# COVID-19 Moderna Vaccine

Indiana Department of Health

December 2020

## Communication with Recipients

- **Please provide a copy of the attached Vaccine Information for Recipients fact sheet (attached) or direct the individual to copy or direct the individual to the website www.modernatx.com/covid19vaccine-EUA prior to receiving the Moderna COVID-19 vaccine.**
- **Explain the following to individuals before administering the vaccine:**
  - FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
  - The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
  - The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
  - Information about available alternative vaccines and the risks and benefits of those alternatives.
  - Ask the patient up front if he or she has a history of allergic reaction. Do not administer the Moderna COVID-19 Vaccine to individuals with known history of severe allergic reaction (e.g. anaphylaxis) to any component of the Moderna COVID-19 Vaccine.
  - Provide individual with vaccination card found in the ancillary kit.
- **Display or have readily available onsite:**
  - Instructions for Dosage and Vaccine Administration (attached)
  - Ingredients of the Moderna COVID-19 Vaccine (attached)

## *Fast Facts*

- The vaccine is 94% effective at preventing COVID-19
- Few side effects were reported, but included headache, fatigue, and soreness at administration site
- It is a two-part vaccine, so you must get a second dose of the same vaccine (ex. 2nd dose Pfizer in 21 days or 2nd dose Moderna in 28 days)
- Vaccine has an EUA from FDA, Centers for Disease Control and Prevention and Indiana Department of Health
- Vaccine is available to healthcare workers who have close contact with patients or infectious material

For additional information:

www.modernatx.com/covid19vaccine-eua

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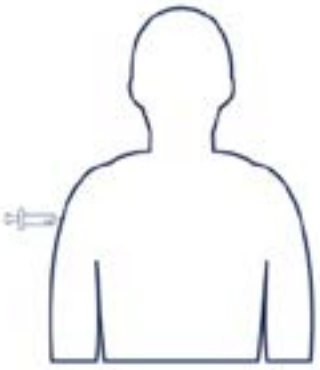
# Dosage and Administration

Consider 5 key points when preparing to administer the Moderna COVID-19 Vaccine:

- In preparation for administration, remove the required number of vials from frozen storage and thaw each vial before use:
    - Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
    - Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
    - After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. Do not shake. Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matte and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Each does is 0.5 mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time for the first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

## Vaccine Administration

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5mL each) 1 month apart.



Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- Verify the final dosing volume of 0.5 mL.
- Confirm there are no other particulates and that no discoloration is observed.
- Do not administer if vaccine is discolored or contains other particulate matter.


Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of the Moderna COVID-19 Vaccine.

## Warnings and Precautions

**Management of Acute Allergic Reactions:** Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID 19 Vaccine.

Limitations of Vaccine Effectiveness: The Moderna COVID 19 Vaccine may not protect all vaccine recipients.

# COVID-19 Vaccine Ingredients

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## 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