

Appendix B: COVID-19 Frozen Vaccine(s)

1/14/2021

Read the full provider guide: [Interim COVID-19 Vaccine Provider Guide \(www.health.state.mn.us/diseases/coronavirus/vaccine/guide.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/guide.pdf).

Moderna COVID-19 (Vaccine B)

Summary of Moderna COVID-19 vaccine

Age indication	Dose route	Schedule	Presentation/preparation	Storage and handling	Notes
18 years and older	0.5 mL IM	0, 1 month (28 days)	Multi-dose: 10 doses per vial. No reconstitution required.	Freezer: -25°C to -15°C (-13°F to 5°F): up to 6 months Refrigerator: 2°C to 8°C (36°F to 46°F): up to 30 days Room temperature: up to 12 hours	Not interchangeable with other COVID-19 vaccines. Use vaccine within 6 hours once vial is punctured. Cannot place thawed vaccine back in freezer.

Shipping

Moderna COVID-19 vaccine arrives frozen to the ordering facility between minus 25 degrees to minus 15 degrees Celsius (minus 13 to plus 5 degrees Fahrenheit). A signature will be required when the vaccine is delivered. Upon receiving the vaccine, unpack the shipment following the manufacturer's instructions and confirm quantity is correct and there are no damaged vials. Vaccine is in multi-dose vials (MDVs), with 10 doses per vial. Minimum order is 100 doses. Ancillary supply kits will be delivered separately from the vaccine. If you need additional ancillary supplies, email health.mdhvaccine@state.mn.us.

Storage

Frozen

Vaccine may be stored frozen for six months at a recommended temperature of minus 25 to minus 15 degrees Celsius (minus 13 to plus 5 degrees Fahrenheit) until ready to use. Protect vaccine from light by storing it in the original carton. Do not store on dry ice or below minus 40 degrees Celsius (minus 40 degrees Fahrenheit).

- **Note:** Temperature range is narrower than for varicella-containing vaccines which are stored at minus 50 to minus 15 degrees Celsius (minus 58 to plus 5 degrees Fahrenheit).

Refrigerated

Once vaccine is removed from the freezer, store multi-dose vials at refrigerator temperatures of 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit) for up to 30 days prior to first use. **Do not refreeze this vaccine once thawed!**

Un-punctured vials

You can store un-punctured vials between 8 degrees to 25 degrees Celsius (46 to 77 degrees Fahrenheit) for up to 12 hours.

Redistribution

MDH has specific guidance for Moderna vaccine if it is to be redistributed to another site. Please find more information at [COVID-19 Vaccine: Redistribution and Off-site Vaccination Guide \(www.health.state.mn.us/diseases/coronavirus/vaccine/vaxredistribution.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/vaxredistribution.pdf).

Vaccine exposed to out-of-range temperatures should not be used until the manufacturer is contacted about the viability of the vaccine. Refer to the Managing out-of-range temperatures (excursions) section in the provider guide.

Expiration dates for vials

Each vial will have lot number and manufacturing date. To determine the expiration date of the vaccine vial, go to [How To Look Up Vial Expiration Date \(www.modernatx.com/covid19vaccine-eua/providers/vial-lookup\)](http://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup), enter the lot number, and press submit.

Use CDC's [COVID-19 Vaccine Expiration Date Tracking Tool \(www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf\)](http://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf) to record updated expiration dates as additional stability data are available from the manufacturer.

Remember, once the vial has been pierced, the vial will have a new beyond-use date or BUD that needs to be listed on the vial. Refer to the main provider guide section titled "Expiration and beyond-use date (BUD)" for more information.

Vaccine recommendations for Moderna COVID-19 vaccine

- Moderna COVID-19 vaccine is a two-dose series administered one month (Days 0 and 28) apart.
 - Every attempt should be made to schedule the person to return at 28 days or shortly thereafter for their second dose. Schedule the appointment for the second dose when the person receives their first dose.
 - With this vaccine, there is a four day grace period for the second dose (i.e., day 24-28) where the dose will be considered valid.
 - If it has been more than 28 days since the first dose, the second dose should be administered at the earliest opportunity (but no doses need to be repeated).
- Moderna COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products.
 - If two doses of different mRNA COVID-19 products are inadvertently administered, no other additional doses of either vaccine is recommended at this time.
- Moderna COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration of any other vaccines.
- If this vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Refer to the recommendations for mRNA COVID-19 vaccines in the full provider guide for information on people with current or a history of COVID-19 infection and special populations.

Contraindications and precautions

Refer to the Contraindications and Precautions sections in the main guide for more information regarding adverse reactions.

Ingredient listing for Moderna COVID-19 Vaccine

Each dose of the Moderna COVID-19 Vaccine includes the following ingredients:

- Total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]),
- 0.31 mg tromethamine,
- 1.18 mg tromethamine hydrochloride,
- 0.043 mg acetic acid,
- 0.12 mg sodium acetate, and
- 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

Taken from the *FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION MODERNA COVID-19 VACCINE* found in [Vaccination Provider Fact Sheet | EUA | Moderna COVID-19 Vaccine \(www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf\)](#).

Appropriate medical treatment used to manage immediate allergic reactions (e.g., epinephrine) must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Potential side effects (adverse reactions)

Adverse reactions reported in a clinical trial after administration of Moderna COVID-19 vaccine include injection site pain, redness, and/or swelling; fatigue (feeling tired); headache; myalgia (muscle pain); arthralgia (joint pain); chill; nausea/vomiting; axillary (armpit) swelling/tenderness; and fever.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Vaccine preparation

Overview

- Vaccine contains a frozen suspension in a **preservative-free** multi-dose vial (MDV) that must be thawed prior to administration. There are ten 0.5 milliliter doses per vial.
- Schedule: Two 0.5 milliliter doses given one month (28 days) apart with the same product.
- No on-site reconstitution required.
- Administer via intramuscular route.

Thawing vials

Before administering, thaw vaccine. After thawing, **do not refreeze!** You can thaw the vaccine one of two ways:

- In the refrigerator at 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administration.
- At room temperature between 15 to 25 degrees Celsius (59 to 77 degrees Fahrenheit) for one hour.

Diluent: None

Reconstitution: None

Preparing of individual doses

Follow strict aseptic technique when preparing the vaccine doses for administration.

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- Swirl vaccine vial gently after thawing and between each withdrawal. **Do not shake vial!** Do not reconstitute (dilute) the vial.
- Moderna COVID-19 vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the vial for other particulate matter and/or discoloration prior to administration and if found, do not administer the vaccine.
- Clean the stopper of the Moderna COVID-19 vaccine multi-dose vial with a single-use alcohol swab.
- Using a 1 milliliter or 3 milliliter syringe, withdraw a 0.5 milliliter dose from the Moderna COVID-19 vaccine multi-dose vial.
- After the first dose has been withdrawn from the multi-dose vial (i.e., pierced with a needle), the punctured vial should be stored between 2 to 25 degrees Celsius (36 to 77 degrees Fahrenheit) in the refrigerator or at room temperature for up to 6 hours. **Discard any unused vaccine after six hours from first puncture regardless of storage.** Do not refreeze. Record date and time of first use on the Moderna COVID-19 vaccine vial label.
 - Since there is no preservative in the Moderna multi-dose vial, discard the vial when there is not enough vaccine to obtain a complete dose. Do **not** "pool" or combine residual vaccine from multiple vials to obtain a dose.

Administration

- Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates.
- During the visual inspection:
 - Verify the final dosing volume of 0.5 milliliters.
 - Confirm there are no other particulates and that no discoloration is observed.
 - Do not administer if vaccine is discolored or contains other particulate matter.
- Administer the Moderna COVID-19 vaccine by the intramuscular (IM) route.

Don't waste vaccine

Don't reconstitute vials in advance as to avoid wasting vaccine. Once you have punctured the vial:

- All the doses need to be administered within 6 hours, or they must be discarded.
 - Make a plan to administer all the doses in the vial.
 - Consider having a waiting list.
 - Be aware of people who may be able to come at short notice to get vaccinated.
- If you have doses left in the vial, and no one immediately available to give them to, try your best to give these to priority groups. **But, above all else, do not waste vaccine.**

Resources

- CDC: [Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites \(www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html)
- Morbidity and Mortality Weekly Report (MMWR): [The Advisory Committee on Immunization Practices' Interim Considerations for the Use of Moderna COVID-19 Vaccine – United States, December 2020 \(www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w\)](https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w)
- Moderna: [Moderna COVID-19 Vaccine \(www.modernatx.com/covid19vaccine-eua/\)](https://www.modernatx.com/covid19vaccine-eua/)
 - EUA Fact Sheet for Healthcare Providers; EUA Fact Sheet for Recipients and Caregivers
 - View vial lot numbers and expiration dates
 - Moderna contact information: **1-866-MODERNA (1-866-663-3762)** 24/7 Call Center. Callers will be routed to one of four (4) areas:
 - General Moderna questions
 - Healthcare provider questions (clinical)
 - Product quality or technical questions (e.g., excursions)
 - Pregnancy registry
- CDC: [Moderna COVID-19 Vaccine \(www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html)
 - Moderna beyond-use date BUD guidance and labels, storage and handling labels, temperature logs, and more.
- [Immunization Courses: Webcasts and Self Study \(www.cdc.gov/vaccines/ed/courses.html\)](https://www.cdc.gov/vaccines/ed/courses.html)
 - Course: Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know
- CDC: [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States \(www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
- Vaccine protocol template: [COVID-19 Moderna mRNA1273 Vaccine \(www.health.state.mn.us/people/immunize/hcp/protocols/covidmoderna.docx\)](https://www.health.state.mn.us/people/immunize/hcp/protocols/covidmoderna.docx)



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Contact health.communications@state.mn.us to request an alternate format.