

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 MNEXSPIKE.com or call 1-866-MODERNA (1-866-663-3762).

Manufactured for:
Moderna US, Inc.
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MNEXSPIKE is a trademark of ModernaTX, Inc.
Patent(s): www.modernatx.com/patents
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Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. Women who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.



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4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/flu.



COVID-19 Vaccine:

What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

COVID-19 vaccine can prevent COVID-19 disease. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

COVID-19 is caused by a coronavirus called SARS-CoV-2 that spreads easily from person to person. COVID-19 can be mild to moderate, lasting only a few days, or it can be severe, requiring hospitalization, intensive care, or a ventilator to help with breathing. COVID-19 can also result in death.

COVID-19 symptoms may appear 2 to 14 days after exposure to the virus. A person can have mild, moderate, or severe symptoms.

- Symptoms can include fever; chills; cough; shortness of breath or difficulty breathing; fatigue (tiredness); muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea; vomiting; and diarrhea.
- More serious symptoms can include trouble breathing; persistent pain or pressure in the chest; new confusion; inability to wake or stay awake; and pale, gray, or blue-colored skin, lips, or nail beds (depending on skin tone).

Older adults and people of any age with certain underlying medical conditions (like heart or lung disease or diabetes) are more likely to get very sick with COVID-19.

After COVID-19 illness, some people get Long COVID, a chronic condition with symptoms lasting 3 months or longer. Symptoms of Long COVID may get better, get worse, or stay the same.

People who are up to date with COVID-19 vaccination have a lower risk of severe illness, hospitalization, and death from COVID-19 than people who are not up to date. COVID-19 vaccination is the best way to prevent Long COVID.

Getting a COVID-19 vaccine helps the body learn how to defend itself from the disease and reduces the risk for severe illness and complications. Additionally, COVID-19 vaccines can offer added protection to people who have already had COVID-19, including protection against being hospitalized if they become infected with COVID-19 again.

2. COVID-19 vaccine

Updated 2024–2025 COVID-19 vaccine is recommended for everyone 6 months of age and older. This includes women who are pregnant, breastfeeding, trying to get pregnant now, or who might become pregnant in the future.

2024–2025 COVID-19 vaccines for infants and children 6 months through 11 years of age are available under Emergency Use Authorization from the U. S. Food and Drug Administration (FDA). Please refer to the Fact Sheets for Recipients and Caregivers for more information.

For people 12 years of age and older, 2024–2025 COVID-19 vaccines, manufactured by ModernaTX, Inc. or Pfizer, Inc., are approved by FDA.

Novavax COVID-19 Vaccine Adjuvanted (2024–2025 Formula) vaccine is available under Emergency Use Authorization from FDA for people 12 years and older. Please refer to the Fact Sheet for Recipients and Caregivers for more information.

- **Everyone 6 months of age and older** is recommended to receive an age-appropriate FDA-approved or authorized updated 2024–2025 COVID-19 vaccine.
- **Certain people, such as those who have medical conditions or are taking medications that affect the immune system,** may need additional doses of COVID-19 vaccine. Your health care provider can advise you.



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3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of COVID-19 vaccine** or has any **severe, life-threatening allergies**
- Has had **myocarditis** (inflammation of the heart muscle) or **pericarditis** (inflammation of the lining outside of the heart)
- Has had **multisystem inflammatory syndrome** (called MIS-C in children and MIS-A in adults)

In some cases, your health care provider may decide to postpone COVID-19 vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill, including with COVID-19, should usually wait until they recover.

COVID-19 vaccine may be given at the same time as other vaccines.

4. Risks of a vaccine reaction

- Pain, swelling, and redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. These risks have been observed most frequently in adolescent and young adult males. The chance of this occurring is low.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

V-Safe is a safety monitoring system that lets you share with CDC how you, or your dependent, feel after getting COVID-19 vaccine. You can find information and enroll in V-Safe at vsafe.cdc.gov.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

Seek medical attention right away if the vaccinated person experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after COVID-19 vaccination. These could be symptoms of myocarditis or pericarditis.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6. Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit the program's website at www.hrsa.gov/cicp, or call **1-855-266-2427**.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for COVID-19 Fact Sheets, package inserts, and additional information at www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's COVID-19 vaccines website at www.cdc.gov/covid/vaccines/index.html.

