

VACCINE INFORMATION STATEMENT

The Moderna COVID-19 Vaccine: *What You Need to Know*

Mayo Clinic created this Vaccine Information Statement for use temporarily until the official CDC versions are available.

1 Why get vaccinated against COVID-19?

This COVID-19 vaccine can prevent the COVID-19 infection.

The COVID-19 infection (also called coronavirus disease 2019) is caused by SARS-CoV-2 virus.

Symptoms can range from no symptoms at all to severe acute respiratory syndrome. Most common symptoms include fever, cough, loss of smell and taste, and fatigue.

Symptoms usually appear 2 to 14 days after infection. Early symptoms may include a loss of taste and smell. Other symptoms include shortness of breath or difficulty breathing, muscle aches, chills, sore throat, runny nose, headache, and chest pain. Some people have experienced rash, nausea, vomiting and diarrhea.

Some people have only mild symptoms or none at all. Children are less likely to have symptoms and more likely to have a mild form of the illness.

Some people develop lung or other organ infections severe enough to result in hospitalization and death. The risk of severe disease increases with age over 50 years, obesity and presence of other medical conditions.

SARS-CoV-2 spreads by respiratory droplets or small particles when an infected person coughs, sneezes, sings, talks or breathes especially when in close contact (within 6 feet) of other people.

Some people have reported they have gotten the virus twice. This is called reinfection. But this is not thought to be common.

This virus is very contagious. It spreads more easily from person to person than the virus that causes flu, also known as influenza. SARS-CoV-2 also is more likely to result in hospitalization, critical care and death.

2 The Moderna COVID-19 vaccine

The Moderna COVID-19 vaccine provides protection against COVID-19 infection. It is one of several vaccines developed to protect against COVID-19 infection.

In a randomized, controlled trial involving over 30,000 volunteers, the vaccine prevented symptomatic

COVID-19 infection in 94% of the people who were vaccinated. The rate was 96% in those 18 to 65 years old and 86% in those 65 years and older.

The Moderna COVID-19 vaccine is recommended for adults 18 years of age and older. The vaccine is given in two doses. The second dose is given 28 days after the first.

If you are immunocompromised, your health care provider may recommend you receive a third dose at least 4 weeks after the second dose.

3 Talk with your health care provider

Tell your vaccine provider if you:

- Have had an allergic reaction after a previous dose of the Moderna COVID-19 vaccine or have a severe life-threatening allergy (anaphylaxis) to components in the vaccine, any other vaccine or any prior injections. While you may get the vaccine, those with history of anaphylaxis need to stay for 30 minutes after the injection to be observed.
- Are experiencing signs or symptoms of COVID-19 infection.
- Are acutely ill or contagious with the COVID-19 infection.
- Had COVID-19 infection in the last 90 days.
- Have a condition that causes your immune system to be weakened or compromised. It is safe to get the vaccine, but this may mean that the vaccine won't be as effective for you.
- Are taking a blood-thinning medication or have a bleeding disorder.
- Are pregnant or breastfeeding. In some situations, your health care provider may decide to postpone the COVID-19 vaccination to a future visit.

People with minor illnesses, such as a bladder infection, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting the COVID-19 vaccine.

Your health care provider can give you more information and answer any questions.

4 Risks of a vaccine reaction

- **Pain.** Most people had pain where the shot was given. This happened with both doses. For some people, the injection pain was severe enough to temporarily prevent them from doing daily activities.
- **Redness or swelling.** About 9 out of 10 people had redness or swelling where the shot was given.
- **Fever.** About 1 in 7 people got a fever after they received the vaccine.
- **Fatigue.** About 7 out of 10 people had fatigue. For some people, it was severe enough to temporarily prevent them from doing daily activities.
- **Chills.** About 2 out of 5 people had chills.
- **Headache.** About 6 out of 10 had a headache.
- **Muscle pain.** About 3 out of 5 people had muscle pain. One out of 10 people had pain that was severe enough to temporarily prevent them from doing daily activities.
- **Joint pain.** About 2 out of 5 had joint pain. One out of 20 people had pain that was severe enough to prevent them from doing daily activities.

These reactions are more frequent and more severe after the second dose and in those 65 years and younger. These side effects generally occurred within 2 days after vaccination and got better in 24 to 48 hours.

- **Myocarditis and pericarditis.** In a few rare cases, people have developed inflammation of the heart muscle, called myocarditis, or inflammation of the lining outside the heart, called pericarditis, after receiving this vaccine. In people who developed these conditions, symptoms began within a few days of the vaccination. Symptoms are more common after the second dose of vaccine. Most of those who developed these conditions were male adolescents and young adults 16 years and older. Seek medical care right away if you have any of these symptoms:
 - Chest pain.
 - Shortness of breath.
 - Heart palpitations, a fast-beating heart, feeling like your heart skips a beat, or like your heart is fluttering.

You should still get the second dose of the Moderna vaccine even if you had one of these reactions after the first dose.

Some people faint after medical procedures, including vaccinations. Tell your provider if you feel dizzy, have vision changes or have ringing in your ears.

As with any medicine, there is a very small chance that a vaccine could cause 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 have signs of a severe allergic reaction, such as hives, swelling of the face or throat, difficulty breathing, a fast heartbeat, dizziness or weakness, call 911 or have someone drive you to the nearest hospital.**

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

Adverse or allergic reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider may 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 does not give medical advice.

6 How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit the CDC at www.cdc.gov/vaccines

7 How can I help?

V-SAFE is a voluntary vaccine safety data collection system. It uses text messaging and web surveys to provide personalized health check-ins after your COVID-19 vaccination. V-SAFE allows you to report any side effects after COVID-19 vaccination to the CDC soon after they occur. It also reminds you to get your second COVID-19 vaccine dose. Sign up for V-SAFE at <https://vsafe.cdc.gov> when you get your first dose of COVID-19 vaccine. You can enroll in V-SAFE on your phone or other mobile device. Mayo Clinic asks all COVID-19 vaccine recipients to take part in V-SAFE.