Information for Recipients and Caregivers

MNEXSPIKE (pronounced em nex' spyk) (COVID-19 Vaccine, mRNA) (2025-2026 Formula)

Please read this information sheet before getting MNEXSPIKE. 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 MNEXSPIKE?

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

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

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

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

Who should not get MNEXSPIKE?

You should not get MNEXSPIKE if you had:

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

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 MNEXSPIKE given?

MNEXSPIKE is given as an injection into the muscle.

What are the risks of MNEXSPIKE?

There is a very small chance that MNEXSPIKE 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 MNEXSPIKE. 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:

- 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. 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 MNEXSPIKE, particularly during the 2 weeks after receiving 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.

Side effects that have been reported in clinical trials with MNEXSPIKE 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, vomiting, and fever.

These may not be all of the possible side effects of MNEXSPIKE. 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.

What are the ingredients in MNEXSPIKE?

MNEXSPIKE 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
- sucrose

MNEXSPIKE does not contain preservatives.

If you would like more information, talk to your healthcare provider or visit <u>MNEXSPIKE.com</u> or call 1-866-MODERNA (1-866-663-3762).

Manufactured for: Moderna US, Inc. Princeton, NJ 08540

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Patent(s): www.modernatx.com/patents

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