Frequently Asked Questions

Explore these topics to find the answers to some of the most common questions we get from healthcare professionals. 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 indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 12 years of age and older.

General

Who is Moderna?

Moderna, Inc. is a biotechnology company developing messenger RNA (mRNA) therapeutics and vaccines to investigate and potentially create a new class of medicines for patients. Moderna was established in 2010 and is headquartered in Cambridge, Massachusetts.

If you would like more information on Moderna, you can visit our website, www.ModernaTX.com.

What does it mean that the vaccine is based on mRNA technology?

A vaccine based on messenger RNA (mRNA) technology, such as SPIKEVAX, does not use inactivated virus, attenuated virus, or any other kind of virus.

SPIKEVAX uses mRNA to provide a blueprint for your cells to build your body's defense against the virus. This allows the body to generate an antibody response, and to retain the information in memory immune cells, in order to attack the virus if the vaccinated individual is exposed to the virus.

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Product & Production

What side effects are seen with this vaccine?

The safety profile of SPIKEVAX is based on data generated from an ongoing Phase 3 placebo-controlled clinical study on subjects ≥ 18 years of age (Study P301, NCT04470427).

Solicited adverse reactions were reported more frequently among subjects in the vaccine group than in the placebo group. The most frequently reported adverse reactions after any dose were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%) and chills (45.4%). The majority of local and systemic adverse reactions had a median duration of 1 to 3 days.

Overall, there was a higher reported rate of solicited adverse reactions in younger age groups; the incidence of lymphadenopathy (axillary swelling/tenderness), fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, fever was higher in adults 18 to 64 years of age than in those 65 years of age and above. Solicited adverse reactions were also more frequent after the second dose, compared to the first one, including grade 3 local and systemic adverse reactions.

Safety data in adolescents (12 to 17 years of age) were collected in an ongoing Phase 2/3 randomised, placebo-controlled, observer-blind clinical trial (Study P203, NCT04649151) conducted in the United States involving 3,726 participants who received at least one dose of SPIKEVAX (n=2,486) or placebo (n=1,240). Of these, 1360 adolescents (vaccine=942, placebo=418) have been followed for at least 2 months (60 days) after the second dose of SPIKEVAX at the time of the analysis (cut-off date May 8, 2021). Overall, solicited adverse reactions at any dose were reported more frequently among adolescents in the vaccine group than in the placebo group. The most frequently reported adverse reactions in adolescent subjects were pain at the injection site (97.2%), headache (78.4%), fatigue (75.2%), myalgia (54.3%), and chills (49.1%).

Anaphylaxis has been reported following SPIKEVAX administration. Very rare cases of myocarditis and/or pericarditis following vaccination with SPIKEVAX have been reported during post-authorization use.

Please see the full **Product Monograph** for more information on adverse reactions

The vaccine was incorrectly handled. Can it still be used?

SPIKEVAX should be stored and handled under the freezer and refrigerator conditions as described in the Storage, Stability and Disposal section of the **Product Monograph**.

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours.

After the first dose has been withdrawn, the vial should be stored between 2° to 25°C (36° to 77°F). Discard vial after 24 hours. Do not refreeze.

How do I know that the vaccine I received is not counterfeit?

Moderna is committed to safety and ensuring that people have accurate information about investigational SPIKEVAX, including how it is accessed and administered.

Moderna is actively monitoring for fraudulent offers of illegitimate SPIKEVAX to protect individuals from products that might be dangerous and lead to serious and life-threatening harm.

SPIKEVAX is not sold online.

The authenticity of products acquired outside of the legitimate supply chain cannot be verified by Moderna. If you suspect the SPIKEVAX you have purchased may be counterfeit, please call Moderna Medical Information at **1-866-MODERNA (1-866-663-3762)**.

The vaccine appears to be defective or damaged. What can I do?

If you have defective or damaged vaccine, please contact Moderna Medical Information at **1-866-MODERNA (1-866-663-3762)**.

SPIKEVAX is a white to off-white dispersion. It may contain white or translucent product-related particulates.

Inspect SPIKEVAX vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

Packages and vials that have not been stored and handled with the appropriate freezer and refrigeration requirements as outlined in the **Product Monograph** should be discarded.

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Vaccine Use in Special Populations

What is known about the safety of the vaccine for special populations (children, pregnant women, elderly people)?

Children: The safety and efficacy of SPIKEVAX in individuals under 12 years of age have not yet been established.

Pregnant women: The safety and efficacy of SPIKEVAX in pregnant women have not yet been established.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to SPIKEVAX during pregnancy. Women who are vaccinated with SPIKEVAX during pregnancy are encouraged to enroll in the registry by calling **1-866-MODERNA (1-866-663-3762)**.

Breastfeeding women: It is unknown if SPIKEVAX is excreted in human milk. A risk to the newborns/ infants cannot be excluded. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunization against COVID-19.

Elderly people: Clinical studies of SPIKEVAX include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.

In clinical studies, there was a higher reported rate of solicited adverse reactions in younger age groups; the incidence of lymphadenopathy (axillary swelling/tenderness), fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, fever was higher in adults 18 to 64 years of age than in those 65 years of age and above. Solicited adverse reactions were also more frequent after the second dose, compared to the first one, including grade 3 local and systemic adverse reactions.

What should I do if a patient only receives one dose?

SPIKEVAX was designed and studied to be given as a series of two doses 28 days apart. There are no available data on a single dose.

All effort should be made to ensure that all vaccine recipients receive 2 doses. Provide a COVID-19 vaccination card to recipients as documentation of the first dose of SPIKEVAX and to remind them when a second dose should be administered.

How do I report adverse events from vaccination?

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)**.

Is mask wearing and social distancing necessary after the first dose? After the second dose?

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

Are there any risks with concomitant vaccines?

There are no data to assess the concomitant administration of SPIKEVAX with other vaccines. Do not mix SPIKEVAX with other vaccines/products in the same syringe.

Are there any known contraindications?

SPIKEVAX is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.

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REPORTING ADVERSE EVENTS

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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

1-866-MODERNA (1-866-663-3762)

24 hours, 7 days a week

Indication and clinical use:

SPIKEVAX™ (elasomeran mRNA vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals 12 years of age and older. The safety and efficacy in individuals under 12 years of age has not been established.

Contraindications:

- Hypersensitivity to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container

Relevant warnings and precautions:

- Hypersensitivity and anaphylaxis
- Myocarditis and pericarditis
- Patients with acute infection
- Patients with hematologic disorders or on anticoagulant therapy
- Patients who are immunocompromised
- Syncope
- Patients may not be optimally protected until after receiving the second dose

For more information:

Please consult the Product Monograph at www.modernacovid19global.com/ca/ for important information relating to adverse reactions, drug interactions, and dosing information which has not been discussed in this piece. The Product Monograph is also available by calling us at 1-866-MODERNA (1-866-663-3762).