# COVID-19 Moderna mRNA1273 Bivalent Booster (Original and Omicron) Vaccine (dark pink cap with yellow border on label)

vaccine protocol for Persons Age 6 months to 5 Years

**Document reviewed and updated: December 12, 2022**

## Condition for protocol

To reduce incidence of morbidity and mortality of COVID-19 disease.

## Policy of protocol

The nurse will implement this protocol for COVID-19 vaccination using the Moderna mRNA1273 Bivalent Booster (Original and Omicron) vaccine product (dark pink cap with yellow border on label) for persons 6 months to 5 years.

## Condition-specific criteria and prescribed actions

**Delete this entire paragraph before printing/signing protocol.**

[Instructions for persons adopting these protocols: The table below lists indication, contraindication, and precaution criteria and suggested prescribed actions that are necessary to implement the vaccine protocol. The prescribed actions include examples shown in brackets but may not suit your institution’s clinical situation and may not include all possible actions. A licensed prescriber must review the criteria and actions and determine the appropriate prescribing action.]

Indications

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Person is currently healthy and age 6 months to 5 years  | Proceed to vaccinate if meets remaining criteria. |
| Person is less than age 6 months. | Do not vaccinate, have child return when older than 6 months.  |
| Person has received two doses of the Moderna monovalent primary series vaccine.  | Proceed to vaccinate. |
| Person has only received one dose of the Moderna monovalent, primary series vaccine.  | Do not vaccinate with this product, give second dose of monovalent vaccine before giving bivalent booster. |
| Person is currently healthy but has a chronic medical condition.  | Proceed to vaccinate. |
| Person with HIV infection, other immunocompromising conditions, or who takes immunosuppressive medications or therapies. | Proceed to vaccinate. Counsel the individual about:1) The potential for reduced immune responses.2) The need to continue to follow current guidance to protect themselves. |
| Person who falls into one of following categories of moderate to severe immunocompromise and is 6 months to 5 years:Active treatment for solid tumor and hematologic malignanciesReceipt of solid-organ transplant and taking immunosuppressive therapyReceipt of CAR-T-cell or hematopoietic stem cell transplant (within two years of transplantation or taking immunosuppression therapy)Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)Advanced or untreated HIV infectionActive treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory | Proceed to vaccinate if they have completed a 3-dose Moderna vaccine primary series.  |

Contraindications

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| --- | --- |
| Criteria: Allergies | Prescribed action |
| Person had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of Moderna mRNA1273 vaccine or any of its components.*See listing below the prescription.* | Do not vaccinate. |

Precautions

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Person is currently ill due to COVID-19. | Defer vaccination. Instruct person to return when their infection is resolved, and they have completed their isolation period. |
| Person was previously ill with COVID-19 and received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. | Proceed to vaccinate when recovered from acute illness and isolation period is complete. |
| Person received monoclonal antibodies or convalescent plasma as post-exposure prophylaxis. | Proceed to vaccinate when quarantine period is complete. |
| Person was previous ill with COVID-19 and had Multisystem Inflammatory Syndrome. | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| Person had a non-severe immediate (within 4 hours) allergic reaction to a previous dose of COVID-19 vaccine or a reaction of any severity to a product that contains polysorbates. | The person may be vaccinated but should seek counsel from an allergist-immunologist to discuss risks and benefits of vaccination.Persons who choose vaccination should be observed for 30 minutes in a vaccination site that has equipment and personnel that is familiar with managing anaphylaxis. |
| History of severe allergic reaction (e.g., anaphylaxis) to any vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous).*This precaution does not include allergies not related to vaccines or injectable therapies (e.g., food, pet, environmental, or latex allergies; oral medications – including the oral equivalents of injectable medications).* | May be vaccinated.Provide counseling on the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of COVID-19 vaccination.Observe them for 30 minutes after vaccination.  |
| Person has a history of myocarditis or pericarditis after a previous dose of mRNA vaccine. | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| Person had a delayed local allergic reaction (e.g., erythema, induration, pruritis at the injection site). | Proceed to vaccinate. Give vaccine in the opposite arm from where the first dose was given. |
| Person was exposed to another person with known COVID-19 disease. | If unvaccinated or partially vaccinated (I.e., received only 1 of a 2-dose series), defer vaccination until the person’s quarantine period has ended. If an exposed but asymptomatic person will not have the opportunity to be vaccinated once quarantine is completed, may proceed to vaccinate. Counsel that vaccination will not prevent illness and may need to be tested if symptoms occur.If the person is a resident in a congregate setting, refer to [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html). |

## Prescription

### Booster dose:

* Give Moderna mRNA1273 bivalent (Original and Omicron) vaccine; 10 micrograms, 0.2 mL, intramuscular (IM); at least 2 months after completion of Moderna primary series.

### Booster dose for immunocompromised persons for 6 months to 5 years:

* Give the Moderna mRNA1273 bivalent (Original and Omicron) vaccine; 10 micrograms, 0.2 mL, intramuscular (IM); at least 2 months after completion of 3 dose Moderna primary series.

## Medical emergency or anaphylaxis

Follow pre-established agency protocol for anaphylaxis.

## Question or concerns

**Insert overseeing medical consultant’s information below and delete this sentence before printing/signing.**

In the event of questions or concerns call (insert name) at (insert phone number).

**This protocol shall remain in effect until rescinded.**

Name of prescriber (please print):

Prescriber signature:

Date:

## Ingredient listing for Moderna mRNA1273 COVID-19 bivalent (Original and Omicron BA.4/BA.5) vaccine

Each 10 mcg (0.2 mL) dose contains 5 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 5 mcg mRNA encoding the pre-fusion stabilized S-protein of the SARS-CoV-2 Omicron variant lineages BA.4and BA.5 (Omicron BA.4/BA.5). The S-proteins of the SARS-CoV-2 Omicron variant lineagesBA.4 and BA.5 are identical.

Each dose also contains:

* 0.2 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) SM-102 (Proprietary to Moderna)
* 0.09 mg Tromethamine
* 0.51 mg Tromethamine hydrochloride
* 0.0042 mg Acetic acid
* 0.02 mg Sodium acetate trihydrate
* 17.4 mg Sucrose

Taken from the *FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION MODERNA COVID-19 VACCINE* found in [FDA: Moderna HCP Fact Sheet Yellow Label 6m-5y 12082022 (www.fda.gov/media/163785/download)](https://www.fda.gov/media/163785/download).