

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS**  
**EMERGENCY USE AUTHORIZATION (EUA) OF MODERNA COVID-19 VACCINE**  
**TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18**  
**YEARS OF AGE AND OLDER**

**Commented [A1]:** SPONSOR COMMENT: Moderna has accepted the Division's changes and updated the font consistency as requested. Tracked changes in this document show changes implemented at the Division's request and minor editorial changes.

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may protect you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to your healthcare provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a series of 2 doses into the muscle of the upper arm. The second dose is administered 1 month after the first dose.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

**WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE**

**WHAT IS COVID-19?**

COVID-19 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 illness that can affect other organs of the body. 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 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.

**WHAT IS THE MODERNA COVID-19 VACCINE?**

The Moderna COVID-19 Vaccine is an investigational (not FDA-approved) vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

## **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?**

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

- Have any allergies
- 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

## **WHO SHOULD GET THE MODERNA COVID-19 VACCINE?**

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

## **WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?**

You should not get the Moderna COVID-19 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 (see **WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?** at the end of this Fact Sheet)

## **HOW IS THE MODERNA COVID-19 VACCINE GIVEN?**

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle of your upper arm.

The Moderna COVID-19 Vaccine vaccination is a series of 2 doses.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

## **HAS THE MODERNA COVID-19 VACCINE BEEN USED SAFELY BEFORE?**

The Moderna COVID-19 Vaccine is an investigational COVID-19 vaccine. In clinical trials, approximately 15,419 adults have received at least 1 dose of the Moderna COVID-19 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 following 2 doses given ~~one~~1 month apart. The duration of protection 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 are:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and

vomiting, and fever

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

#### **WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?**

It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

#### **ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?**

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to protect against COVID-19.

#### **CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

#### **WHAT IF I AM PREGNANT OR BREASTFEEDING?**

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

#### **WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?**

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

#### **KEEP YOUR VACCINATION CARD**

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of Moderna COVID-19 Vaccine. Remember to bring your card when you return.

#### **SERIOUS SIDE EFFECTS**

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

#### **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 “Moderna COVID-19 Vaccine EUA” in the first line of box #18 of the report form. You can also report side effects to Moderna by calling 1-866-MODERNA (1-866-663-3762).

#### **WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?**

Moderna COVID-19 Vaccine contains a synthetic messenger ribonucleic acid (mRNA) coding for a SARS-CoV-2 protein in a suspension of four lipids (SM-102, PEG2000-DMG, cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]). The suspension also contains tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

#### **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
- Visit the Moderna COVID-19 Vaccine website at [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua)

To access the most recent Fact Sheets, please scan the QR code provided below [or visit www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).



#### **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program 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. To learn more about this program, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp) or call 1-855-266-2427.

#### **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The 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.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared 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 during the COVID-19 pandemic.

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

©2020 Moderna, Inc. All rights reserved.

Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)

Revised: 00/2020