

Information for Recipients and Caregivers
SPIKEVAX (pronounced SPĪK-văx)
(COVID-19 Vaccine, mRNA)
(2025-2026 Formula)

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

What is SPIKEVAX?

SPIKEVAX is a vaccine to protect against COVID-19. SPIKEVAX is for people who are:

- 65 years of age and older, or
- 6 months through 64 years of age at high risk for severe COVID-19.

Vaccination with SPIKEVAX may not protect all people who receive the vaccine.

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

Who should not get SPIKEVAX?

You or your child should not get SPIKEVAX if you or your child had:

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

What should I tell the healthcare provider?

Tell the healthcare provider about all of your or your child's medical conditions, including if you or your child:

- 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.

What are the risks of SPIKEVAX?

Severe allergic reactions have occurred in some people who have received SPIKEVAX and Moderna COVID-19 vaccines. 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 1 hour after getting a dose of SPIKEVAX. For this reason, the healthcare provider may ask you or your child to stay for a short time at the place where you or your child received the vaccine.

Signs of a severe allergic reaction can include:

- Trouble 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 mRNA COVID-19 vaccines, including SPIKEVAX and Moderna COVID-19 vaccines. Myocarditis and pericarditis following administration of mRNA COVID-19 vaccines have occurred most commonly in males 12 years through 24 years of age. In most of these people, symptoms began within a week following vaccination. Based on available data, estimated rates of myocarditis and/or pericarditis from 1 through 7 days after getting a dose of the 2023-2024 Formula of mRNA COVID-19 vaccines were approximately 8 cases per million doses in people 6 months through 64 years of age and approximately 27 cases per million doses in males 12 years through 24 years of age.

In most people who have had myocarditis or pericarditis after receiving an mRNA COVID-19 vaccine, symptoms have gone away a few days after receiving treatment with medicines used to reduce inflammation.

In a study, follow-up information was collected on people who developed myocarditis after receiving the original formula of a COVID-19 vaccine; most people had received an mRNA COVID-19 vaccine. Some people in the study reported having heart symptoms approximately 3 months after developing myocarditis. Some people in the study had heart MRIs (scans that show detailed images of the heart muscle) initially after developing myocarditis and again approximately 5 months later. The initial and follow-up heart MRIs commonly showed signs of injury to the heart muscle, with improvement over time in most people. It is not known if these heart MRI findings might predict long-term heart effects of myocarditis. Studies are underway to find out if there are long-term heart effects in people who have had myocarditis after receiving an mRNA COVID-19 vaccine.

You should seek medical attention right away if you or your child has any of the following symptoms after receiving SPIKEVAX, particularly during the 2 weeks after receiving a dose of the vaccine:

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

These could be symptoms of myocarditis or pericarditis.

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in clinical trials with SPIKEVAX and Moderna COVID-19 vaccines include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection or in the groin, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever, rash, irritability/crying, sleepiness, and loss of appetite

Other side effects that have been reported include:

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine
- Febrile seizures (convulsions during a 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 or my child is pregnant or breastfeeding?

If you are or your child is pregnant or breastfeeding, discuss your options with your or your child's healthcare provider.

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
- sucrose

SPIKEVAX does not contain preservatives.

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:
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