

Package leaflet: Information for the user

Spikevax XBB.1.5
50 micrograms dispersion for injection
in pre-filled syringe
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
2. What you need to know before you are given Spikevax XBB.1.5
3. How Spikevax XBB.1.5 is given
4. Possible side effects
5. How to store Spikevax XBB.1.5
6. Contents of the pack and other information

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 adolescents aged 12 years 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 the body 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

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- 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 in younger males, and more often after the second vaccination.

Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen.

The chance of having this occur is very low. 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

Sometimes the symptoms of myocarditis and pericarditis may not be specific and could include tiredness, dizziness, nausea and vomiting, abdominal pain, swelling, and cough.

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 an additional dose of Spikevax. The efficacy of Spikevax XBB.1.5 even after an additional 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

Table 1. Spikevax XBB.1.5 posology

Age(s)	Dose	Additional recommendations
Individuals 12 years of age and older	One dose of 0.5 mL, given intramuscularly	Spikevax XBB.1.5 should be administered in accordance with official recommendations.

* Do not use the pre-filled syringe to deliver a partial volume of 0.25 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 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

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- 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)

- severe allergic reactions (anaphylaxis)
- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (Swelling of the face may occur in individuals 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 not known

- Hypersensitivity
- Erythema multiforme
- Mechanical urticaria
- Chronic urticaria
- Cerebral venous thrombosis

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 50 mcg dispersion for injection in pre-filled syringe	Pre-filled syringe	1 dose of 0.5 mL For single-use only.	One dose (0.5 mL) contains 50 micrograms of andusomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 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 for injections.

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

Pre-filled syringe

Spikevax XBB.1.5 is a white to off white dispersion supplied in a pre-filled syringe (cyclic olefin polymer) with plunger stopper and a tip cap (without needle).

The pre-filled syringe is packaged in 1 clear blister containing 1 pre-filled syringe or 5 clear blisters containing 2 pre-filled syringes in each blister.

Pack sizes:

1 pre-filled syringe

10 pre-filled syringes

Not all pack sizes may be marketed.

Product owner:

MODERNA BIOTECH SPAIN, S.L.

C/ Julián Camarillo nº 31

28037 Madrid

Spain

Manufacturers:

For pre-filled syringe:

Rovi Pharma Industrial Services, S.A.

Paseo de Europa, 50

28703. San Sebastián de los Reyes

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Madrid, Spain

Rovi Pharma Industrial Services, S.A.
Calle Julián Camarillo 35
28037 Madrid,
Spain

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

This leaflet was last revised in 09/2024.

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. Swirl the vial gently after thawing and before withdrawal.

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.

Pre-filled syringe

Do not shake or dilute the contents of the pre-filled syringe.

Each pre-filled syringe is for single use only. The vaccine comes ready to use once thawed.

One (1) dose of 0.5 mL can be administered from each pre-filled syringe.

Spikevax XBB.1.5 is supplied in a single-dose, pre-filled syringe (without needle) containing 0.5 mL (50 micrograms of andusomeran) mRNA and must be thawed prior to administration.

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During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thaw each pre-filled syringe before use following the instructions below. Syringes may be thawed in the blister packs (each blister containing 1 or 2 pre-filled syringes, depending on pack size) or in the carton itself, either in the refrigerator or at room temperature (Table 2).

Table 2. Thawing instructions for Spikevax XBB.1.5 pre-filled syringes and cartons before use

Configuration	Thaw instructions and duration			
	Thaw temperature (in a refrigerator) (°C)	Thaw duration (minutes)	Thaw temperature (at room temperature) (°C)	Thaw duration (minutes)
Pre-filled syringe in blister pack	2 – 8	55	15 – 25	45
Carton	2 – 8	155	15 – 25	140

Handling instructions for the pre-filled syringes

- Let each pre-filled syringe stand at room temperature (15°C to 25°C) for 15 minutes before administering.
- Do not shake.
- Pre-filled syringe should be inspected visually for particulate matter and discolouration prior to administration.
- 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.
- Needles are not included in the pre-filled syringe cartons.
- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Uncap the needle when ready for administration.
- Administer the entire dose intramuscularly.
- After thawing, do not refreeze.

Disposal

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

Dosing and schedule

Table 3. Spikevax XBB.1.5 dosing

Age(s)	Dose	Additional recommendations
Individuals 12 years of age and older	One dose of 0.5 mL, given intramuscularly	Spikevax XBB.1.5 should be administered in accordance with official recommendations.

* Do not use the pre-filled syringe to deliver a partial volume of 0.25 mL.

If you are immunocompromised, you may receive an additional dose in accordance with official

recommendations.

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 post-vaccination in accordance with the official recommendations.

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. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

Pre-filled syringes

Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner). Remove tip cap from pre-filled syringe by twisting in a counter-clockwise direction. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe. Uncap the needle when ready for administration. Administer the entire dose intramuscularly. Discard syringe after use. For single-use only.

