# Moderna COVID-19 Vaccine

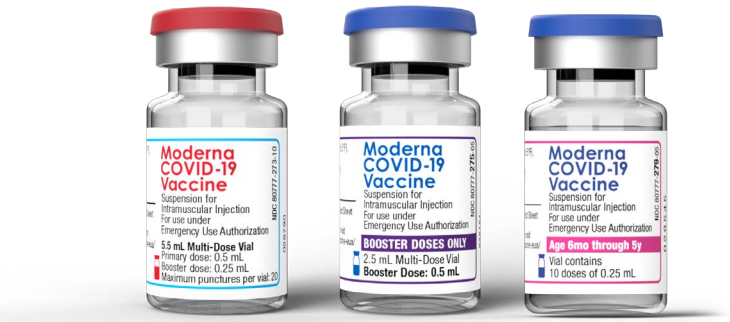
## Dosing and Administration

**AUTHORIZED USE**

- Emergency uses of the vaccine have not been approved or licensed by the FDA, but have been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in either individuals 6 months of age and older or as a booster dose in individuals 18 years of age and older, as appropriate.
- The EUA for this product is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.
- For more information on the EUA authorized uses of the vaccine, refer to the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information.

## Administration

The Moderna COVID-19 Vaccine does not require dilution. Swirl vial gently after thawing and between each withdrawal. **Do not shake or dilute. After thawing, do not refreeze.**




**NDC Code for 5.5 mL vial:** 80777-273-10

**NDC Code for 2.5 mL booster vial:** 80777-275-05*

**NDC Code for 2.5 mL 6 months-5 yrs vial:** 80777-279-05

### Prior to injection, inspect each dose to:

- Confirm liquid is **white to off-white** in color in both vial and syringe
- The vaccine may contain white or translucent product-related particulates. Do not administer the vaccine if it is discolored or contains other particulate matter. The vaccine does not contain a preservative. For detailed information regarding storage and handling, see the Fact Sheet
- Verify syringe volume of:
  - **0.5 mL** (100 mcg) for Primary Series dose or **0.25 mL** (50 mcg) for Booster Dose from red cap vial with a light blue border
  - **0.5 mL** (100 mcg) for Primary Series dose from dark blue cap vial with a teal border
  - **0.5 mL** (50 mcg) for Booster Dose from dark blue cap vial with a purple border
  - **0.25 mL** (25 mcg) for Primary Series dose from dark blue cap and magenta border
- If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and contents. Do not pool excess vaccine from multiple vials. **Discard vial 12 hours after first puncture**, even if vaccine remains in the vial. **Record date and time of the first use on the vial label**
- Administer the Moderna COVID-19 Vaccine **intramuscularly**
- For more information refer to the Fact Sheet for Healthcare Providers

Provide a vaccination card to the recipient or their caregiver with the date the recipient needs to return for any **ADDITIONAL DOSES** of Moderna COVID-19 Vaccine.

**For any questions, contact Moderna Medical Information at:**
1-866-MODERNA (1-866-663-3762)

**IMPORTANT SAFETY INFORMATION**
**Contraindications**
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.

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# Moderna COVID-19 Vaccine

## Dosing and Administration

### Dosing Schedule

| | Primary Series | | | Booster Doses | | |
|---|---|---|---|---|---|---|
| **Age group** | **Volume administered per dose** | **Number of doses in Primary Series** | **Interval between doses** | **Volume administered per dose** | **Number of Booster Doses available** | **Interval between Primary Series & Booster Doses** |
| Eligible individuals ≥50 years of age |  0.5 mL (100 mcg) | **2** | 1 month between doses 1 & 2 |  0.25 mL (50 mcg) **OR**  0.5 mL* (50 mcg) | **2** | **First Dose** ≥5 months **Second Dose** ≥4 months |
| Eligible individuals ≥18 years of age |  0.5 mL (100 mcg) | **2** | 1 month between doses 1 & 2 |  0.25 mL (50 mcg) **OR**  0.5 mL* (50 mcg) | **1** | ≥5 months |
| Eligible immuno-compromised individuals ≥18 years of age |  0.5 mL (100 mcg) | **3** | 1 month between doses 1 & 2 Minimum of 1 month between doses 2 & 3 |  0.25 mL (50 mcg) **OR**  0.5 mL* (50 mcg) | **2** | **First Dose** ≥5 months **Second Dose** ≥4 months |
| Eligible individuals 6-11 years of age | Primary series doses of 0.5 mL (50 mcg)* can be provided from the Moderna COVID-19 Vaccine vial labeled as "Booster Doses Only" (multiple-dose vial with a dark blue cap and purple label) | **2** | 1 month between doses 1 & 2 | | | |
| Eligible immuno-compromised individuals 6-11 years of age | | **3** | 1 month between doses 1 & 2 Minimum of 1 month between doses 2 & 3 | | | |
| Eligible individuals 6 months-5 years of age |  0.25 mL (25 mcg) | **2** | 1 month between doses 1 & 2 | | | |
| Eligible immuno-compromised individuals 6 months-5 years of age |  0.25 mL (25 mcg) | **3** | 1 month between doses 1 & 2 Minimum of 1 month between doses 2 & 3 | | | |

*The Moderna COVID-19 Vaccine vial labeled "BOOSTER DOSES ONLY" is also authorized to provide primary series doses (0.5 mL each) for individuals 6 through 11 years of age. Please see the Dear HCP Letter for more information.

**The maximum number of times the vial stopper can be punctured is 11 doses in Primary Series (≥ 12 years of age); 20 doses for Booster Dose only/combo Primary Series Doses and Booster Doses (≥18 years of age); 5 doses for Booster Dose (≥18 years of age or Primary Series Doses for 6-11 years of age); and 10 doses in Primary Series (6 months-5 years of age).**

For additional information regarding immunocompromised individuals and Booster Doses, please review the CDC Administration Overview for Moderna COVID-19 Vaccine at https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html.

**IMPORTANT SAFETY INFORMATION (CONT.)**

**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/clinical-considerations/managing-anaphylaxis.html).

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## IMPORTANT SAFETY INFORMATION (CONT.)

**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/clinical-considerations/managing-anaphylaxis.html).
- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is highest in males 18 through 24 years of age. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **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.

**Adverse Reactions**

Adverse reactions reported in clinical trials for individuals 6 years of age and older following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, erythema at the injection site, swelling at the injection site, and arthralgia.

Adverse reactions in children 6 months through 5 years of age following administration of Moderna COVID-19 Vaccine include pain at the injection site, irritability/crying, fatigue, sleepiness, loss of appetite, headache, fever, myalgia, chills, nausea/vomiting, axillary (or groin) swelling/tenderness, arthralgia, erythema at the injection site, and swelling at the injection site.

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event
- serious adverse events (irrespective of attribution to vaccination)
- cases of Multisystem Inflammatory Syndrome (MIS)
- cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. Reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

Report to ModernaTX, Inc. by calling 1-866-MODERNA (1-866-663-3762) or provide a copy of the VAERS form by faxing 1-866-599-1342 or emailing ModernaPV@modernatx.com.

***Please see the Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information for:***

- ***Booster dose for 18+ years***
- ***Primary series for 12+ and Booster dose 18+ years***
- ***Primary series for 6-11 years***
- ***Primary series for 6 months-5 years***

**Learn more about mRNA at ModernaTX.com**

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