

# Frequently Asked Questions

Can't find the answer to your question? Give us a call at **1-866-MODERNA (1-866-663-3762)**.

SPIKEVAX™ (elasomeran mRNA vaccine) is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus.

SPIKEVAX can be given to individuals aged 12 years and older.

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## General

### Who is Moderna?

Moderna, Inc. is a biotechnology company founded in 2010 and headquartered in Cambridge, Massachusetts. Moderna is pioneering a class of medicines and vaccines based on messenger RNA (mRNA). mRNA carries the instructions for the cells of the body to make proteins, and this affects many aspects of our biology, including health and disease.

If you would like to learn more about Moderna, you can visit [www.modernatx.com/about-us](http://www.modernatx.com/about-us).

## Product & Production

### What do we know about the vaccine safety?

In clinical trials, approximately 17,600 individuals 12 years of age and older have received at least 1 dose of SPIKEVAX. Like all vaccines, SPIKEVAX can cause side effects. See *What side effects might I have from the vaccine?* on the next page for a list of common or very common side effects of SPIKEVAX.

### Will SPIKEVAX give me COVID-19?

No. SPIKEVAX does not contain SARS-CoV-2 and cannot give you COVID-19.

### Does the vaccine contain preservatives, antibiotics or products from human or animal origin?

SPIKEVAX contains no preservatives, no antibiotics, and no products from human or animal origin.

The vial stoppers are not made with natural rubber latex.

SPIKEVAX contains the following ingredients: messenger RNA (mRNA-1273 SARS-CoV-2), 4 fatty substances (lipid SM-102, PEG2000 DMG [1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, and water for injection.

## My Vaccination

### What side effects might I have from the vaccine?

Like all vaccines, SPIKEVAX can cause side effects.

The following are common or very common side effects of SPIKEVAX. 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)
- Dizziness

Non-severe allergic reactions (such as rash, itching, hives or swelling of the face), severe allergic reactions and facial paralysis / Bell's palsy have been reported.

These are not all the possible side effects you may have when taking SPIKEVAX. 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 immediately. 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.

### What should I do if I experience side effects?

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.

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 Therapeutics Inc. cannot provide medical advice.

### Do I still have to wear a mask and socially distance after the first vaccine? After the second vaccine?

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

Cont'd

## My Vaccination (Cont'd)

### Do not use SPIKEVAX if:

- You are allergic to the active substance or any of the other ingredients of this vaccine
- 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

### What should I tell my healthcare provider before I get the vaccine?

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

- Have any allergies or previous problems following administration of SPIKEVAX such as an allergic reaction or breathing problems
- Have a bleeding problem, bruise easily or use a blood thinning medication
- Have a high fever or severe infection
- Have any serious illness
- Have a weakened immune system due to a medical condition or are on a medicine that affects your immune system
- 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 no information on the use of SPIKEVAX with other vaccines.

Tell your healthcare professional if you have recently received any other vaccine.

### Will it still work if I only get 1 dose?

SPIKEVAX will be given to you as two 0.5 mL injections. Each injection will be given on a separate visit 1 month apart.

If you receive one dose of SPIKEVAX, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

It is very important that you return for the second injection, or the vaccine may not work as well.

### How much time should there be between doses? What's the most and least amount of time?

SPIKEVAX will be given to you as two 0.5 mL injections. Each injection will be given on a separate visit 1 month apart. It is very important that you return for the second injection, or the vaccine may not work as well.

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

### Can I get the vaccine if my immune system is compromised?

SPIKEVAX may not work as well in people who are immunocompromised or are on a medicine that affects the immune system. Please talk to your healthcare provider about this condition.

## REPORTING ADVERSE EVENTS

Managing marketed health product-related side effects depends on healthcare professionals and patients reporting them. Any serious or unexpected side effects in patients receiving SPIKEVAX should be reported to your local Health Unit.

If a patient experiences a side effect following immunization, please complete the **Adverse Events Following Immunization (AEFI) Form** appropriate for your province/territory and send it to your local Health Unit.

In addition, you can report side effects to Moderna at **1-866-MODERNA (1-866-663-3762)**.

## PRODUCT CONCERNS

All designated vaccination sites need to maintain security around the storage of SPIKEVAX within their facilities.

Make sure that vials of SPIKEVAX arrive and are stored in their original packaging. If you suspect that the SPIKEVAX you have purchased may be counterfeit, if there are any irregularities with packaging, and/or with the arrival of the shipments, please contact us at **1-866-663-3762** or visit **www.modernatx.com**, or **report a complaint to Health Canada**.

About Moderna

**[www.ModernaTX.com](https://www.ModernaTX.com)**  
**1-866-MODERNA (1-866-663-3762)**  
**24 hours, 7 days a week**

## IMPORTANT SAFETY INFORMATION

SPIKEVAX™ (elasomeran mRNA vaccine) is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to individuals aged 12 years and older. As with any vaccine, SPIKEVAX may not fully protect all those who receive it. Even after you have had both doses of the vaccine, continue to follow the recommendations of local public health officials to prevent the spread of COVID-19. Individuals may not be optimally protected until after receiving the second dose of the vaccine.

The most common or very common side effects of SPIKEVAX are pain at the injection site, tiredness, headache, muscle ache and stiffness, chills, fever, swelling or redness at the injection site, nausea and/or vomiting and enlarged lymph nodes. Allergic reactions may also occur.

Vaccination may not be suitable for everyone, so ask your healthcare professional if SPIKEVAX is right for you. Full product information can be found on <https://www.modernacovid19global.com/ca/>. To report an adverse event, please call **1-866-MODERNA (1-866-663-3762)**.