

# Moderna COVID-19 Vaccine, BIVALENT (Original and Omicron BA.4/BA.5) [ DARK BLUE Cap with GRAY Label Border ] Formulation, Storage, Preparation, Dispensing and Administration Instructions for Use

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals who meet certain criteria.

The FDA Moderna COVID-19 Vaccines website has the most up-to-date information.

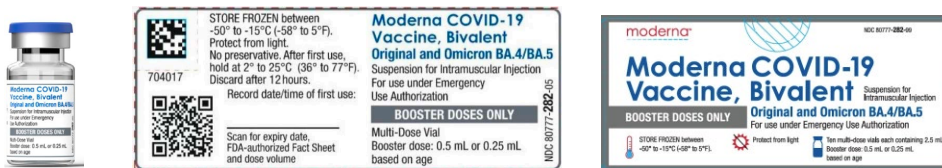
(<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines>)

## 1. VACCINE FORMULATION AND DESCRIPTION

The Moderna Bivalent COVID-19 Vaccine with **dark blue cap** and **gray label border** is supplied as a frozen suspension for intramuscular injection in multiple dose vials containing 2.5 mL per vial. The vaccine must be thawed prior to preparation and administration. **DO NOT DILUTE PRIOR TO USE.**

Each 0.5 mL booster dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), supplied in a multiple-dose vial with a dark blue cap and a label with a gray border, contains 25 mcg nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 25 mcg mRNA encoding the pre-fusion stabilized S-protein of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 (Omicron BA.4/BA.5). The S-proteins of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 are identical. Each 0.5 mL dose also includes the following ingredients: a total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.

The Moderna Bivalent COVID-19 Vaccine does not contain preservative, and the vial stoppers are not made with natural rubber latex.



NDC 80777-282-05: Multiple dose vial; contains 10 doses of 0.25 mL or 5 doses of 0.5 mL

NDC 80777-282-99: Carton of 10 multiple dose vials

Reference: *Fact Sheet For Healthcare Providers Administering Vaccine: Emergency Use Authorization of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Revised Apr/17/2023*  
(<https://www.fda.gov/media/167208/download>)

## **2. STORAGE AND HANDLING**

Moderna Bivalent COVID-19 Vaccine vials with **dark blue caps** and **gray label borders** 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.

### **2.1. Vaccine Storage Prior to Use**

**2.1.1. Freezer:** Once the shipment is received, remove the vial cartons from the shipping container and store vaccine in a freezer at -50°C to -15°C (-58°F to 5°F) until the expiration date.

**2.1.2. Refrigerator:** Frozen vials may be transferred to the refrigerator [2°C to 8°C (36°F to 46°F)] and stored for up to 30 days prior to first use, 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 up to 2 hours to thaw in the refrigerator. Once vials are thawed, they should not be refrozen.

### **2.2. Vaccine Storage During Use**

#### **2.2.1. Vaccine Vial Storage**

If not previously thawed at 2°C to 8°C (36°F to 46°F), allow vials to thaw at room temperature [15°C to 25°C (59°F to 77°F)] for 45 minutes.

Moderna Bivalent COVID-19 Vaccine 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 2°C to 25°C (36°F to 77°F) and used within 12 hours.

#### **2.2.2. Prepared Syringe Storage**

Prepared syringes of the Moderna Bivalent COVID-19 vaccine should be stored between 2° to 25°C (36° to 77°F) and used within 12 hours after the first vial puncture. Discard punctured vial and prepared syringes after 12 hours. Do not refreeze prepared syringes.

### **2.3. 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.

### **4. VACCINE DOSE PREPARATION AND DISPENSING**

#### **4.1. SUPPLIES NEEDED**

- Moderna BIVALENT COVID-19 Vaccine vial with **dark blue cap** and **gray 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 BIVALENT COVID-19 Vaccine has a **dark blue cap** and **gray label border** and the label states “**Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)**”
4. Thaw Moderna BIVALENT COVID-19 Vaccine vial before use either by:
  - a. Thawing in the refrigerator [2°C to 8°C (36°F to 46°F)] for 2 hours and letting the vial stand at room temperature [15°C to 25°C (59°F to 77°F)] for 15 minutes
  - b. Allowing vial to sit at room temperature [15°C to 25°C (59°F to 77°F)] for 45 minutes.
  - c. Do not refreeze the vaccine after thawing.
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.
  - b. Do not use if liquid is discolored or if other particles are observed. Complete an Investigational Product Complaint Form M and submit to DAIT
6. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw the protocol-specified dose of Moderna Bivalent COVID-19 Vaccine using the provided syringes and needles.
  - a. The administration needle size will depend on the participant’s weight and size
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. Store the prepared syringes between 2°C to 25°C (36°F to 77°F).
14. 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.