Moderna COVID-19 Vaccine

Helping Recipients Understand What to Expect

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.

Familiarize yourself with Moderna's online resources

Refer to the Fact Sheets and resources on **https://eua.modernatx.com/covid19vaccine-eua/providers/resources**.

Prepare yourself to answer patient questions. **For more information and resources, direct vaccine recipients to modernatx.com/covid19vaccine-eua/recipients/.**

After providing the vaccine, recipients may have questions

Be sure to review the commonly reported local and systemic adverse events with recipients so they know what to expect.

- ❍ Pain at the injection site
- ❍ Fatigue
- ❍ Headache
- ❍ Myalgia
- ❍ Arthralgia
- ❍ Chills
- ❍ Nausea/vomiting
- ❍ Axillary (or groin) swelling/tenderness
- ❍ Fever
- ❍ Swelling at the injection site
- ❍ Erythema at the injection site
- ❍ Rash

Other less common adverse events include **severe allergic reactions**, **myocarditis**, **pericarditis**, and **syncope**. These are not all of the potential adverse reactions. Please refer to the Fact Sheets for more information.

In clinical study participants, the median duration of solicited local and systemic reactions ranged from 1-3 days following administration of the Moderna COVID-19 vaccine.

Share a copy of the **Fact Sheet for Recipients and Caregivers** and **Moderna What to Expect Sheet** to help prepare recipients.

You must report certain events, including serious adverse events, to the Vaccine Adverse Event Reporting System (VAERS). Please see the Fact Sheets for the full list of mandatory reporting requirements. You may report other adverse events to VAERS.

ONLINE: https://vaers.hhs.gov/reportevent.html **PHONE**: 1-800-822-7967

Moderna COVID-19 Vaccine primary series recipients REQUIRE a second dose of the Moderna COVID-19 Vaccine and should receive their next injection **1 month** after their first dose. **To help them remember:**

Schedule their **next appointment** right away

Give them a written **additional dose reminder card** to display prominently at home

Suggest they **add a reminder** on their mobile phone or calendar and visit cdc.gov/vsafe for more tools

A third primary series dose at least 1 month following the second dose is authorized for individuals at least 6 months of age who have been determined to have certain kinds of immunocompromise.

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.

moderna®

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, arthralgia, 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***

 US-COV-2100125 06/2022

moderna