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.
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 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 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 18+ years: https://eua.modernatx.com/covid19vaccine-eua/bivalent-dose-HCP.pdf
• Primary series for 12+ years: https://eua.modernatx.com/covid19vaccine-eua/primary-series-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