Moderna COVID-19 Vaccines

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). 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 months through 5 years of age at least 2 months after the Moderna COVID-19 Vaccine primary series and is authorized in individuals 6 years of age and older at least 2 months after any authorized or approved vaccine.
- 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.

Currently Available Dose Presentations

	Moderna COVID-19 Vaccine, Bivalent Booster Dose* (6 months through 5 years of age)	**Moderna COVID-19 Vaccine, Bivalent Booster Dose** (6 years of age and older)	**Moderna COVID-19 Vaccine Primary Series** (6 months through 5 years of age)	**Moderna COVID-19 Vaccine Primary Series†** (6 through 11 years of age)	**Moderna COVID-19 Vaccine Primary Series** (12 years of age and older)
Dose Per Vial	Bivalent Booster Dose for 6 months through 5 years of age: **2 doses**	Bivalent Booster Dose for 12 years of age and older: **5 doses** Bivalent Booster Dose for 6 through 11 years of age: **10 doses**	Primary Series Doses: **10 doses**	Primary Series Doses: **5 doses**	Primary Series Doses only: **maximum of 11 doses (range: 10-11 doses)**
Dose Volume	**Bivalent Booster Doses** 6 months through 5 years of age: **Each 0.2 mL**	**Bivalent Booster Doses** 12 years of age and older: **Each 0.5 mL** 6 through 11 years of age: **Each 0.25 mL**	Primary Series Dose: **Each 0.25 mL**	Primary Series Dose: **Each 0.5 mL**	Primary Series Dose: **Each 0.5 mL**
Vial Label	**Yellow box**  NDC 80777-283-02	Gray border  NDC 80777-282-05	**Magenta border**  NDC 80777-279-05	**Purple border**  NDC 80777-275-05	**Blue border**  NDC 80777-273-10
Carton	**Yellow box**  NDC 80777-283-99	Gray border  NDC 80777-282-99	**Magenta border**  NDC 80777-279-99	**Purple border**  NDC 80777-275-99	**Blue border**  NDC 80777-273-99

*Moderna COVID-19 Vaccine, Bivalent is authorized as a booster dose in individuals 6 months through 5 years of age at least 2 months after completing the Moderna COVID-19 Vaccine primary series. Moderna COVID-19 Vaccine, Bivalent is authorized as a booster dose in individuals 6 years of age and older at least 2 months after any authorized or approved vaccine.

†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 at https://eua.modernatx.com/covid19vaccine-eua/providers

For further details about the vaccines, please see Important Safety Information below and on the next page and 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 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 next page.

moderna

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

moderna