

Vaccines & Immunizations

Moderna COVID-19 Vaccine



General Information:

Multidose vial: 10 doses per vial Dosage: 0.5 mL

Do NOT mix with a diluent.
Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Age Indications:

18 years of age and older

Schedule:

2-dose series separated by 28 days A series started with COVID-19 vaccine (Moderna) should be completed with this product.

Administer:

Intramuscular (IM) injection in the deltoid muscle



EUA



Interim Clinical Considerations



Moderna COVID-19 Vaccine FAQs



ACIP Recommendations



Get the Moderna COVID-19 Vaccine Training Module for Healthcare Professionals

Administration Overview

Before administering vaccine, screen recipients for contraindications and precautions, even if this is the second dose. The recipient's health condition or recommendations regarding contraindications and precautions for vaccination may change from one visit to the next.

To assess patients correctly and consistently, vaccination providers should use a standardized, comprehensive screening tool.

Contraindications and Precautions

What are the Contraindications and Precautions

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- Contraindications:
 - Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine

- Immediate allergic reaction* of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [(PEG]). See /Appendix B: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines.
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

Precautions:

- History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
- Moderate to severe acute illness

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis, that occur within 4

How to Thaw, Prepare, and Administer the Moderna Vaccine

How to Thaw the Vaccine +

- Vaccine may be thawed in the refrigerator or at room temperature.
- Refrigerator: Between 2°C and 8°C (36°F and 46°F) for 2 hours and 30 minutes
- Room temperature: Between 15°C and 25°C (59°F and 77°F) for 1 hour
- Vials that have not been punctured may be kept between 8°C and 25°C (46°F and 77°F) for up to 12 hours. Do **NOT** refreeze thawed vaccine.

How to Prepare the Vaccine

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- 1. Assess recipient status:
 - Screen for contraindications and precautions.
 - Review vaccination history.
- 2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*
- 3. Unpunctured vials: Check the expiration date.
 - Never use expired vaccine.
 - Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.
- 4. With the vial upright, gently swirl the vaccine. Do NOT shake. If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.
- 5. Examine the vaccine. It should be white to off-white in color and may contain white particles. Do not use if liquid contains other particulate matter or is discolored.
- 6. Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.
- 7. Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

How to Administer the Vaccine

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- 1. Withdraw 0.5 mL of vaccine into the syringe. † Ensure the prepared syringe is not cold to the touch.
- 2. Note the date and time the vial was first punctured. Keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours.

- 3. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
- 4. Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated).
- 5. Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
- 6. Observe recipients after vaccination for an immediate adverse reaction:
 - **30 minutes**: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
 - 15 minutes: All other persons

[†]Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated.

Scheduling Doses +

- Persons age 18 years and older should receive 2 doses at least 28 days apart.
 - Second doses administered up to 4 days before the recommended date (24 or more days after first dose) are considered valid. However, doses administered earlier do not need to be repeated.
 - Second doses should be administered as close to the recommended interval as possible.
 - Do not use the grace period to schedule appointments for the second dose.
 - There is no maximum interval between the first and second dose.
- Both doses should be Moderna COVID-19 vaccine.
 - The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product. However, if 2 doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.
- Administer the vaccine series alone. Do not administermRNA COVID-19 vaccine at the same time as other vaccines, and wait a minimum interval of 14days before or after administration of any other vaccine.
 - If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

COVID-19 Vaccine (Moderna) Administration Resources

| Moderna COVID-19 Vaccine Standing Orders | Prevaccination Screening Form English |
|---|--|
| Preparation and Administration Summary Vaccine Expiration Date Tracking Tool | Vaccine administration training and clinical materials |



Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., immunization information system) as soon as practicable and no later than 72 hours after administration.

Storage and Handling Overview



Store vaccine in a freezer or refrigerator. See guidance below for each storage unit.

- The vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F).
- The ancillary supply kit will arrive separately from the vaccine.
- Unpack the vaccine shipment following the manufacturer's directions.

How to Store the Moderna COVID-19 Vaccine

Storing in a Freezer +

- Vaccine may be stored in a freezer between -25°C and -15°C (-13°F and 5°F).
- Note: These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter.
 - If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
 - Document storage unit temperatures using the freezer storage temperature log (Celsius or Fahrenheit).

Storing in a Refrigerator +

- Vaccine vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days before vials are punctured.
 - After 30 days, remove any remaining vials from the refrigerator and discard following manufacturer and jurisdiction guidance on proper disposal.
- Thawed vaccine cannot be refrozen.
- Use beyond-use date labels to track how long the vaccine has been in the refrigerator.
 - Remove the box from frozen storage.
 - Complete the information on the storage label and attach it to the box holding the vaccine vials.
 - Once labeled, store vaccine in the refrigerator.

Monitoring Temperature +

Storage unit temperatures must be monitored regularly and checked and recorded at the beginning of each workday to determine if any excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log and one of the options below:

- Option 1: Minimum/Maximum Temperatures (preferred) Most DDLs display minimum and maximum (min/max)
 temperatures. Check and record the min/max temperatures at the start of each workday.
- Option 2: Current Temperature If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

For CDC temperatures logs, see Storage and Handling Resources below.

Temperature Excursions +

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges is considered a temperature excursion. Responses to temperature excursion reports are dependent on information given by the provider to the manufacturer. Completing the Vaccine Troubleshooting Record for temperature excursions can help provide needed information for manufacturers to determine the viability of the vaccine.

COVID-19 Vaccine (Moderna Storage and Handling Resources)

| Storage and Handling Summary 🔼 | Refrigerator Storage Temperature Log (Fahrenheit) |
|--|---|
| Moderna BUD Guidance and Labels 🔼 | Freezer Storage Temperature Log (Celsius) |
| Storage and Handling Labels 🔼 | Freezer Storage Temperature Log (Fahrenheit) |
| Refrigerator Storage Temperature Log (Celsius) | Vaccine Storage Troubleshooting Record for temperature excursions ► ☑ |



Report Adverse Events

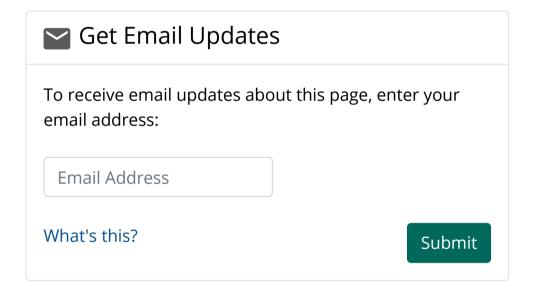
Adverse events that occur in a recipient after COVID-19 vaccination are required to be reported to the Vaccine Adverse Event Reporting System (VAERS). FDA requires vaccination providers to report vaccine administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under an EUA. Reporting is encouraged for other clinically significant adverse events, even if it is not clear that a vaccine caused the adverse event. Complete and submit reports to VAERS online ...

For further assistance with reporting to VAERS, call 1-800-822-7967.



What to Expect after a COVID-19 Vaccination

Print information for your patients on common side effects, helpful tips, and when to call a doctor after a COVID-19 vaccination.



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