Fact sheet for recipients and caregivers of individuals receiving Moderna COVID-19 vaccine

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 U.S. Food and Drug Administration has granted an Emergency Use Authorization (EUA) that allows healthcare providers to administer the Moderna COVID-19 vaccine to prevent COVID-19.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 28 days apart, into the muscle.

This fact sheet may be updated. To ensure you have the most current version, visit www.modernatx.com. For additional information, go to https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine

What you need to know before you receive a COVID-19 vaccine

WHAT IS COVID-19?
COVID-19 is a disease is caused by a new coronavirus called SARS-CoV-2. 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. 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 was developed to help prevent COVID-19.

WHAT APPROVAL HAS THE VACCINE RECEIVED?
The FDA has issued an Emergency Use Authorization (EUA) allowing use of the Moderna COVID-19 vaccine to prevent COVID-19 in individuals 18 years of age and older.

WHAT IS AN EMERGENCY USE AUTHORIZATION?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.

Under an EUA, the FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Vaccines must meet specific standards for safety and effectiveness in order to receive an EUA. You can learn more about the EUA process for COVID-19 vaccine here.

Guidance for recipients and caregivers

WHO IS ELIGIBLE?
FDA has authorized the emergency use of the Moderna COVID-19 vaccine in individuals 18 years of age and older. The vaccine is not yet authorized for individuals younger than 16 or pregnant women.

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

WHAT INFORMATION DO I NEED TO GIVE THE VACCINE PROVIDER?
Tell the 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

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 vaccine includes the following ingredients:

Active Ingredient

- mRNA (Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2

Lipids

- Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- Cholesterol
- SM-102 (Proprietary to Moderna)

Salts

- Thromethamine
- Thomethamine hydrocholoride
- Acetic acid
- Sodium Acetate

Other

- Sucrose

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 vaccine will be given to you as an injection into the muscle.
The Moderna COVID-19 vaccine vaccination series is 2 doses given 28 days apart.
If you receive one dose of the Moderna COVID-19 vaccine, you should receive a second dose of this same vaccine 4 weeks later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 vaccine is a new vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least one 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 be approximately 94 percent effective at preventing COVID-19 following 2 doses given at least 4 weeks apart. How long that protection lasts is still being studied.

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
- tiredness
- headache
- muscle pain
- chills
- joint pain
- injection site swelling
- injection site redness

- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

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 you can 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.

Anyone who has received a COVID-19 vaccine is also asked to register for v-safe, a new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-safe uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19.

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