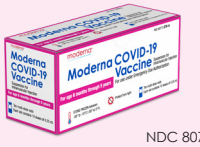
Moderna COVID-19 Vaccine

Presentations

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.

Currently Available Dose Presentations

	Primary Series (≥12 years of age) **Booster Doses** (≥18 years of age)	**Primary Series** (6-11 years of age) **Booster Doses** (≥18 years of age)	**Primary Series** (6 months-5 years of age)
Dose Per Vial	Primary Series Doses only: **maximum of 11 doses (range: 10-11 doses)** Booster Doses only: **maximum of 20 doses** Combination of Primary Series Doses and Booster Doses: **maximum of 20 doses**	Primary Series Doses: **5 doses** Booster Series Doses: **5 doses**	Primary Series Doses only: **10 doses**
Dose Volume	Primary Series Dose: **Each 0.5 mL** Booster Dose: **0.25 mL**	Primary Series Dose: **0.5 mL** Booster Series Dose: **0.5 mL**	Primary Series Dose: **Each 0.25 mL**
Vial Cap Color	**Red** 	**Dark Blue** 	**Dark Blue** 
Vial Label	**Blue border**  NDC 80777-273-10	**Purple border**  NDC 80777-275-05	**Magenta border**  NDC 80777-279-05
Carton	**Blue border**  NDC 80777-273-99	**Purple border**  NDC 80777-275-99	**Magenta border**  NDC 80777-279-99

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.

For further details about the Moderna COVID-19 Vaccine, please see the appropriate Fact Sheet or 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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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***

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