

# Getting the Moderna COVID-19 Vaccine

## What to Expect During & After Your Injection

### EMERGENCY USE AUTHORIZATION

For certain indications, the Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by the FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. There are two presentations/formulations of the Moderna COVID-19 Vaccine authorized for use.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.

### Before you get the vaccine

Tell your vaccination provider if you:

- Have any allergies
- 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 another COVID-19 vaccine
- Have ever fainted in association with an injection

For more information, visit [modernatx.com/covid19vaccine-eua/recipients/](https://www.modernatx.com/covid19vaccine-eua/recipients/)

### After you get the vaccine

Side effects that have been reported in clinical trials with the Moderna COVID-19 Vaccine 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, fever, and rash

Talk to your vaccination provider if you have side effects that bother you or do not go away.

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

**If you think you're having an allergic reaction to the vaccine, call 9-1-1.**

Signs of a severe allergic reaction can include: difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness and weakness.

## A second dose of the Moderna COVID-19 Vaccine is REQUIRED

Complete vaccination **1 month** after your first dose of the Moderna COVID-19 Vaccine.

To help remember that appointment:

Immediately schedule your next appointment after the first dose of your vaccine



Ask for an **additional dose reminder card** to display prominently at home



Set a reminder on your mobile phone or calendar



A first booster dose of the Moderna COVID-19 Vaccine may be administered at least **5 months** after completion of a primary series to certain individuals. A second booster dose may be administered at least **4 months** after your first booster for certain individuals. Please check with your healthcare provider regarding eligibility for and scheduling of booster doses.

**For more information, talk to your vaccination provider or call Moderna Customer Care at: 1-866-MODERNA (1-866-663-3762)**

### What is the Moderna COVID-19 Vaccine?

Moderna COVID-19 Vaccine is authorized to provide:

- a two-dose primary series to individuals 18 years of age and older;
- a third primary series dose to individuals 18 years of age and older with certain kinds of immunocompromise;
- a first booster dose to individuals 18 years of age and older who have completed a primary series with Moderna COVID-19 Vaccine or SPIKEVAX (COVID-19 Vaccine, mRNA);
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series;
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and
- a second booster dose to individuals 18 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine.

FDA has approved SPIKEVAX (COVID-19 Vaccine, mRNA) as a two-dose primary series one month apart for prevention of COVID-19 in individuals ages 18 years of age and older.

Please see the [Fact Sheet for Recipients and Caregivers](#) for more information.

For information regarding SPIKEVAX, please see the [SPIKEVAX Full Prescribing Information and Information for Recipients and Caregivers](#).

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## IMPORTANT SAFETY INFORMATION

### What should you mention to your vaccination provider before you get the vaccine?

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

- have any allergies
- 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 another COVID-19 vaccine
- have ever fainted in association with an injection

### Who should **not** get the vaccine?

You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

### What are the risks of the vaccine?

There is a remote chance that the vaccine 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 the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad 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 the 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 vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- 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 the vaccine 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, fever, and rash

**Please see the [Fact Sheet for Recipients and Caregivers](#) for more information.**

**For information regarding SPIKEVAX, please see the [SPIKEVAX Full Prescribing Information](#) and [Information for Recipients and Caregivers](#).**

## IMPORTANT SAFETY INFORMATION (CONT.)

Side effects that have been reported during post-authorization use of the vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

### **What should I do about side effects?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include either "SPIKEVAX (COVID-19 Vaccine, mRNA)" or "Moderna COVID-19 Vaccine EUA," as appropriate, in the first line of box #18 of the report form.

In addition, you can also report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

### **What if I am immunocompromised?**

If you are immunocompromised, you may receive a third primary series dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

### **What if I am pregnant or breastfeeding?**

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

*Please see the [Fact Sheet for Recipients and Caregivers](#) for more information.*

*For information regarding SPIKEVAX, please see the [SPIKEVAX Full Prescribing Information](#) and [Information for Recipients and Caregivers](#).*