

FACT SHEET FOR VACCINATION PROVIDERS

EMERGENCY USE AUTHORIZATION (EUA) OF MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product **MODERNA COVID-19 VACCINE** for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccination errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of Moderna COVID-19 Vaccine. See “[MANDATORY REQUIREMENTS FOR THE MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION](#)” for reporting requirements.

- The Moderna COVID-19 Vaccine is a suspension for intramuscular injection.
- The Moderna COVID-19 Vaccine is administered as a series of two doses (0.5 mL each). The second dose is administered 1 month after the first dose.

See the [Full EUA Prescribing Information](#) for instructions for preparation and administration.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the vial and carton labels.

Storage Prior to Use

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Commented [A1]: SPONSOR COMMENT: Moderna has accepted the Division's changes and updated the font consistency as requested. Tracked changes in this document show changes implemented at the Division's request, changes to align with Division comments in the Sections 1-8 of the PI, and proposals for additional changes by Moderna.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light. Do not store on dry ice or below -40°C (-40°F).

Remove the required number of vial(s) from storage and thaw each vial before use. Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unopened vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each). The second dose is administered 1 month after the first dose.

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.

Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not return the vial to the freezer.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Inspect Moderna COVID-19 Vaccine vials visually for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- A maximum of 10 doses can be withdrawn from the multiple-dose vial.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

Administration Information

Visually inspect each dose of Moderna COVID-19 Vaccine in the dosing syringe prior to

administration. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there is no discoloration.

If the visual inspection fails, do not administer the vaccine.

Administer the Moderna COVID-19 Vaccine intramuscularly, [preferably](#) in the deltoid muscle.

CONTRAINDICATION

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of the Moderna COVID-19 Vaccine or any component of the Moderna COVID-19 Vaccine (see [Full EUA Prescribing Information](#)).

WARNINGS AND PRECAUTIONS

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.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

See the [Full EUA Prescribing Information](#) for additional Warnings and Precautions.

ADVERSE REACTIONS

Common adverse reactions that have been reported for the Moderna COVID-19 Vaccine are pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, gastrointestinal symptoms, lymphadenopathy, fever, swelling at the injection site, and erythema at the injection site ([See-see Full EUA Prescribing Information](#)).

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES

There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua ~~www.vvv.com~~ to obtain the Fact Sheet) prior to the individual receiving the Moderna COVID-19 Vaccine, including:

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- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.
2. The vaccination provider enrolled in the federal COVID-19 Vaccination Program must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving the Moderna COVID-19 Vaccine.
3. The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS) and to Moderna ~~by fax~~:
 - 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, and
 - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report.

Report to Moderna ~~TX Inc.~~ using the contact information below or ~~provide by providing~~ a copy of the VAERS form to Moderna ~~TX Inc.~~

Website Email	Fax number	Telephone number
ModernaPV@modernatx.com www.yyy.com	1-866-599-1342xxxx	1-866-MODERNA (1-866-663-3762)xxxxx

4. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.


REPORTING OF OTHER ADVERSE EVENTS TO VAERS AND MODERNA ~~TX INC.~~

Vaccination providers may report to VAERS and Moderna ~~TX Inc.~~ other adverse events that are not required to be reported using the contact information above.

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code ~~or~~ visit the website provided below.

Global w Website	Telephone number
www.modernatx.com/covid19vaccine-eua www.yyyy.com QR 	1-866-MODERNA (1-866-663-3762) xxxxxxx

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

As a vaccination provider, you must comply with the mandatory requirements of the EUA (see above).

FDA issued this EUA, based on Moderna's request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the [Full EUA Prescribing Information](#).

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit <http://www.hrsa.gov/cicp>, email cicp@hrsa.gov, or call: 1-855-266-2427.

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Patent(s): www.modernatx.com/patents

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