Moderna COVID-19 Vaccine, MONOVALENT

[Red Cap with LIGHT BLUE Label Border]

Primary Series for 12 Years and Older

Instructions for Use: Formulation, Storage, Preparation, Dispensing and Administration

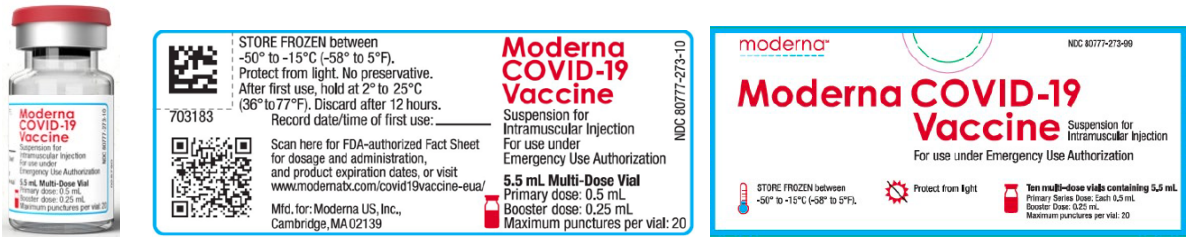
The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals who meet certain criteria.
The FDA Moderna COVID-19 Vaccines website has the most up-to-date information.
(https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines)

1. VACCINE FORMULATION AND DESCRIPTION

Moderna COVID-19 Vaccine with **red cap** and **light blue label border** is supplied as a frozen suspension for intramuscular injection in multiple dose vials containing 5.5 mL per vial or 7.5 mL per vial. The vaccine must be thawed prior to preparation and administration. **DO NOT DILUTE PRIOR TO USE.**

Each **0.5 mL** dose of Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a **red cap** and **light blue label border** contains **100 mcg** of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Wuhan-Hu-1 strain. Each 0.5 mL dose also contains the following ingredients: 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, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose.

The Moderna COVID-19 Vaccine **red cap** and **light blue label border** does not contain preservative, and the vial stoppers are not made with natural rubber latex.



NDC 80777-273-10: Multiple dose vial; contains 10 doses of 0.5 mL or 20 doses of 0.25 mL
NDC 80777-273-99: Carton of 10 multiple dose vials

Reference: *Fact Sheet For Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (Red Cap and Light Blue Label Border) Revised 08 December 2022*
(https://www.fda.gov/media/157233/download)

2. STORAGE AND HANDLING

Moderna COVID-19 Vaccine with **red cap** and **light blue label border** will be shipped to sites frozen in thermal containers. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Refer to the protocol-specific pharmacy manual for quantities of initial and subsequent shipments sent to your site. (***As of August 31, 2022, this formulation is no longer used in DAIT studies***)

2.1. Vial Storage Prior to Use

2.1.1. Freezer: Once the shipment is received, remove the vial cartons from the shipping container and store vaccine frozen at -50ºC to -15ºC (-58ºF to 5ºF)

2.1.2. Refrigerator: Frozen vials may be transferred to the refrigerator [2ºC to 8ºC (36ºF to 46ºF)], thawed and stored for up to 30 days, but not past the vial expiration date. The 30-day refrigerated expiry date should be recorded on the carton at the time of transfer. Vials may take 2 hours and 30 minutes (5.5 mL vial) or 3 hours (7.5 mL vial) to thaw in the refrigerator. Once vials are thawed, they should not be refrozen.

2.2. Vial Storage During Use

If not previously thawed at 2ºC to 8ºC (35ºF to 46ºF), allow vials to thaw at room temperature [up to 25ºC (77ºF)] for 1 hour (5.5 mL vial) or 1 hour and 30 minutes (7.5 mL vial).

Moderna COVID-19 Vaccine, multiple dose vials, may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours.

After first puncture, multiple dose vials should be held between 2ºC to 25°C (35°F to 77°F) and used within 12 hours.

2.3. Prepared Syringe Storage

Prepared syringes of the Moderna COVID-19 Vaccine should be stored between 2°C to 25°C (35°F to 77°F) and used within 12 hours after the first puncture of the vial. Discard punctured vials and prepared syringes after 12 hours. Do not refreeze prepared syringes.

2.4. Transportation of Vials

If local redistribution is needed, vials may be transported at -50°C to -15°C (-58°F to 5°F) or at 2°C to 8°C (36°F to 46°F) when using shipping containers which have been qualified to maintain temperature and under routine transport conditions with shaking and vibration minimized. **Transporting punctured vials is not allowed**.

Approvals are needed from DAIT/ NIAID for any local transportations greater than 10 minutes.

3. DOSAGE, SCHEDULE, AND ADMINISTRATION

Refer to each DAIT protocol for the protocol-specific dose, dosing frequency and administration schedule. (***As of August 31, 2022, this formulation is no longer used in DAIT studies)***

4. VACCINE DOSE PREPARATION AND DISPENSING

4.1. SUPPLIES NEEDED

- Moderna COVID-19 Vaccine vial with **red cap** and **light blue label border** **(thaw each vial before use)**
- 1 mL syringes (provided by DAIT)
- 23 – 25 gauge 1" or 1.5" needles (provided by DAIT)
- Sterile alcohol pads
- Pre-printed protocol-specific participant syringe dispensing labels
- Pre-printed syringe labels for public vaccination (if applicable)

4.2. PREPARATION AND DISPENSING INSTRUCTIONS

1. Receive a Protocol-Specific COVID-19 Vaccination Prescription Form or electronic order
2. Place all supplies necessary for preparation into the laminar flow hood/biosafety cabinet.
3. Verify that the vial of Moderna COVID-19 Vaccine has a **red cap** and **light blue label border**.

4. Thaw Moderna COVID-19 Vaccine vial before use either by:
    a. Thawing in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for 2 hours and 30 minutes (5.5 mL vial) or 3 hours (7.5 mL vial) and letting vial stand at room temperature for 15 minutes.
    b. Allowing vial to sit at room temperature [15ºC to 25ºC (59ºF to 77ºF)] for 1 hour (5.5 mL vial) or 1 hour and 30 minutes (7.5 mL vial).
    c. After thawing, do not refreeze.

5. Before preparing each dose, swirl the vaccine vial gently between each withdrawal. **Do not shake**. **DO NOT DILUTE PRIOR TO PREPARATION**.
    a. Inspect the liquid in the vial. The vaccine is a white to off-white suspension and may contain white or translucent product-related particulates. Do not use if vaccine is discolored or if other particles are observed.

6. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw the protocol-specified dose of Moderna COVID-19 Vaccine using the provided syringes and needles.

7. Cap the syringe with an administration needle or syringe cap, according to your institution's procedure, and keep sterile.

8. Label each prepared syringe with the provided pre-printed protocol-specific participant labels.
    a. Complete the syringe label with the following information: Participant ID, Participant Initials, Dose, Vaccine Preparation Date and Time, Expiration Date and Time, Pharmacist Initials

9. Repeat Steps 5 through 8 for study participants.
    a. Document preparation/dispensing information on the COVID-19 Vaccine Accountability Record (Form G) and the Participant-Specific Accountability, Preparation, And Treatment Assignment Record

10. If the protocol and your institution allow providing public doses of vaccine, follow steps 5 through 7 and label the prepared syringe with non-protocol-specific pre-printed labels for public vaccination
    a. Refer to the most recent Emergency Use Authorization instructions for the age-appropriate dose
    b. Document preparation/dispensing information on the Patient / Recipient-Specific Accountability and Preparation, and Administration Record (if applicable) and follow the instructions on the form to fill in the required information

11. Record the date and time of first puncture on the vial label.
12. If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.
13. Do not puncture the vaccine vial more than 20 times.
14. Store the prepared syringes between 2°C to 25°C (35°F to 77°F).
15. Document any unused syringes on the COVID-19 Vaccine Accountability Record (Form G) and discard them 12 hours after the first vial puncture, according to your institution's destruction policy.