Moderna COVID-19 Vaccine

Dosing and Administration

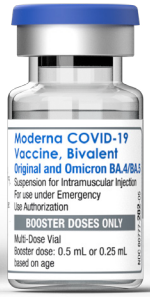
AUTHORIZED USE

- 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). The Moderna COVID-19 Vaccine is authorized in individuals 6 months of age and older as a primary series. The Moderna COVID-19 Vaccine, Bivalent is authorized as a booster dose in individuals 6 years of age and older.
- The EUA for these products 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

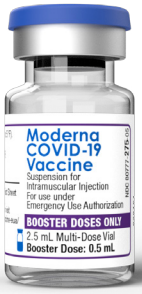
Moderna COVID-19 Vaccines do not require dilution. Swirl vial gently after thawing and between each withdrawal.
Do not shake or dilute. After thawing, do not refreeze.

NDC Code for Primary Series (12 years of age and older):
80777-273-10



NDC Code for Bivalent booster (6 years of age and older):
80777-282-05

NDC Code for Primary Series (6 months through 5 years of age):
80777-279-05



NDC Code for Primary Series (6 through 11 years of age):
80777-275-05

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

Bivalent Booster Dose

- For patients 12 years of age and older, verify syringe volume of 0.5 mL from the Moderna COVID-19 Vaccine, Bivalent vial with a dark blue cap and gray border
- For patients 6 through 11 years of age and older, verify syringe volume of 0.25 mL from the Moderna COVID-19 Vaccine, Bivalent vial with a dark blue cap and gray border

Primary Series Dose

- For patients 12 years of age and older, verify syringe volume of 0.5 mL from the Moderna COVID-19 Vaccine vial with a red cap and light blue border
- For patients 6 through 11 years of age, verify syringe volume of 0.5 mL from the Moderna COVID-19 Vaccine vial with a dark blue cap and purple border
- For patients 6 months through 5 years of age, verify syringe volume of 0.25 mL from the Moderna COVID-19 Vaccine vial with a dark blue cap and magenta border

For administration of all vaccines:

- 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 Moderna COVID-19 Vaccines **intramuscularly**
- For more information refer to the Fact Sheets for Healthcare Providers available at https://eua.modernatx.com/covid19vaccine-eua/providers/
- Provide a vaccination card to the recipient or their caregiver with the date the recipient receives a dose of the 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 vaccines to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent.

See additional Important Safety Information on the following pages.

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Moderna COVID-19 Vaccine

Dosing and Administration

Moderna COVID-19 Vaccine, Bivalent: Booster Dose Schedule

Age group	Volume administered per dose	Number of Booster Doses recommended	Interval between Primary Series & Booster Doses
Eligible individuals 12 years of age and older	 0.5 mL	1	2 months
Eligible individuals 6 through 11 years of age	 0.25 mL	1	2 months

Moderna COVID-19 Vaccine: Primary Series Schedule

Age group	Volume administered per dose	Number of doses in Primary Series	Interval between doses
Eligible individuals 12 years of age and older	 0.5 mL	2	1 month between doses 1 & 2
Eligible immuno-compromised individuals 12 years of age and older	 0.5 mL	3	1 month between doses 1 & 2 Minimum of 1 month between doses 2 & 3
Eligible individuals 6 through 11 years of age*	 0.5 mL	2	1 month between doses 1 & 2
Eligible immuno-compromised individuals 6 through 11 years of age*	 0.5 mL	3	1 month between doses 1 & 2 Minimum of 1 month between doses 2 & 3
Eligible individuals 6 months through 5 years of age	 0.25 mL	2	1 month between doses 1 & 2
Eligible immuno-compromised individuals 6 months through 5 years of age	 0.25 mL	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 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.

Please see Dear HCP Letter and Fact Sheet for more information on the Moderna COVID-19 Vaccine, Bivalent at https://eua.modernatx.com/covid19vaccine-eua/providers/

IMPORTANT SAFETY INFORMATION

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 vaccines. Monitor 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).

See additional Important Safety Information on the following page.

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IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following receipt of the second primary series dose or first booster 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 vaccines.
- **Limitations of Vaccine Effectiveness:** The vaccines 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 vaccines.

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 myocarditis
- cases of pericarditis
- 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" or "Moderna COVID-19 Vaccine, Bivalent 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 Vaccine Fact Sheets for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information for:

- ***Bivalent Booster Dose for 6+ years: https://eua.modernatx.com/covid19vaccine-eua/bivalent-dose-HCP.pdf***
- ***Primary series for 12+ years: https://eua.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf***
- ***Primary series for 6-11 years: https://eua.modernatx.com/covid19vaccine-eua/6-11y-facts-HCP.pdf***
- ***Primary series for 6 months-5 years: https://eua.modernatx.com/covid19vaccine-eua/6m-5y-facts-HCP.pdf***

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