FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT MODERNA COVID-19 VACCINE (2024-2025 FORMULA) WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE

Your child is being offered Moderna COVID-19 Vaccine (2024-2025 Formula)[1] to prevent coronavirus disease 2019 (COVID-19), which is caused by the virus SARS-CoV-2.[2] This Fact Sheet contains information to help you understand the risks and benefits of Moderna COVID-19 Vaccine (2024-2025 Formula), hereafter referred to as Moderna COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make Moderna COVID-19 Vaccine available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). Moderna COVID-19 Vaccine is not an FDA-approved vaccine in the United States. Read this Fact Sheet for information about Moderna COVID-19 Vaccine.

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close contact with another person who has the virus.

It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

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[1] Moderna COVID-19 Vaccine (2024-2025 Formula) encodes the spike protein of the SARS-CoV-2 Omicron variant KP.2.

[2] If your child is immunocompromised and turning from 11 to 12 years of age during the vaccination series for immunocompromised individuals, you may receive this Fact Sheet because your child is being offered SPIKEVAX (COVID-19 Vaccine, mRNA) (2024-2025 Formula) (hereafter referred to as SPIKEVAX). SPIKEVAX is an FDA-approved vaccine for prevention of COVID-19 in individuals 12 years of age and older that is authorized under EUA to complete the dosing schedule for immunocompromised individuals who turn from 11 years to 12 years of age during the vaccination series. Under the authorized dosing schedule, these individuals receive the Moderna COVID-19 Vaccine before they turn 12 years old, and complete the vaccination series with SPIKEVAX on or after the date the individual turns 12 years old. The dosing schedule is a three-dose series, with each dose one month apart. The information in this Fact Sheet about the Moderna COVID-19 Vaccine, including information about the benefits, risks, and ingredients of that vaccine, also applies to your child's use of SPIKEVAX, except with respect to the dosing schedule and the ages authorized for use.

WHAT IS MODERNA COVID-19 VACCINE?

Moderna COVID-19 Vaccine is a vaccine for use in individuals 6 months through 11 years of age to prevent COVID-19. The FDA has authorized the emergency use of Moderna COVID-19 Vaccine under an EUA.

Moderna COVID-19 Vaccine may not protect everyone.

WHAT SHOULD YOU MENTION TO THE VACCCINATION PROVIDER BEFORE YOUR CHILD GETS MODERNA COVID-19 VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

Moderna COVID-19 Vaccine is given as an injection into the muscle.

Individuals 6 months through 4 years of age:

- **Unvaccinated individuals:** Two doses of Moderna COVID-19 Vaccine are administered. The second dose is administered 1 month after the first.
- **Individuals who have received one previous dose of a Moderna COVID-19 vaccine[3]:** A single dose of Moderna COVID-19 Vaccine is administered 1 month after a previous Moderna COVID-19 vaccine.
- **Individuals who have received two or more previous doses of a Moderna COVID-19 vaccine[2]:** A single dose of Moderna COVID-19 Vaccine is administered at least 2 months after the last previous dose of a Moderna COVID-19 vaccine.

Individuals 5 years through 11 years of age:

- A single dose of Moderna COVID-19 Vaccine is administered to individuals who have not received a COVID-19 vaccine (2024-2025 Formula). You must wait at least 2 months since your last dose of any COVID-19 vaccine.

[3] Previous dose refers to a dose with any prior Moderna COVID-19 vaccine that is no longer authorized for use in the United States.

Immunocompromised individuals 6 months through 11 years of age:
Additional doses of Moderna COVID-19 Vaccine may be administered. For more information, talk to your child's healthcare provider.

WHO SHOULD NOT GET MODERNA COVID-19 VACCINE?

Your child should not get Moderna COVID-19 Vaccine if your child had:

- a severe allergic reaction after a previous dose of any Moderna COVID-19 vaccine.
- a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THIS VACCINE?

Moderna COVID-19 Vaccine 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, acetic acid, sodium acetate trihydrate, and sucrose.

HAS THIS VACCINE BEEN USED BEFORE?

Millions of individuals 6 months of age and older have received a Moderna COVID-19 vaccine under EUA. In clinical trials, approximately 5,000 individuals 6 months through 5 years of age, 4,000 individuals 6 years through 11 years of age, and 30,000 individuals 12 years of age and older have received at least 1 dose of Moderna COVID-19 Vaccine (Original monovalent).[4]

WHAT ARE THE BENEFITS OF MODERNA COVID-19 VACCINE?

FDA has authorized Moderna COVID-19 Vaccine to provide protection against COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF MODERNA COVID-19 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. For this reason, the vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the 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 Moderna COVID-19 vaccines have occurred most commonly in young adult males 18 years through 24 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very

[4] Moderna COVID-19 Vaccine (Original monovalent) refers to Moderna COVID-19 Vaccine that encodes the spike protein of only the Original SARS-CoV-2. This vaccine is no longer authorized for use in the United States.

low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in clinical trials with Moderna COVID-19 vaccines include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection or in the groin, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever, rash, irritability/crying, sleepiness, and loss of appetite

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

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine
- Febrile seizures (convulsions during a fever)

These may not be all the possible side effects. Serious and unexpected side effects may occur. The possible side effects are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child 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 "Moderna COVID-19 Vaccine (2024-2025 Formula) 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-MODERNA (1-866-663-3762).

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET MODERNA COVID-19 VACCINE?
Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care.

ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under EUA, including vaccines that encode the spike protein of the SARS-CoV-2 Omicron variant lineage KP.2 (Omicron KP.2).

CAN MY CHILD RECEIVE MODERNA COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
If you are considering having your child receive Moderna COVID-19 Vaccine with other vaccines, discuss your options with your child's healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?
Immunocompromised individuals 6 months through 11 years of age may receive additional doses of Moderna COVID-19 Vaccine (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, your child should continue to maintain physical precautions to help prevent COVID-19. Your child's close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If your child is pregnant or breastfeeding, discuss the options with your child's healthcare provider.

WILL THIS VACCINE GIVE MY CHILD COVID-19?
No. This vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

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 (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The FDA has made Moderna COVID-19 Vaccine available under an emergency access mechanism call an EUA. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used under EUA during the COVID-19 pandemic.

The EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used under the EUA).

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

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To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry.

Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

The mRNA vaccines (those by Pfizer and Moderna) did not use a fetal cell line to produce or manufacture the vaccine. However, a fetal cell line was used in a very early phase to confirm efficacy prior to production and manufacturing.

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