Providing the Moderna COVID-19 Vaccine

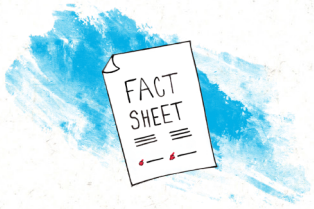
Helping Recipients Understand What to Expect

EMERGENCY USE AUTHORIZATION

The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. There is no FDA-approved vaccine to prevent COVID-19.

The EUA for the Moderna COVID-19 Vaccine 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.

Familiarize yourself with Moderna's online resources



Familiarize yourself with the **Fact Sheet, Storage & Handling,** and **Dosing & Administration**

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 (92%)
- Fatigue (70%)
- Headache (64.7%)
- Myalgia (61.5%)
- Arthralgia (46.4%)
- Chills (45.4%)
- Nausea/vomiting (23%)
- Axillary swelling/tenderness (19.8%)
- Fever (15.5%)
- Swelling at the injection site (14.7%)
- Erythema at the injection site (10%)

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 2 to 3 days.

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

Any adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS)

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

Moderna COVID-19 Vaccine 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 **2nd 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

For any questions, contact Moderna Medical Information at:
1-866-MODERNA (1-866-663-3762)

AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. Moderna COVID-19 Vaccine is investigational and not approved by FDA.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.

Please see next page for additional Important Safety Information. See Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information, and Fact Sheet for Recipients and Caregivers beginning on page 3 of this document.

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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/).
- **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 a clinical trial 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, swelling at the injection site, and erythema at the injection site.

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) in adults
- 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.

Pregnancy and Lactation

Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

See Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information, and Fact Sheet for Recipients and Caregivers beginning on page 3 of this document.

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