

# Moderna COVID-19 Vaccine

## Summary of Recent Changes and Updates

Webpage content and individual PDFs are updated when there's new guidance concerning the Moderna COVID-19 vaccine. Expand each section below to see a summary of new and updated items spanning the past month.

#### **General Information Updates**

+

Updates on 4/21/2021

- Presentation information has been updated to:
  - Multidose vial: maximum of 11 doses per vial
- There has been an update to the COVID-19 Vaccine Quick Reference Guide for Healthcare Professionals 🔼 :
  - Multidose vial: maximum of 11 doses per vial
  - Storage and handling temperatures
  - Reference the pause in Janssen (Johnson & Johnson) Covid-19 vaccine. This does not change the Moderna COVID-19 Vaccine information.

#### **Preparation and Administration Information Updates**

+

Updates on 4/21/2021

- The Prevaccination Screening Form A has been updated to reference the pause in Janssen (Johnson & Johnson) Covid-19 vaccine. This does not change the Moderna COVID-19 Vaccine information.

#### Storage and Handling Information Updates

+

*Updates on 4/21/2021* 



- Keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours.
- If storing in a freezer:
  - Vaccine may be stored in a freezer between -50°C and -15°C (-58°F and 5°F).
- If 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, contact the manufacturer for guidance on viability.
    - If instructed to dispose of the vaccine, dispose of the vial(s) and packaging as medical waste according to local and state regulations. Refer to your jurisdiction's immunization program for guidance.
- Updates were made to the following documents to reflect these changes.
  - Moderna Storage and Handling Summary
  - Moderna Storage Labels
  - Moderna Temp Log (C)
  - Moderna Temp Log (F)
  - Moderna Vaccine Transport

## **General Vaccine Information**

Vaccine: Moderna COVID-19 Vaccine

Dosing Information +

Multidose vial: maximum of 11 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 Indication +

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.

Administration +

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 the recipient is scheduled to receive 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

- Contraindications:
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
  - Immediate allergic reaction<sup>†</sup> of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

**Note:** Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 vaccine (see footnote).<sup>±</sup>

#### • Precautions:

- History of an immediate allergic reaction<sup>†</sup> to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
- People with a contraindication to Janssen COVID-19 vaccine have a precaution to both mRNA vaccines (see footnote). ±
- Moderate to severe acute illness

tFor 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 hours following exposure to a vaccine or medication.

<sup>±</sup> Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVID vax Project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a
  precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine
  dose should wait at least 28 days to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

## 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). Unpunctured vials may be stored in the refrigerator for up to 30 days.
- Room temperature: Between 8°C and 25°C (46°F and 77°F).
  - Unpunctured vials may be held at room temperature for up to 12 hours.
- Do NOT refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from the freezer.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures.

#### How to Prepare the Vaccine

- 1. Assess recipient status:
  - Screen for contraindications and precautions.

- keview vaccination nistory.
- Review medical considerations.
- 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.
  - Scan the QR code on the outer carton, or
  - ∘ Go to www.modernatx.com/covid19vaccine-eua 🖸
  - Use CDC's expiration date tracker to document expiration date changes.
  - Do not discard vaccine until ensuring the expiration date has passed.
     As the expiration date approaches, check the expiration date again using the same process.
     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. Ensure the needle and syringe are secured tightly together.
- 8. Withdraw 0.5 mL of vaccine into the syringe. Ensure the prepared syringe is not cold to the touch. †
  - 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.
  - Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.5 mL.
- 9. 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.

\*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.

†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.

#### How to Administer the Vaccine

- Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
- 2. Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients (if tolerated).
- 3. Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
- 4. 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, contraindication to Janssen COVID-19 Vaccine who received Moderna COVID-19 Vaccine, 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 should be administered as close to the recommended interval as possible.

- If it is not feasible to adhere to the recommended interval, you may schedule the second dose up to 6 weeks (42 days) after the first dose; there is limited efficacy data beyond this window, but a dose after this time does not need to be repeated.
- Doses inadvertently given less than 28 days apart do not need to be repeated
- Both doses should be Moderna COVID-19 vaccine.
  - Every effort should be made to determine which vaccine product was received as the first dose.
  - In exceptional situations, if the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
- Administer the vaccine series alone. Separate mRNA COVID-19 vaccines 14 days 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 Preparation and Administration Summary	Prevaccination Screening Form  English
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.

- Vaccine will arrive frozen between -50°C and -15°C (-58°F and 5°F).
- An 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 -50°C and -15°C (-58°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 (preferred): Minimum/Maximum Temperatures 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)

Transport Temperature Log [A. (new)	Refrigerator Storage Temperature Log (Fahrenheit)
Storage and Handling Summary 🔼	Freezer Storage Temperature Log (Celsius)
Moderna BUD Guidance and Labels	Freezer Storage Temperature Log (Fahrenheit)
Storage and Handling Labels 🔼	Vaccine Storage Troubleshooting Record for temperature excursions
Refrigerator Storage Temperature Log (Celsius)	Transporting Vaccine to Off-Site Clinics

**Report Adverse Events** 

What to Expect after a COVID-19



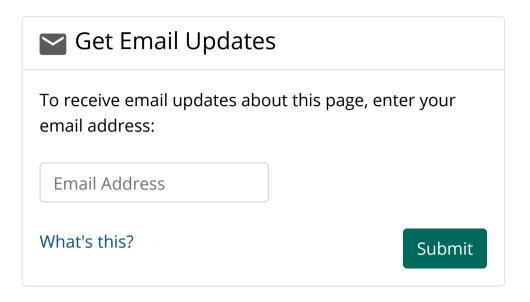
Adverse events that occur in a recipient after COVID-19 vaccination are required to be reported to the Vaccine Adverse Event Reporting System (VAERS). FDA requires vaccination providers to report vaccine administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases 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.



## Vaccination

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



Page last reviewed: February 22, 2021