

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

SPIKEVAX Bivalent™ Original / Omicron BA.4/5

[COVID-19 mRNA vaccine, Bivalent (Original/Omicron B.1.1.529 (BA.4-BA.5) Variant)]

Elasomeran / davesomeran mRNA vaccine, Dispersion for Intramuscular Injection

Read this carefully before you start taking **SPIKEVAX Bivalent Original/Omicron BA.4/5**. 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 Bivalent Original/Omicron BA.4/5**.

What is SPIKEVAX Bivalent Original/Omicron BA.4/5 used for?

SPIKEVAX Bivalent Original/Omicron BA.4/5 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 18 years and older.

The safety and effectiveness of a booster dose of SPIKEVAX Bivalent (elasomeran/davesomeran) Original/Omicron BA.4/5 mRNA vaccine for individuals 18 years of age and older is inferred from studies of a booster dose of SPIKEVAX Bivalent (Original/Omicron BA.1).

How does SPIKEVAX Bivalent work?

SPIKEVAX Bivalent Original/Omicron BA.4/5 works by causing the body to produce its own protection (antibodies) against the SARS-CoV-2 virus that causes the COVID-19 infection. SPIKEVAX Bivalent Original/Omicron BA.4/5 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 Bivalent Original/Omicron BA.4/5 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.

Individuals may not be optimally protected until after receiving the second dose of the vaccine.

What are the ingredients in SPIKEVAX Bivalent Original/Omicron BA.4/5?

Medicinal ingredients: Elasomeran and davesomeran (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 Bivalent Original/Omicron BA.4/5 comes in the following dosage forms:

White to off-white dispersion for injection provided in a multidose vial. For individuals 18 years of age the SPIKEVAX Bivalent Original/Omicron BA.4/5 dose is 50 micrograms.

Do not receive SPIKEVAX Bivalent Original/Omicron BA.4/5 if:

- you are allergic to the active substance or any of the other ingredients of this vaccine (see What are the ingredients in SPIKEVAX Bivalent Original/Omicron BA.4/5?)
- 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 Bivalent Original/Omicron BA.4/5. 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 Bivalent Original/Omicron BA.4/5 with other vaccines. Tell your healthcare professional if you have recently received any other vaccine.

How is SPIKEVAX Bivalent Original/Omicron BA.4/5 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:

A booster dose of 50 mcg may be administered intramuscularly at least 4 months after completion of a primary series and/or a previous booster dose in individuals 18 years of age or older.

Overdose:

In the event of suspected overdose with SPIKEVAX Bivalent Original/Omicron BA.4/5, 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 Bivalent Original/Omicron BA.4/5?

Like all vaccines, SPIKEVAX Bivalent Original/Omicron BA.4/5 can cause side effects.

The following are common or very common side effects of SPIKEVAX Bivalent Original/Omicron BA.4/5. 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
- headache
- muscle ache and stiffness
- chills
- fever
- swelling or redness at the injection site
- 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.

These are not all the possible side effects you may have when taking SPIKEVAX Bivalent Original/Omicron BA.4-BA.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 ModernaTX, Inc. 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 Bivalent Original/Omicron BA.4/5, as well as disposing of any unused product correctly.

Keep out of reach and sight of children.

If you want more information about SPIKEVAX Bivalent Original/Omicron BA.4/5:

- 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 ModernaTX, Inc.

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