

COVID-19 Vaccine, mRNA (Moderna)

Brand Name(s): Spikevax[®]

Other Name(s): mRNA COVID-19 vaccine , mRNA-1273 , SARS-CoV-2 (COVID-19) vaccine, mRNA spike protein, Zorecimeran

Notification: COVID-19 vaccine, mRNA (Moderna; Spikevax), is approved by the FDA as a primary (2-dose) series to prevent COVID-19 caused by the SARS-CoV-2 virus in people 18 years of age and older.

Information from clinical trials is available at this time to support the use of Moderna COVID-19 vaccine to prevent COVID-19.

The FDA has also approved an EUA for the COVID-19 vaccine, mRNA (Moderna; Spikevax) to allow:

- a **third dose** in certain people 18 years of age and older who are immunocompromised (have a weakened immune system).
- a **single booster dose** to people 18 years of age and older who have completed a primary series with Moderna COVID-19 vaccine.
- a **single booster dose** to people 18 years of age and older who have completed a primary series with a different authorized COVID-19 vaccine.
- a **second booster dose** to people 50 years of age and older who have received a first booster dose with any authorized or approved COVID-19 vaccine.
- a **second booster dose** to people 18 years of age and older who are immunocompromised (have weakened immune system) who have received a first booster dose with any authorized or approved COVID-19 vaccine.

Talk to your doctor or vaccine provider about the risks and benefits of receiving this medication.

What is COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory (lung) illness, but it can also affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever, chills, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, runny nose, nausea, vomiting, or diarrhea.

How is the Moderna COVID-19 vaccine given?

The Moderna COVID-19 vaccine will be given to you as an injection into the muscle. For most individuals, the Moderna COVID-19 vaccine primary vaccination series is 2 doses given 1 month (4 weeks) apart. If you receive one dose of the Moderna COVID-19 vaccine, you should receive a second dose of this *same* vaccine 1 month later. If you are immunocompromised (have a weakened immune system), you may receive a third dose of the *same* vaccine at least 1 month after the second dose.

This leaflet does not contain all the possible information about this drug. Your doctor or pharmacist can give you additional information to answer any questions you may have.

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As authorized under an EUA, the Moderna COVID-19 vaccine may be given as:

- a **single booster dose** may be given at least 5 months after the primary series is completed in people 18 years of age and older.
- a **single booster dose** to people 18 years of age and older who have completed a primary series with a different authorized or approved COVID-19 vaccine. Please check with your healthcare provider regarding the timing of the booster.
- a **second booster dose** may be given at least 4 months after the first booster dose of any FDA-approved COVID-19 vaccine in people 50 years of age or older or 18 years of age and older who are immunocompromised (have weakened immune systems).

What should you tell the person who is giving the vaccine?

Tell your vaccine 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 such as warfarin (Coumadin, Jantoven).
- have a weakened immune system 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 after getting a vaccine or a shot
- have had a severe allergic reaction after a previous dose of this vaccine.
- have had a serious allergic reaction to any ingredient in this vaccine.

What are the benefits of the Moderna COVID-19 vaccine?

In an ongoing clinical trial, the Moderna COVID-19 vaccine has been shown to prevent COVID-19 after getting 2 doses given 1 month apart. How long you are protected against COVID-19 is currently unknown.

What are the risks of the Moderna COVID-19 vaccine?

Side effects that have been reported with the Moderna COVID-19 vaccine include:

- injection site pain, swelling, and redness
- tenderness and swelling of lymph nodes (in the same arm where you got the injection)
- tiredness
- headache

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- muscle pain
- joint pain
- chills
- nausea
- vomiting
- fever
- rash
- fainting at the time you receive your injection

There is a remote chance that the Moderna COVID-19 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 Moderna COVID-19 vaccine.

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 and pericarditis have occurred in some people who have received the Moderna COVID-19 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 after getting the second dose of the Moderna COVID-19 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 Moderna COVID-19 vaccine:

- chest pain
- shortness of breath
- feelings of having a fast-beating, fluttering, or pounding heart

These may not be all the possible side effects of the Moderna COVID-19 vaccine. Serious and unexpected side effects may occur. Moderna COVID-19 vaccine is still being studied in clinical trials.

What should I do about side effects?

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.

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- 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 "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.
- In addition, you can report side effects to ModernaTX, Inc. at 1-866-663-3762.
- You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: <http://www.cdc.gov/vsafe>.

What if I am immunocompromised?

If you are immunocompromised (have a weakened immune system), you may receive a third dose of the Moderna COVID-19 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.

Will the Moderna COVID-19 vaccine give me COVID-19?

No. The Moderna COVID-19 vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

Keep your vaccination card

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Moderna COVID-19 vaccine. If you are immunocompromised (have a weakened immune system), you may receive information on when to return for a third dose. Remember to bring your card when you return.

Where will my vaccination information be recorded?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for your next dose of Moderna COVID-19 vaccine. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

How can I learn more?

You can learn more:

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <http://bit.ly/3qI0njF>.

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- Contact your local or state public health department.

Can I be charged an administration fee for receiving the COVID-19 vaccine?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

Where can I report cases of suspected fraud?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

What is the 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 year from the date of receiving the vaccine. To learn more about this program, visit <http://www.hrsa.gov/cicp/> or call 1-855-266-2427.

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