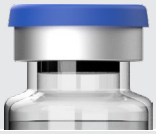
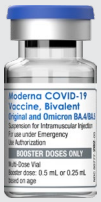
Moderna COVID-19 Vaccine, Bivalent

For individuals 6 months of age and older

AUTHORIZED USE

- Moderna COVID-19 Vaccine, Bivalent has not been approved or licensed by the FDA, but has been authorized by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19). Moderna COVID-19 Vaccine, Bivalent is authorized for use in individuals 6 months through 5 years of age who were previously unvaccinated or vaccinated with one or two doses of Moderna COVID-19 Vaccine (no longer authorized). Moderna COVID-19 Vaccine, Bivalent is authorized for use in individuals 6 years of age and older who were previously unvaccinated or vaccinated with one or more doses of an approved or authorized monovalent COVID-19 vaccine at least 2 months after receipt of any monovalent COVID-19 vaccine. Certain additional uses are authorized for immunocompromised patients and patients 65 years and older.
- 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 Sheet for Healthcare Providers Administering Vaccine.

Bivalent Dose Presentation

Age Group	6 years of age and older*		6 months to 5 years of age†		
COVID-19 Vaccination History	Unvaccinated	≥1 monovalent COVID-19 vaccine dose‡	Unvaccinated	1 monovalent Moderna COVID-19 Vaccine dose‡	2 monovalent Moderna COVID-19 Vaccine doses‡
Dose Volume	6 through 11 years of age: **Each 0.25 mL** 12 years of age and older: **Each 0.5 mL**	6 through 11 years of age: **Each 0.25 mL** 12 years of age and older§: **Each 0.5 mL**	**Each 0.25 mL**	**Each 0.25 mL**	**Each 0.2 mL**
Dose Per Vial	6 through 11 years of age: **10 doses** 12 years of age and older: **5 doses**	6 through 11 years of age: **10 doses** 12 years of age and older§: **5 doses**	**10 doses**	**10 doses**	**2 doses**
Vial Cap Color	**Dark Blue** 				**Dark Pink** 
Vial Label	**Gray Border** NDC 80777-282-05 				**Yellow Box** NDC 80777-283-02 
Carton	**Gray Border** NDC 80777-282-99 				**Yellow Box** NDC 80777-283-99 

*Immunocompromised individuals 6 years of age and older are eligible to receive 1 additional age-appropriate dose of Moderna COVID-19 Vaccine, Bivalent at least 2 months following the initial dose of a bivalent COVID-19 vaccine.

†Immunocompromised individuals 6 months through 5 years of age are eligible to receive 1 additional 0.25 mL dose of Moderna COVID-19 Vaccine, Bivalent from the vial with a dark blue cap and a label with a gray border at least 1 month following the most recent dose.

‡The monovalent Moderna COVID-19 Vaccine is no longer authorized for use in the United States.

§Individuals 65 years of age and older may receive 1 additional dose of 0.5 mL from the vial with a dark blue cap and a label with a gray border at the discretion of the vaccination provider at least 4 months after the first dose of a bivalent COVID-19 vaccine.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the vaccine 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.

See additional Important Safety Information on the following pages.

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Bivalent Dosing Schedule

Age Group	Number of Previous Doses of Any Monovalent COVID-19 Vaccine	Moderna COVID-19 Vaccine, Bivalent	
		Vial Cap and Label Color	Dosing Regimen, Dose, and Schedule*
≥65 years	Unvaccinated	Dark blue cap, gray border	Single dose,† 0.5 mL
	≥1 previous dose	Dark blue cap, gray border	Single dose, 0.5 mL, ≥2 months after receipt of any monovalent COVID-19 vaccine
12-64 years	Unvaccinated	Dark blue cap, gray border	Single dose, 0.5 mL
	≥1 previous dose	Dark blue cap, gray border	Single dose, 0.5 mL, ≥2 months after receipt of any monovalent COVID-19 vaccine
6-11 years	Unvaccinated	Dark blue cap, gray border	Single dose, 0.25 mL
	≥1 previous dose	Dark blue cap, gray border	Single dose, 0.25 mL, ≥2 months after receipt of any monovalent COVID-19 vaccine
6 months-5 years	Unvaccinated	Dark blue cap, gray border	2 doses, 0.25 mL each, ≥1 month apart
	1 previous dose‡	Dark blue cap, gray border	Single dose, 0.25 mL, 1 month after receipt of Moderna COVID-19 Vaccine
	2 previous doses‡	Dark pink cap, yellow box	Single dose, 0.2 mL, ≥2 months after receipt of Moderna COVID-19 Vaccine

*Immunocompromised individuals 6 years of age and older may receive 1 additional age-appropriate dose of Moderna COVID-19 Vaccine, Bivalent at least 2 months following the initial dose of a bivalent COVID-19 vaccine. Immunocompromised individuals 6 months through 5 years of age who have received 2 previous 0.25 mL doses (Moderna COVID-19 Vaccine or Moderna COVID-19 Vaccine, Bivalent) may receive 1 additional 0.25 mL dose of Moderna COVID-19 Vaccine, Bivalent from the vial with a dark blue cap and a label with a gray border at least 1 month after the most recent dose. Additional age-appropriate doses of Moderna COVID-19 Vaccine, Bivalent may be administered at the discretion of the vaccination provider.

† One additional dose, 0.5 mL, may be administered ≥4 months after the first dose of an authorized bivalent COVID-19 vaccine.

‡ Patients 6 months through 5 years of age who have received 1 or 2 doses of a monovalent COVID-19 vaccine must have received the Moderna COVID-19 Vaccine in order to receive Moderna COVID-19 Vaccine, Bivalent.

IMPORTANT SAFETY INFORMATION

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 vaccine. 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.

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Administration

Provide a vaccination card to the recipient or their caregiver with the date when the recipient receives a dose of Moderna COVID-19 Vaccine, Bivalent.

Moderna COVID-19 Vaccine, Bivalent 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:

1

- 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

2

- **For individuals 12 years of age and older, verify syringe volume of 0.5 mL (50 mcg)** from the vial with a dark blue cap and a label with a gray border
- **For individuals 6 through 11 years of age, verify syringe volume of 0.25 mL (25 mcg)** from the vial with a dark blue cap and a label with a gray border
- **For individuals 6 months through 5 years of age, verify syringe volume of 0.25 mL (25 mcg)** from the vial with the dark blue cap and a label with a gray border
- **For individuals 6 months through 5 years of age who have received the primary series Moderna COVID-19 Vaccine, verify syringe volume of 0.2 mL (10 mcg)** from the vial with a dark pink cap and a label with a yellow box

3

- If the amount of vaccine remaining in the vial cannot provide a full dose, 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 Moderna COVID-19 Vaccine, Bivalent **intramuscularly**
- For more information refer to the **Fact Sheet for Healthcare Providers**

Please see "Dear HCP Letter" and Fact Sheet for more information on Moderna COVID-19 Vaccine, Bivalent available at https://eua.modernatx.com/providers

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

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. 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)

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Frozen Storage

Can be stored frozen until expiration date*

–50°C to –15°C (–58°F to 5°F)

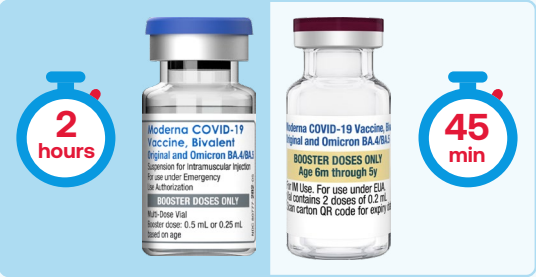
During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.

*Confirm vaccine expiration date by looking up the lot number at https://modernacovid19global.com/vial-lookup

Thaw Each Vial Before Use

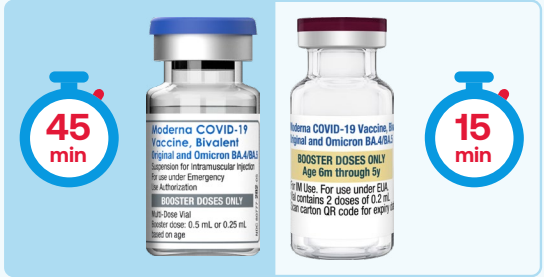
Refrigerator

2°C to 8°C (36°F to 46°F)



Room temperature

15°C to 25°C (59°F to 77°F)



Let vial sit at room temperature for 15 minutes before administering.
Vial images for illustrative purposes only.

Thawed Shelf Life

Unpunctured Vial: Maximum Time

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).

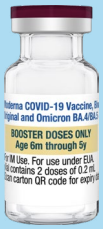
Discard vials with a dark blue cap and labels with a gray border 12 hours after first puncture.

After First Dose Has Been Withdrawn: Maximum Time

8 hours — **Refrigerator or room temperature**

Vial should be held between 2°C to 25°C (36°F to 77°F).

Discard vials with a pink cap and label with a yellow box 8 hours after first puncture.



NEVER refreeze thawed vaccine

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **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

Age group	Vaccine CPT Code*	Vaccine Administration CPT Code†	NDC 10/NDC 11 Labeler Product ID (Vial)	CVX Code
6 months through 5 years of age	91316 Bivalent, 10 mcg/0.2 mL	0164A	80777-283-02 80777-0283-02 Carton 80777-283-99	230
6 months through 11 years of age	91314 Bivalent, 25 mcg/0.25 mL	0141A Dose 1 0142A Dose 2 0144A Additional Dose	80777-282-05 80777-0282-05 Carton 80777-282-99	229
12 years and older	91313 Bivalent, 50 mcg/0.5 mL	0134A	80777-282-05 80777-0282-05 Carton 80777-282-99	229

*If required by the payer for Centers for Disease Control and Prevention (CDC) COVID-19 vaccine acquired product, use the vaccine CPT code that describes the dose administered and vial presentation used.
†The administration CPT codes align with the associated dose and vial presentation used for administration. CPT administration codes report the actual work of administering the vaccine, in addition to all necessary counseling provided to patients or caregivers and updating the records.
‡Note: For NCPDP billing, the quantity dispensed should be submitted with the value that represents the quantity of vaccine product administered (0.5 mL, 0.25 mL, 0.2 mL as appropriate).

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

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

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to Moderna COVID-19 Vaccine, Bivalent.

- **Limitations of Vaccine Effectiveness:** The Moderna COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

See additional Important Safety Information on the next page.

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IMPORTANT SAFETY INFORMATION

Contraindications
Do not administer the vaccine 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 vaccine. 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)

- **Myocarditis and Pericarditis:** Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. 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.

- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to Moderna COVID-19 Vaccine, Bivalent.

- **Limitations of Vaccine Effectiveness:** The Moderna COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Adverse Reactions

Solicited adverse reactions included:

- **6 months through 36 months of age:** Injection site erythema, pain and swelling; axillary (or groin) swelling/tenderness, fever, irritability/crying, loss of appetite and sleepiness
- **37 months of age and older:** Injection site erythema, pain and swelling; arthralgia, axillary (or groin) swelling/tenderness, chills, fatigue, fever, headache, myalgia, nausea/vomiting, and rash

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, Bivalent EUA” in the description section of the report.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762) or by visiting (https://report.moderna.convergehealthsafety.com/)

Please see the accompanying Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) Fact Sheet for Healthcare Providers Administering Vaccine for more information.

- ***https://eua.modernatx.com/covid19vaccine-eua/bivalent-facts-providers***

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