Moderna COVID-19 Vaccine

For Children 6 Months-5 Years of Age

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.

Dose Presentation

Age Group	**6 months-5 years of age**
Dose Volume	Primary Series Dose: **Each 0.25 mL**
Dose Per Vial	Primary Series Doses: **10 doses**
Vial Cap Color	**Dark Blue** 
Vial Label	**Magenta Border** NDC 80777-279-05 
Carton	**Magenta Border** NDC 80777-279-99 

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.

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).

Links to https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

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Administration

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for any **additional doses** of Moderna COVID-19 Vaccine.

The Moderna Covid-19 vaccine does not require dilution. Swirl vial gently after thawing and between each withdrawal. **Do not shake or dilute.** After thawing, do not refreeze.

Prior to injection, inspect each dose to:

- Confirm liquid is **white to off-white** in color in both vial and syringe
- The vaccine may contain white or translucent product-related particulates. Do not administer the vaccine if it is discolored or contains other particulate matter
- Verify syringe volume of 0.25 mL (25 mcg) for Primary Series dose from the vial with a dark blue cap and a label with a magenta border
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials. **Record date and time of the first use on the vial label**
- Administer the Moderna COVID-19 Vaccine **intramuscularly**
- For more information refer to the Fact Sheet for Healthcare Providers

Primary Series Dosing Schedule

Age group	Volume administered per dose	Number of doses in Primary Series	Interval between doses
Eligible individuals aged 6 months-5 years	 0.25 mL (25 mcg)	2	1 month between doses 1 & 2
Eligible immunocompromised individuals aged 6 months-5 years	 0.25 mL (25 mcg)	3	1 month between doses 1 & 2 Minimum of 1 month between doses 2 & 3

For additional information regarding immunocompromised individuals, please review the CDC Administration Overview for Moderna COVID-19 Vaccine at https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html.

Links to https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

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

IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (cont.)

- **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).

Links to https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

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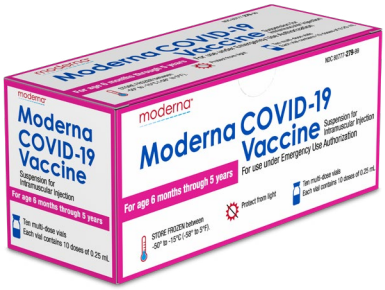
Frozen Storage



Can be stored frozen until expiration date*

–50°C to –15°C (–58°F to 5°F)

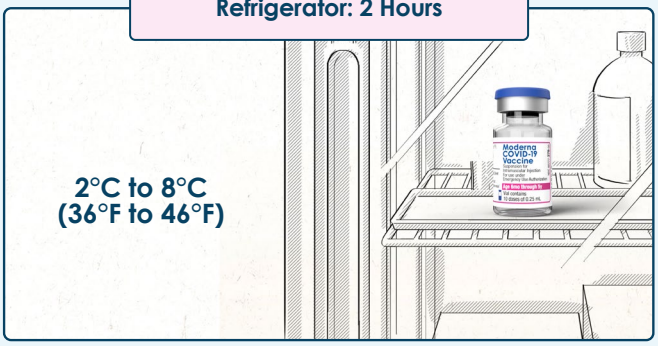
During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

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

Links to https://eua.modernatx.com/covid19vaccine-eua

Thaw Each Vial Before Use

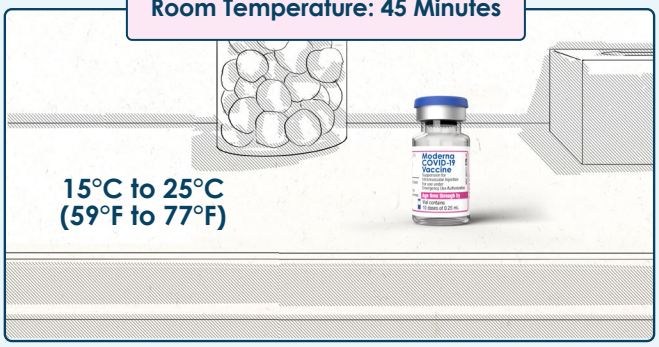
Refrigerator: 2 Hours



Let vial sit at room temperature for 15 minutes before administering

OR

Room Temperature: 45 Minutes



Vial images for illustrative purposes only

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).

Discard punctured vial after 12 hours.

NEVER refreeze thawed vaccine

IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (cont.)

- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

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Reimbursement Codes

Vaccine CPT Code*	Vaccine Administration CPT Codes†	NDCs by Presentation‡	CVX Code
91311 – 25 mcg/0.25 mL	0111A First Dose (25 mcg/0.25 mL IM) 0112A Second Dose (25 mcg/0.25 mL IM)	Primary Dose Presentation With 10 Doses Vial: 80777-279-05	228

*If required by the payer, use the vaccine CPT code that describes the pediatric dose administered (1st or 2nd dose).

†Administration COVID-19 vaccine CPT codes align with the associated dose (1st or 2nd) and report the work of administering the vaccine, all necessary counseling provided to caregivers and patients, and the recordkeeping.

‡Note, for NCPDP billing, pediatric doses are billed as 0.25 mL.

Other codes that may be needed for billing: ICD-10: Z23 - Encounter for Immunization

This vaccine is available for emergency use through the CDC COVID-19 Vaccination Program (the Vaccination Program). To participate in the Vaccination Program, healthcare providers must enroll as providers and comply with the provider requirements. Vaccination providers in the Vaccination Program may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Links to https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html

For questions related to billing, contact Moderna Customer Care at:
1-866-MODERNA (1-866-663-3762)

IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (cont.)

- **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.

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IMPORTANT SAFETY INFORMATION (CONT.)

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 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

Links to https://vaers.hhs.gov/reportevent.html

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***

Links to HCP Booster Only Fact Sheet
https://eua.modernatx.com/covid19vaccine-eua/eua-fact-sheet-booster-providers.pdf

Links to Primary Series for 12+ and Booster Dose over 18 HCP Fact Sheet
https://eua.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

Links to Primary series 6-11 years HCP Fact Sheet
https://eua.modernatx.com/covid19vaccine-eua/6-11y-facts-recipient.pdf

Links to Primary Series 6 months-5 years HCP Fact Sheet
https://eua.modernatx.com/covid19vaccine-eua/6m-5y-facts-HCP.pdf

Learn more about mRNA at ModernaTX.com

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