Moderna COVID-19 Vaccine

Storage & Handling

AUTHORIZED USE

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. 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.

Moderna COVID-19 Vaccine is authorized for individuals 18 years of age and older to provide:

- a two-dose primary series;
- a third primary series dose to individuals who have been determined to have certain kinds of immunocompromise;
- a single booster dose to individuals who have completed a primary series with Moderna COVID-19 Vaccine, SPIKEVAX (COVID-19 Vaccine, mRNA), or another authorized or approved COVID-19 vaccine.

FDA has approved SPIKEVAX (COVID-19 Vaccine, mRNA) as a two-dose primary series one month apart for prevention of COVID-19 in individuals ages 18 years of age and older.

FDA-approved SPIKEVAX and the EUA-authorized Moderna COVID-19 Vaccine can be used interchangeably.

The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations: 5.5 mL and 7.5 mL. Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.

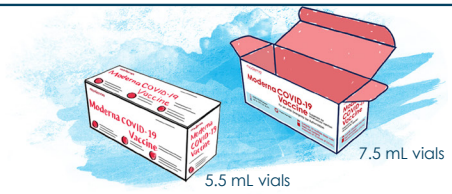
Frozen Storage

Can be stored frozen until expiration date*

–50°C to –15°C (–58°F to 5°F)

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

*Confirm vaccine expiration date by looking up the lot number at modernatx.com/covid19vaccine-eua

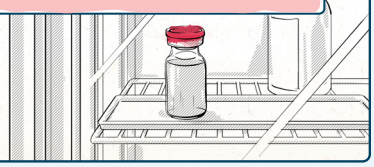


Thaw Each Vial Before Use

Vial images for illustrative purposes only

Refrigerator
5.5 mL vials: 2 hours 30 minutes
7.5 mL vials: 3 hours

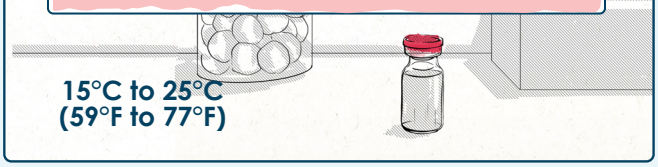
2°C to 8°C (36°F to 46°F)



OR

Room temperature
5.5 mL vials: 1 hour
7.5 mL vials: 1 hour 30 minutes

15°C to 25°C (59°F to 77°F)



Let vial sit at room temperature for 15 minutes before administering

Thawed Shelf Life

Unpunctured Vial

Maximum times

30 days — **Refrigerator**
2°C to 8°C (36°F to 46°F)

24 hours — **Cool storage up to room temperature**
8°C to 25°C (46°F to 77°F)

After First Dose Has Been Withdrawn

Maximum time

12 hours — **Refrigerator or room temperature**

Vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the vial label.

Discard punctured vial after 12 hours.

NEVER **refreeze thawed vaccine**

The maximum number of times a vial stopper can be punctured is 20.

Please see the HCP Fact Sheet PDF for more information on primary series, third, and booster doses.

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.

Please see the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information.

For information regarding SPIKEVAX, please see the SPIKEVAX Full Prescribing Information.

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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/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 higher among males under 40 years of age than among females and older males. 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 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, erythema at the injection site, and rash.

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) 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.

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For information regarding SPIKEVAX, please see the SPIKEVAX Full Prescribing Information.

Learn more about mRNA at ModernaTX.com

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