

Information for Recipients and Caregivers

SPIKEVAX (pronounced SPĪK-văx) (COVID-19 Vaccine, mRNA)

Commented [A1]: SPONSOR COMMENT: Moderna has accepted CBER's comments received by email Dec. 14, 2021. Minor editorial changes for consistency and updated revision date are provided in tracked changes.

Please read this information sheet before getting SPIKEVAX. This summary is not intended to take the place of talking with your healthcare provider. If you have questions or would like more information, please talk with your healthcare provider.

What is SPIKEVAX?

SPIKEVAX is a vaccine to help protect you against COVID-19. SPIKEVAX is for people 18 years of age and older. Vaccination with SPIKEVAX may not protect all people who receive the vaccine.

Who should not get SPIKEVAX?

You should not get SPIKEVAX if you:

- had a severe allergic reaction after receiving a previous dose of SPIKEVAX (also called Moderna COVID-19 Vaccine);
- had a severe allergic reaction to any ingredient of this vaccine (see **What are the ingredients in SPIKEVAX?**)

What should I tell my healthcare provider?

Tell your healthcare provider about all of your medical conditions, including if you:

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received any other COVID-19 vaccine
- have ever fainted in association with an injection

How is SPIKEVAX given?

SPIKEVAX is given as an injection into the muscle. The SPIKEVAX vaccination series is 2 doses given 1 month apart. If you receive one dose of SPIKEVAX, you should receive a second dose of SPIKEVAX (also called Moderna COVID-19 Vaccine) 1 month later to complete the vaccination series.

What are the risks of SPIKEVAX?

Severe allergic reactions have occurred in some people who have received SPIKEVAX (also called Moderna COVID-19 Vaccine). There is a very small chance that SPIKEVAX could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of SPIKEVAX. For this reason, your healthcare provider may ask you to stay for a short time at the place where you received your vaccine. Signs of a severe allergic reaction can

include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received SPIKEVAX (also called Moderna COVID-19 Vaccine), more commonly in males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of ~~the Moderna COVID-19 Vaccine~~ SPIKEVAX. The chance of this happening is very low. You should seek medical attention right away if you have any of the following symptoms after receiving SPIKEVAX:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in clinical trials with SPIKEVAX include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

These may not be all of the possible side effects of SPIKEVAX. Ask your healthcare provider about any side effects that concern you. You may report side effects to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <https://vaers.hhs.gov>.

What if I am pregnant or breastfeeding?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

A pregnancy exposure registry is available. You are encouraged to contact the registry as soon as you become aware of your pregnancy by calling 1-866-MODERNA (1-866-663-3762), or ask your healthcare provider to contact the registry for you.

What are the ingredients in SPIKEVAX?

SPIKEVAX contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

SPIKEVAX does not contain SARS-CoV-2, the virus that causes COVID-19. SPIKEVAX cannot give you COVID-19.

SPIKEVAX does not contain preservatives.

What else do I need to know?

Keep your vaccination card. When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of [SPIKEVAX \(also called](#) the Moderna COVID-19 Vaccine). Remember to bring your card when you return.

If you would like more information, talk to your healthcare provider or visit www.spikevax.com or call 1-866-MODERNA (1-866-663-3762).

Manufactured for:
Moderna US, Inc.
Cambridge, MA 02139

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Approval	(b) (6) Commercial 16-Dec-2021 14:18:40 GMT+0000
Approval	Colleen McGraw Regulatory 16-Dec-2021 14:19:02 GMT+0000
Approval	Barbara Kuter Medical 16-Dec-2021 14:29:59 GMT+0000
Approval	Rituparna Das Clinical 16-Dec-2021 15:04:58 GMT+0000
Approval	Jerome Maddox Legal 16-Dec-2021 15:48:10 GMT+0000
Approval	Carla Vinals Regulatory 16-Dec-2021 16:05:32 GMT+0000
Approval	Walter Straus Pharmacovigilance 16-Dec-2021 16:11:45 GMT+0000

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