

# COVID-19 Vaccine FAQ for Patients



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## What is an EUA?

An Emergency Use Authorization is allowed in instances where a public health threat is identified and there is no approved or adequate existing products. The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits outweigh potential risks. For more information about EUAs visit <https://www.youtube.com/watch?v=iGkwaESsGBQ>.

Source: FDA. (2020). Emergency Use Authorization for Vaccine Explained. Retrieved from <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

## What is Operation Warp Speed?

Operation War Speed's goal is to make a safe and effective COVID-19 vaccine widely available as soon as possible. In traditional vaccine development timelines, manufacturing steps are carried out in a sequential basis, however, with Operation Warp Speed manufacturing steps are carried out simultaneously. This increases the financial risk, but does not compromise the safety of the vaccine.

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>

## Is Natural Immunity better than vaccine-induced immunity? Am I better off getting COVID-19 instead of getting the vaccine?

Natural immunity comes from fighting off a virus, however, COVID-19 can have serious, life-threatening complications, there is no way to know how COVID-19 will affect a person. There are potential serious, long-term health issues after recovering from COVID-19. It is not known whether getting COVID-19 protects you from getting the virus again in the future, or how long natural immunity lasts. Additionally, when you become infected with the virus, you risk transmitting it to the people around you.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>

## Can I stop wearing a mask/social distancing after I get the vaccine?

While the vaccine greatly reducing your risk of contracting COVID-19, it is not a perfect fix, you will still need to practice precautions like wearing a mask, social distancing, and other hygiene measures until public health experts say otherwise.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>

## Could the vaccine cause long term side effects or other problems that we do not know about yet?

The FDA and CDC are continuing the monitor the safety of the vaccine, to identify any possible long-term side effects. The ACIP will take action to address any safety issues that are identified. When you receive the vaccine, you will be provided with resources to report any adverse reaction to the vaccine.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>

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## Moderna COVID-19 Vaccine

### What is mRNA?

The Moderna COVID-19 Vaccine is an mRNA vaccine. mRNA vaccines are not made up of the actual pathogen, they are made up of genetic information and not parts of the virus. The mRNA must be taken up into the body's cells, and the cells are then able to produce the protein that stimulates the immune response. mRNA vaccines train the body to identify and attack the coronavirus protein. Receiving an mRNA vaccine will not affect your DNA.

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from <https://www.acsh.org/news/2020/10/21/how-pfizers-rna-vaccine-works-15104>

### Will the vaccine make you sick?

The vaccine cannot give someone COVID-19 because it does not contain the live virus. Side effects can occur with any vaccine, as they are a sign that the immune system is working to build up protection against a virus. Symptoms from the vaccine typically resolve within a week, but patients should know when to seek medical care if their symptoms do not go away.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>

### Is the Moderna COVID-19 Vaccine safe?

The Food and Drug Administration (FDA) and Advisory Committee on Immunization Practices (ACIP) carefully review all safety data from clinical trials before authorizing emergency vaccines and recommend the vaccine for use only when the expected benefits outweigh potential risks. The FDA and CDC will continue to monitor the safety of these vaccines. There is a reporting system in place to identify any possible side effects or adverse events.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>

### What is the Vaccine Adverse Event Reporting System? What is the V-safe Monitoring System?

The Vaccine Adverse Event Reporting System (VAERS) is a national monitoring system that tracks instances of vaccine adverse events. Healthcare personal and vaccine manufacturers are required to report adverse events that occur after vaccination in VAERS. V-safe is a new smartphone-based health monitoring system for people who receive the COVID-19 vaccine. V-safe uses text messaging and web surveys to provide daily health check-ins with COVID-19 vaccine recipients and will provide telephone follow up to anyone who reports medically important adverse events. A VAERS report will be taken during telephone follow up, if appropriate.

Source: CDC. (2020). Ensuring the Safety of COVID-19 Vaccines in the United States. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

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### How is the Moderna COVID-19 Vaccine administered?

The Moderna COVID-19 Vaccine is administered intramuscularly in a series of two injections, with a waiting period of 28 days between the injections. After administration, the person receiving the vaccine will be monitored for 15 minutes by vaccination staff.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from <http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf>.

### What are the ingredients in the Moderna COVID-19 Vaccine?

The Moderna COVID-19 Vaccine contains: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from <http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf>.

### What are the potential risks and side effects of the Moderna COVID-19 Vaccine?

Side effects that have been reported 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 include fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever.

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. 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.

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from <http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf>.

### If I have an allergic reaction to the first dose of Moderna COVID-19 Vaccine can I get the second dose?

If you have an allergic reaction to the first dose of the Moderna COVID-19 Vaccine it is not recommended that you get the second dose of the vaccine.

Source: Moderna. (2020). Fact Sheet for Recipients and Caregivers. Retrieved from <http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf>.

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### If I have already had COVID-19 how long do I need to wait to get the COVID-19 Vaccine?

If you have had a previous COVID-19 infection, you are still able to receive the COVID-19 Vaccine. People with a known current COVID-19 infection should wait until they have recovered from the acute illness and criteria have been met to end the isolation period. If you received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, it is recommended that you wait 90 days before vaccination . If you did not receive any of these treatments for a COVID-19 infection, there is no recommended minimum interval between infection and vaccination.

Source CDC. (2020). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

### Can I get the COVID-19 Vaccine if I'm pregnant or breast feeding?

There are currently no available data on the safety of COVID-19 Vaccines in pregnant individuals. However, studies are ongoing and expected to be available soon. The mRNA in the vaccine is degraded quickly in the body by normal cell processes, and experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant. However, pregnant people who develop a COVID-19 infection are at increased risk of adverse pregnancy outcomes. Pregnant people may choose to be vaccinated. A conversation between the patient and their doctor may assist with decisions of whether or not to vaccinate. When making a decision pregnant people should consider their level of COVID-19 community transmission, their own level of exposure to COVID-19, the side effects of the vaccine, and the risks of a COVID-19 infection to the patient and potential risk to the fetus.

There are no data on the safety of COVID-19 vaccines in lactating people. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person may choose to be vaccinated.

Source CDC. (2020). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

### Can I get the vaccine if I have had food/ bee allergy?

If you have a history of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies you can still receive the Moderna COVID-19 Vaccination. A 30 minute observation period following vaccination is recommended for anyone with a history of a severe allergic reaction.

Source CDC. (2020). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>