

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

SPIKEVAX® XBB.1.5

[COVID-19 mRNA vaccine, monovalent (Omicron subvariant XBB.1.5)]

Andusomeran mRNA vaccine, Dispersion for Intramuscular Injection

Read this carefully before you start taking **SPIKEVAX XBB.1.5**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SPIKEVAX XBB.1.5**.

What is SPIKEVAX XBB.1.5 used for?

SPIKEVAX XBB.1.5 is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to people aged 6 months and older.

The safety and effectiveness of SPIKEVAX XBB.1.5 mRNA vaccine for individuals 6 months of age and older is inferred from several studies of a primary series and booster dose of SPIKEVAX Bivalent (Original/Omicron BA.1) in individuals 6 months to 5 years of age, a booster dose of SPIKEVAX Bivalent (Original/Omicron BA.1) in individuals >18 years of age, a booster dose study of SPIKEVAX XBB.1.5 in individuals > 18 years of age as well as data from studies which evaluated the primary series and booster vaccination with SPIKEVAX (Original).

How does SPIKEVAX XBB.1.5 work?

SPIKEVAX XBB.1.5 works by causing the body to produce its own protection (antibodies) against the SARS-CoV-2 virus that causes the COVID-19 infection. SPIKEVAX XBB.1.5 uses a molecule called messenger ribonucleic acid (mRNA, the genetic code for a piece of the virus) to deliver the set of instructions that cells in your body can use to make antibodies to help fight the virus that causes COVID-19. The vaccine is given by injection with a needle in the upper arm.

You cannot get COVID-19 from this vaccine.

As with any vaccine, SPIKEVAX XBB.1.5 may not fully protect all those who receive it. Even after you have had the vaccine, continue to follow the recommendations of local public health officials to prevent spread of COVID-19.

What are the ingredients in SPIKEVAX XBB.1.5?

Medicinal ingredients: Andusomeran (mRNA)

Non-medicinal ingredients:

- acetic acid
- cholesterol
- DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)
- PEG2000-DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol)
- lipid SM-102
- sodium acetate trihydrate

- sucrose
- trometamol
- trometamol hydrochloride
- water for injection

SPIKEVAX XBB.1.5 comes in the following dosage forms:

White to off-white dispersion for injection provided in a multidose vial.

Do not receive SPIKEVAX XBB.1.5 if:

- you are allergic to the active substance or any of the other ingredients of this vaccine (see What are the ingredients in SPIKEVAX XBB.1.5?)
- you have had an allergic reaction to a previous dose of SPIKEVAX
- you currently have symptoms that could be due to COVID-19. Talk with your healthcare professional about your symptoms and getting a COVID-19 test. Your healthcare professional will advise you when you are able to receive the vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SPIKEVAX XBB.1.5. Talk about any health conditions or problems you may have, including if you:

- have any allergies
- have had previous problems following administration of SPIKEVAX such as an allergic reaction or breathing problems
- have a weakened immune system due to a medical condition or are on a medicine that affects your immune system
- have a bleeding problem, bruise easily or use a blood thinning medication
- have a high fever or severe infection
- have any serious illness
- have previously had episodes of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining outside the heart)
- are pregnant, think you may be pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There is limited information on the use of SPIKEVAX XBB.1.5 with other vaccines. Tell your healthcare professional if you have recently received any other vaccine.

How is SPIKEVAX XBB.1.5 given:

- 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 15 minutes to monitor for signs of an allergic reaction.

Usual dose:

- 12 years of age and older: One (1) dose of SPIKEVAX XBB.1.5 is 50 micrograms.
- 5 to 11 years of age: One (1) dose of SPIKEVAX XBB.1.5 is 25 micrograms.

- 6 months to 4 years of age:
 - *If the child has not been previously vaccinated:* Two (2) doses of SPIKEVAX XBB.1.5 of 25 micrograms each.
 - *If the child has had 1 or more COVID-19 vaccine doses previously:* One (1) dose of SPIKEVAX XBB.1.5 is 25 micrograms.

Overdose:

In the event of suspected overdose with SPIKEVAX XBB.1.5, contact your regional poison control centre.

Missed Dose:

If you forget to go back to your healthcare professional at the scheduled time for your next dose, ask your healthcare professional for advice.

What are possible side effects from using SPIKEVAX XBB.1.5?

Like all vaccines, SPIKEVAX XBB.1.5 can cause side effects.

The following are common or very common side effects of SPIKEVAX XBB.1.5. Most of these side effects are mild and do not last long. Tell your doctor if you have side effects that bother you:

- pain at the injection site
- tiredness, sleepiness
- headache
- muscle ache and stiffness
- chills
- fever
- swelling or redness at the injection site
- decreased appetite
- nausea and/or vomiting
- enlarged lymph nodes
- hypoaesthesia (decreased sense of touch or sensation, numbness) or paraesthesia (tingling, itching or pricking sensation)
- dizziness

Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions, erythema multiforme (red round patches on the skin) and facial paralysis / Bell’s palsy have been reported with the administration of SPIKEVAX. Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported following SPIKEVAX administration.

These are not all the possible side effects you may have when taking SPIKEVAX XBB.1.5. If you experience any side effects not listed here, tell your healthcare professional.

Should you develop any serious symptoms or symptoms that could be an allergic reaction, seek medical attention right away. Symptoms of an allergic reaction include:

- hives (bumps on the skin that are often very itchy)
- swelling of the face, tongue or throat

- difficulty breathing

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Moderna Biopharma Canada Corp. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

Storage:

Your doctor or pharmacist is responsible storing, supplying and administering SPIKEVAX XBB.1.5, as well as disposing of any unused product correctly.

Keep out of reach and sight of children.

If you want more information about SPIKEVAX XBB.1.5:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.modernacovid19global.com/ca/>, or by calling 1-866-MODERNA (1-866-663-3762).

This leaflet was prepared by Moderna Biopharma Canada Corp.

Last Revised 12 September 2023