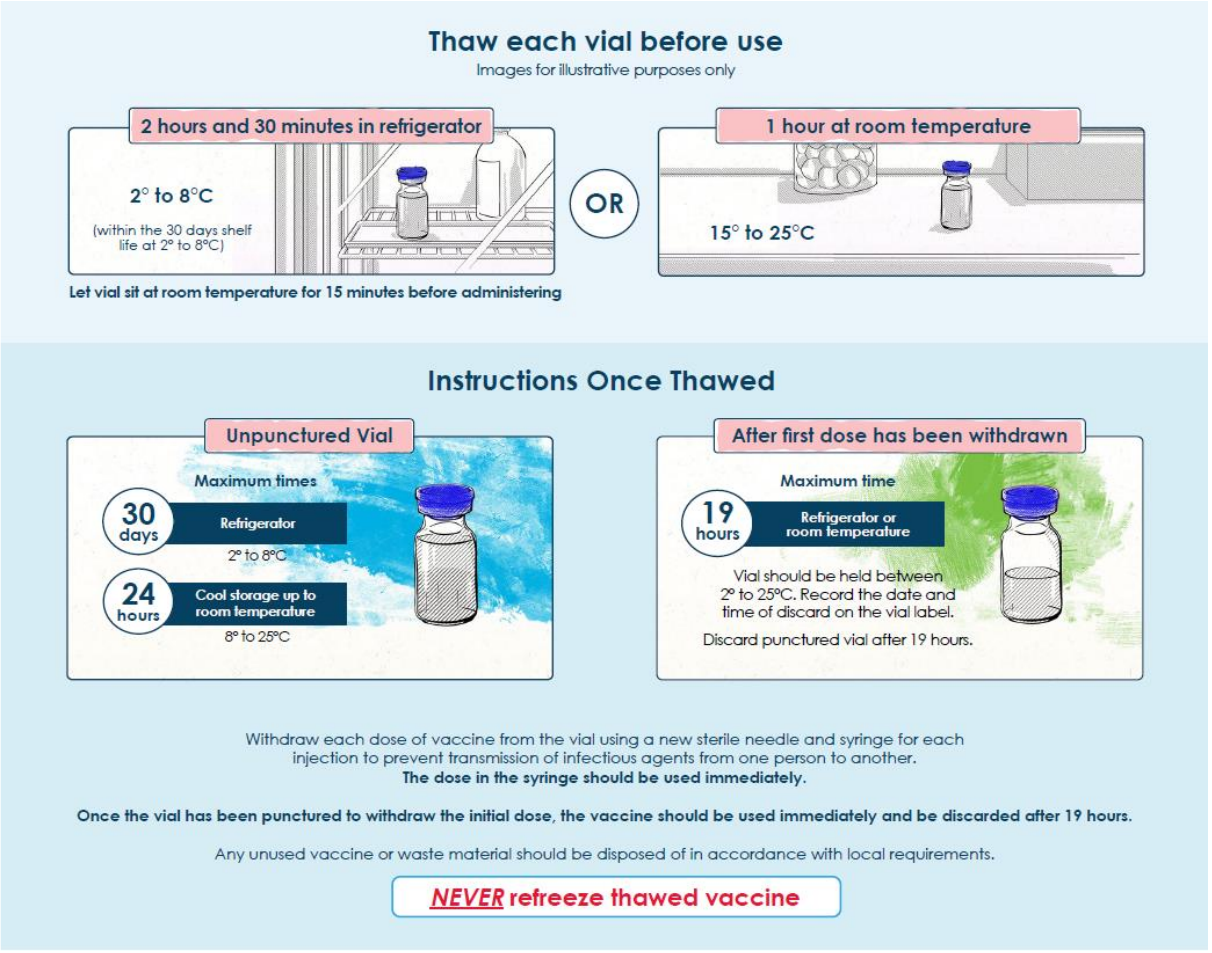
Verify that the vial has a blue flip-off cap and the product name is Spikevax XBB.1.5.

Thaw each multidose vial before use following the instructions below (Table 3). When the vial is thawed in the refrigerator, let it sit at room temperature for 15 minutes before administering.

Table 3. Thawing instructions for multidose vials before use

Configuration	**Thaw instructions and duration**			
	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



Disposal

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

Dosing and schedule

Vaccination	**0.10 mg/mL concentration**
Primary series It is recommended to get the second dose 28 days after the first dose. If a child has received one prior dose of any Spikevax vaccine, one dose of Spikevax XBB.1.5 should be administered to complete the two-dose series.	*Children 6 months through 5 years of age* two 0.25 mL injections *Children 6 years through 11 years of age* two 0.50 mL injections
Booster dose	*Individuals 12 years of age and older* 0.5 mL

A third dose may be given to individuals who are immunocompromised.

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 XBB.1.5.

Individuals should be observed by a healthcare professional for at least 30 minutes following the primary series, and at least 15 minutes for subsequent dose(s).

There are no data to assess the concomitant administration of Spikevax XBB.1.5 with other vaccines. Spikevax XBB.1.5 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, or in infants and young children, the anterolateral aspect of the thigh. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

Multidose vials