Package leaflet: Information for the user

Spikevax XBB.1.5
0.1 mg/mL dispersion for injection
Spikevax XBB.1.5
50 micrograms dispersion for injection
Spikevax XBB.1.5
50 micrograms dispersion for injection in pre-filled syringe
COVID-19 mRNA Vaccine

andusomeran

▼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 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 caused by SARS-CoV-2. It is given to adults and children 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 (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 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 12 years.

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
The efficacy of Spikevax XBB.1.5 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. Since differences

between the two products are only related to the spike protein in the vaccine, and there are no clinically meaningful differences, Spikevax XBB.1.5 can be used during pregnancy.

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. Spikevax XBB.1.5 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 XBB.1.5 contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, 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, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	Spikevax XBB.1.5 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.
Individuals 65 years of age and older	One dose of 0.5 mL, given intramuscularly	One additional dose may be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Table 2. Spikevax XBB.1.5 posology for immunocompromised individuals

Age(s)	Dose	Additional recommendations
Immunocompromised individuals 12 years of age and older, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	Additional age-appropriate dose(s) may be administered in severely immunocompromised at least 2 months following the most recent dose of a COVID-19 vaccine at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

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.

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
- 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
- raised, itchy rash (urticaria) (which may occur from the time of injection and up to approximately two weeks after the injection)

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 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 not known
- 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@sfda.gov.sa
Website: https://ade.sfda.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 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

Table 3. Composition by container type

Strength	**Container**	**Dose(s)**	**Composition**
Spikevax XBB.1.5 0.1 mg/mL dispersion for injection	Multidose 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).

Strength	Container	Dose(s)	Composition
Spikevax XBB.1.5 50 mcg dispersion for injection	Single-dose 0.5 mL vial	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).
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 (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 XBB.1.5 looks like and contents of the pack

Spikevax XBB.1.5
0.1 mg/mL dispersion for injection

Spikevax XBB.1.5 is a white to off white dispersion supplied in a glass multidose vial with a rubber stopper and blue flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials. Each vial contains 2.5 mL.

Spikevax XBB.1.5
50 micrograms dispersion for injection

Spikevax XBB.1.5 is a white to off white dispersion supplied in a glass single-dose vial with a rubber stopper and blue flip-off plastic cap with aluminium seal.

Pack sizes:
1 single-dose vial
10 single-dose vials
Each vial contains 0.5 mL.

Not all pack sizes may be marketed.

Spikevax XBB.1.5
50 micrograms dispersion for injection in 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.

Marketing Authorisation Holder
Tabuk Pharmaceutical Manufacturing Co.
Address: 2nd Industrial City
Postal code: 31421
City: Dammam
Country: Saudi Arabia

Manufacturers

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

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

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

Patheon Italia S.p.a.
Viale G.B. Stucchi
110 20900 Monza
Italy

Patheon Italia S.p.A.
2 Trav. SX Via Morolense 5
03013 Ferentino (FR)
Italy

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

This leaflet was last revised in 10/2023.

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.

Spikevax XBB.1.5
0.1 mg/mL dispersion for injection (multidose vials with a blue flip-off cap)

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.

The vaccine 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.

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

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.

Verify that the vial has a blue flip-off cap and the product name is Spikevax XBB.1.5. If the vial has a blue flip-off cap and the product name is Spikevax 0.1 mg/mL, Spikevax bivalent Original/Omicron BA.1 or Spikevax bivalent Original/Omicron BA.4-5, please make reference to the Summary of Product Characteristics for that formulation.

Thaw each multidose vial before use following the instructions below (Table 4). When the vial is thawed in the refrigerator, let it sit at room temperature for 15 minutes before administering.

Table 4. 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

Spikevax XBB.1.5
50 micrograms dispersion for injection (single-dose vials)

The vaccine comes ready to use once thawed.

Do not shake or dilute. Swirl the vial gently after thawing and before withdrawal.

Verify that the vial has a blue flip-off cap and the product name is Spikevax XBB.1.5. If the vial has a blue flip-off cap and the product name is Spikevax bivalent Original/Omicron BA.1 or Spikevax bivalent Original/Omicron BA.4-5, please make reference to the Summary of Product Characteristics for that formulation.

Thaw each single-dose vial before use following the instructions below. Each single-dose vial or the carton containing 10 vials may be thawed either in the refrigerator or at room temperature (Table 5).

Table 5. Thawing instructions for single-dose vials 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)**
Single-dose vial	2°C to 8°C	45 minutes	15°C to 25°C	15 minutes
Carton	2°C to 8°C	1 hour 45 minutes	15°C to 25°C	45 minutes

If vials are thawed at 2°C to 8°C, let each vial stand at room temperature (15°C to 25°C) for approximately 15 minutes before administering.

Spikevax XBB.1.5
50 micrograms dispersion for injection in 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.

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 6).

Table 6. 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

Verify that the product name of the pre-filled syringe is Spikevax XBB.1.5. If the product name is Spikevax 50 micrograms, Spikevax bivalent Original/Omicron BA.1 or Spikevax bivalent

Original/Omicron BA.4-5, please make reference to the Summary of Product Characteristics for that formulation.

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).
- Remove tip cap from 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.
- 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 5. Spikevax XBB.1.5 dosing

Age(s)	**Dose**	**Additional recommendations**
Individuals 12 years of age and older, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	Spikevax XBB.1.5 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.
Individuals 65 years of age and older	One dose of 0.5 mL, given intramuscularly	One additional dose may be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Table 6. Spikevax XBB.1.5 posology for immunocompromised individuals

Age(s)	Dose	Additional recommendations
Immunocompromised individuals 12 years of age and older, with or without prior vaccination	One dose of 0.5 mL, given intramuscularly	Additional age-appropriate dose(s) may be administered in severely immunocompromised at least 2 months following the most recent dose of a COVID-19 vaccine at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

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.

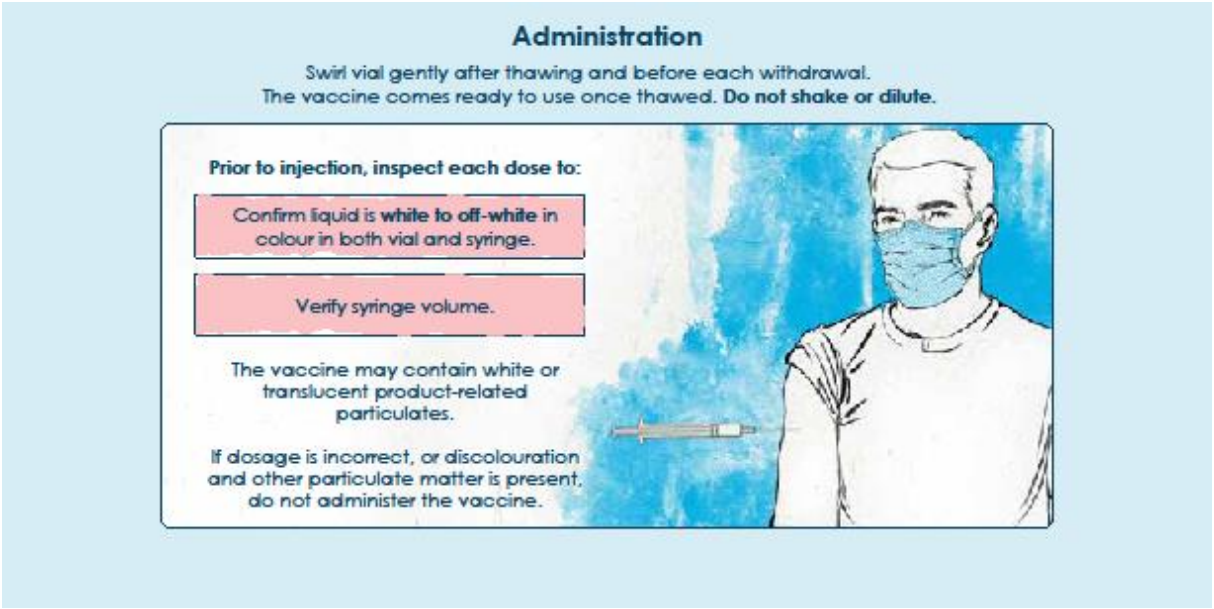
Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.

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.

Multidose vials



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.