

# Moderna COVID-19 Vaccine

## Storage and Handling

### 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). The Moderna COVID-19 Vaccine is authorized in individuals 6 months of age and older as a primary series. The Moderna COVID-19 Vaccine, Bivalent is authorized as a booster dose in individuals 6 years of age and older.
- The EUA for these products 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.

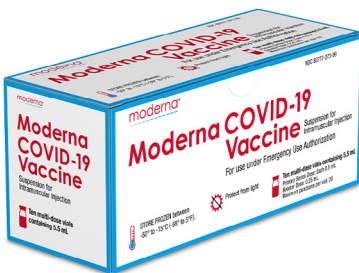
## Frozen Storage

All Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent presentations can be stored and handled in a consistent way and can be stored frozen until expiration date\*

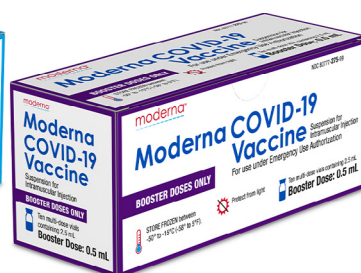
**-50°C to -15°C (-58°F to 5°F)**

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.  
Do not refreeze once thawed.

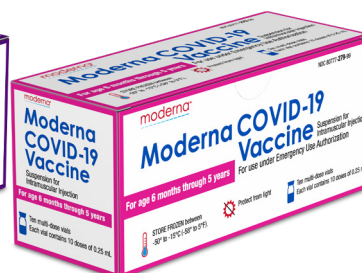
\*Confirm vaccine expiration date by looking up the lot number at [eua.modernatx.com/covid19vaccine-eua](http://eua.modernatx.com/covid19vaccine-eua).



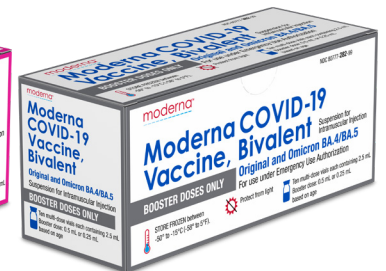
5.5 mL vials  
for Primary Series Doses  
(12 years of age and older)



2.5 mL vials  
for Primary Series Doses  
(6 through 11 years  
of age)\*



2.5 mL vials  
for Primary Series Doses  
(6 months through 5 years  
of age)



2.5 mL vials  
for Bivalent Booster Dose  
(6 years of age and older)

\*The Moderna COVID-19 Vaccine vial labeled "BOOSTER DOSES ONLY" is authorized to provide Primary Series doses (0.5 mL each) for individuals 6 through 11 years of age. Please see the Dear HCP Letter for more information.

## 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.

### 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>).

See additional Important Safety Information on the following pages.



# Moderna COVID-19 Vaccine

## Storage and Handling


### Thaw Each Vial Before Use

Vial images for illustrative purposes only

**Refrigerator**

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

**2°C to 8°C  
(36°F to 46°F)**

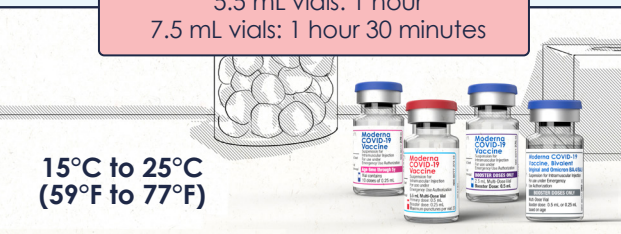


OR

**Room Temperature**

2.5 mL vials: 45 minutes  
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

**Please see the HCP Fact Sheet PDF for more information on Primary Series, third, and Booster Doses.**

### IMPORTANT SAFETY INFORMATION

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following receipt of the second primary series dose or first booster 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.

See additional Important Safety Information on the following page.

**moderna**<sup>®</sup>

- **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](mailto: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 6+ years:** <https://eua.modernatx.com/covid19vaccine-eua/bivalent-dose-HCP.pdf>
- **Primary series for 12+ years:** <https://eua.modernatx.com/covid19vaccine-eua/eua-fact-sheet-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>