Moderna COVID-19 Vaccine

Administration & Dosing

AUTHORIZED USE

For certain indications, the Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by the FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. There are two presentations/formulations of the Moderna COVID-19 Vaccine authorized for use.

The EUA for the Moderna COVID-19 Vaccine 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. Moderna COVID-19 Vaccine is authorized to provide:

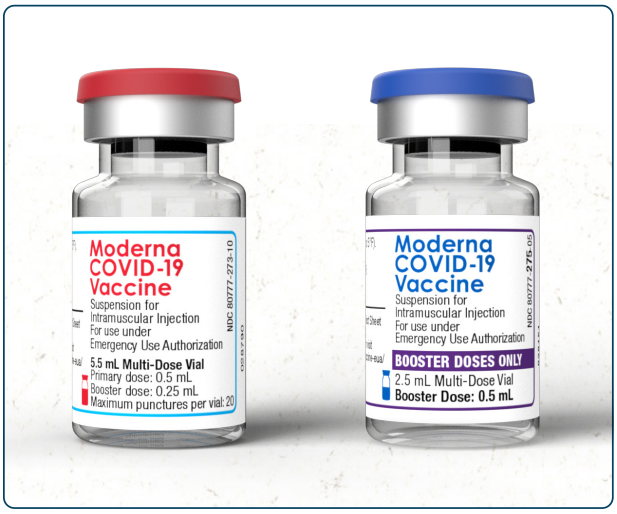
- a two-dose primary series to individuals 18 years of age and older;
- a third primary series dose to individuals 18 years of age and older with certain kinds of immunocompromise;
- a first booster dose to individuals 18 years of age and older who have completed a primary series with Moderna COVID-19 Vaccine or SPIKEVAX (COVID-19 Vaccine, mRNA);
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination;
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and
- a second booster dose to individuals 18 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine.

FDA has approved SPIKEVAX (COVID-19 Vaccine, mRNA) as a two-dose primary series one month apart for prevention of COVID-19 in individuals ages 18 years of age and older.*

Administration

Swirl vial gently after thawing and between each withdrawal. The vaccine comes ready to use once thawed. **Do not shake or dilute.**

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, or **0.5 mL** (50 mcg) for booster dose from blue cap vial with a purple border.

If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials. Pierce the stopper at a different site each time. Discard vial 12 hours after first puncture, even if vaccine remains in the vial.

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

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

NDC Code for 7.5 mL vial: 80777-273-15

Administer the Moderna COVID-19 Vaccine by **intramuscular (IM) injection only**.

Provide a vaccination card to the recipient or their caregiver with the date the recipient needs to return for any ***ADDITIONAL DOSES*** and the ***BOOSTER DOSE(S)*** 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.

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).

Please see the

- ***Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information (Booster Dose Only Presentation)***
- ***Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information (Primary Series and Booster Dose Presentation)***

For information regarding SPIKEVAX, please see the SPIKEVAX Full Prescribing Information.

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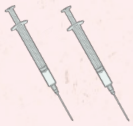
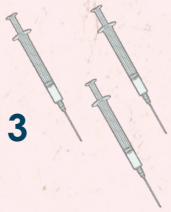
Dosing Schedule

	Primary Series			Booster Doses		
Population	**Number of doses in primary series**	**Interval between doses**	**Volume administered per dose**	**Number of booster doses available**	**Interval between primary series & booster doses**	**Volume administered per dose**
Eligible individuals ≥50 years of age	**2** 	1 month between dose 1 & 2	**Red cap vial with light blue border** 0.5 mL (100 mcg)	**2** 	**First Dose** ≥5 months **Second Dose** ≥4 months	**Red cap vial with light blue border** 0.25 mL (50 mcg) **Blue cap vial with purple border** 0.5 mL (50 mcg)
Eligible individuals ≥18 years of age	**2** 	1 month between dose 1 & 2	**Red cap vial with light blue border** 0.5 mL (100 mcg)	**1** 	≥5 months	**Red cap vial with light blue border** 0.25 mL (50 mcg) **Blue cap vial with purple border** 0.5 mL (50 mcg)
Eligible immuno-compromised individuals ≥18 years of age	**3** 	1 month between dose 1 & 2 Minimum of 1 month between dose 2 & 3	**Red cap vial with light blue border** 0.5 mL (100 mcg)	**2** 	**First Dose** ≥5 months **Second Dose** ≥4 months	**Red cap vial with light blue border** 0.25 mL (50 mcg) **Blue cap vial with purple border** 0.5 mL (50 mcg)

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.

The maximum number of times the vial stopper can be punctured is 20. This includes when extracting a combination of primary series and booster doses from either vial presentation. Regardless of volume of vaccine withdrawn, vials should be discarded 12 hours after the first puncture. If the vial stopper has been punctured 20 times, discard the vial and contents.

IMPORTANT SAFETY INFORMATION (CONT.)

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. 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).

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IMPORTANT SAFETY INFORMATION (CONT.)

- **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 following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, erythema at the injection site, and rash.

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine 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) in adults
- 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 (Booster Dose Only Presentation)***
- ***Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information (Primary Series and Booster Dose Presentation)***

For information regarding SPIKEVAX, please see the SPIKEVAX Full Prescribing Information.

*As described in the Letter of Authorization, the FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and the two EUA-authorized presentations of the Moderna COVID-19 Vaccine (supplied in multiple-dose vials with red caps and multiple-dose vials with dark blue caps) can be used to provide a booster dose. The FDA-approved SPIKEVAX (COVID-19 Vaccine, mRNA) and the EUA-authorized presentation of the Moderna COVID-19 Vaccine supplied in multiple-dose vials with red caps can be used interchangeably to provide primary series and booster doses without presenting any safety or effectiveness concerns.

Learn more about mRNA at ModernaTX.com

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