

# COVID-19 Vaccine Information Brief

June 24, 2022

Changes to the document from the previous version are highlighted in yellow.

## **IMPORTANT/NEW COVID-19 Vaccine Information**

- ACIP Recommends Moderna COVID-19 Vaccine for Children 6 Years Through 17 Years of Age
- Vaccine Dosage
  - Moderna Pediatric Vaccine Formulation for Children Aged 6 months – 5 years
  - Moderna Vaccine Formulation for Children 6 Years – 11 Years of Age
  - Moderna Vaccine Formulation for Individuals 12 Years of Age and Older
- Moderna COVID-19 Vaccine Products
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- Patient and Parent/Guardian Counseling: Side Effects
- V-Safe After Vaccination Health Checker

## **ACIP Recommends Moderna COVID-19 Vaccine for Children 6 Years Through 17 Years of Age**

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted June 23, 2022 to recommend Moderna's COVID-19 Vaccine for Children 6 years through 17 years of age. All children, including those who have already had COVID-19, should get vaccinated.

- Moderna COVID-19 vaccine for children 6 years through 11 years is anticipated to be available for the June 27, 2022, vaccine allocation.
- Effective immediately, Modera Adult vaccine, previously authorized for individuals 18 years of age and older (red cap and a label with a light blue border) can be administered to patients 12 years of age and older.

## **Resources**

- [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#)
- [FAQs for the Interim Clinical Considerations](#)
- [At-A-Glance COVID-19 Vaccination Schedule](#)
- [US COVID-19 Vaccine Product Information](#)
- [Recipient Education](#)
- [COVID-19 Vaccination for Children](#)

## Vaccine Dosage

Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.

- If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.

### Moderna Pediatric Vaccine Formulation for Children Aged 6 months – 5 years

- The FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 months through 5 years of age.
- Moderna Pediatric COVID-19 vaccine formulation for Children Aged 6 months – 5 years is supplied in multiple-dose vials with a **dark blue cap** and a label with a **magenta border**. This vaccine should NOT be used in individuals 6 years of age and older because of the potential for vaccine administration errors, including dosing errors.



#### Moderna COVID - 19 Vaccine Dosing for Children Aged 6 months – 5 years

- Administered as a primary series of two doses (0.25 mL each) 1 month apart to individuals 6 months through 5 years of age. The Moderna COVID-19 vaccine for children aged 6m–5 years **DOES NOT** require diluent.
- A third primary series dose (0.25 mL) of the Moderna COVID-19 Vaccine supplied in a multiple dose vial with a **dark blue cap** and a label with a **magenta border** is authorized for administration at least 1 month following the second dose to individuals 6 months through 5 years of age with certain kinds of [immunocompromise](#).

### Moderna Vaccine Formulation for Children 6 Years – 11 Years of Age

- The FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 years through 11 years of age.
- Moderna Pediatric COVID-19 vaccine formulation for Children Aged 6 years – 11 years is supplied in multiple-dose vials with a **dark blue cap** and a label with a **purple border**. **The cartons and vial labels state “BOOSTER DOSES ONLY.” This presentation may be used to provide primary series doses to individuals 6 years through 11 years of age.** A [Dear Healthcare Provider Letter](#) from Moderna describes the prescribing information for this product. The Moderna COVID-19 Vaccine is not authorized to provide booster doses to individuals 6 years through 11 years of age.



#### Moderna COVID - 19 Vaccine Dosing for Children Aged 6 Years-11 Years

- Administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 6 years through 11 years of age. The Moderna COVID-19 vaccine for children aged 6 years–11 years **DOES NOT** require diluent. A third primary series dose (0.5 mL) of the Moderna COVID-19 Vaccine supplied in a multiple dose vial with a **dark blue cap** and a label with a **purple border** is authorized for administration at least 1 month following the second dose to individuals 6 years through 11 years of age with certain kinds of [immunocompromise](#).

**Moderna Vaccine Formulation for Individuals 12 Years of Age and Older**

- The FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 12 Years of Age and Older.
- Moderna COVID-19 vaccine formulation for individuals 12 years of age and older is supplied in multiple-dose vials with a **red cap** and a label with a **light blue border**.



**Moderna COVID - 19 Vaccine Dosing for Individuals 12 Years of Age and Older**

- Administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 12 years of age and older. The Moderna COVID-19 vaccine for individuals 12 years of age and older **DOES NOT** require diluent. A third primary series dose (0.5 mL) of the Moderna COVID-19 Vaccine supplied in a multiple dose vial with a **red cap** and a label with a **light blue border** is authorized for administration at least 1 month following the second dose to individuals 12 years of age and older with certain kinds of **immunocompromise**. **The Moderna COVID-19 Vaccine is not authorized to provide booster doses to individuals 12 years through 17 years of age.**

**Moderna COVID-19 Vaccine Products**

Authorized Age group	 <b>6 months–5 years</b> (primary series)	 <ul style="list-style-type: none"> <li>• <b>6–11 years</b> (primary series)</li> <li>• <b>18 years and older</b> (booster doses)</li> </ul>	 <ul style="list-style-type: none"> <li>• <b>12 years and older</b> (primary series)</li> <li>• <b>18 years and older</b> (booster doses)</li> </ul>
Vial cap color	Dark blue	Dark blue	Red
Label border color	Magenta	Purple	Light blue
Dose (mRNA concentration)	25 mcg	50 mcg	100 mcg
Injection volume volume	0.25 mL	0.5 mL	0.5 mL(primary, age 12+); 0.25mL(booster, age 18+)
Dilution required	No	No	No
Doses per vial	10	5	Maximum of 11

## Moderna Vaccine Storage and Handling

- **Shipping**
  - The product will ship at -20°C, like all current Moderna COVID-19 vaccines.
- **Frozen Storage**
  - Store frozen between -50°C to -15°C (-58°F to 5°F)
- **Storage after Thawing - Do not refreeze once thawed**
  - Storage at 2°C to 8°C (36°F to 46°F):
    - Vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
    - Once open, doses in vials should be used within 12 hours. Clinics should consider vial size (10-doses) and 12-hour time frame when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.
  - Storage at 8°C to 25°C (46°F to 77°F):
    - Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours. Vials should be discarded 12 hours after the first puncture.
    - Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.
- **Preparation for Administration**
  - The Moderna COVID-19 Vaccine multiple-dose vials with both the dark blue cap and a label with a purple border and a red cap and label with a light blue border are supplied as a frozen suspension that does not contain a preservative and must be thawed prior to administration.
  - Thaw each vial before use following the instructions below.

- [Dark blue cap purple border thaw instructions](#)

Thaw in Refrigerator	Thaw at Room Temperature
Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes.

- [Red cap light blue border:](#)

Multiple-Dose Vial Containing	Thaw in Refrigerator	Thaw at Room Temperature
5.5 mL	Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 1 hour.
7.5 mL	Thaw between 2°C to 8°C (36°F to 46°F) for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 1 hour and 30 minutes.

**Moderna COVID-19 Vaccine Presentations - Wall Chart**

Age Group	6 months through 5 years (Primary Series)	6 years through 11 years (Primary Series)  Currently unavailable (Use the vial with dark blue cap and a label with a purple border)	6 years through 11 years (Primary Series)  18 years and older (Booster Dose)	12 years and older (Primary Series)  18 years and older (Booster Dose)
Vial Cap Color	Dark Blue	Dark Blue	Dark Blue	Red
Vial Label Border Color	MAGENTA	TEAL	PURPLE	LIGHT BLUE
Vial Image				
Primary Dose Volume	0.25 mL	0.5 mL	0.5 mL	0.5 mL
Booster Dose Volume	None	None	0.5 mL	0.25 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	 <a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a>	 <a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a>	 <a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a>	 <a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a>

**Resources:**

- [Moderna Letter of Authorization](#)
- [Moderna EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) - 6 years through 11 years of age
- [Moderna EUA Fact Sheet for Recipients and Caregivers](#) - 6 years through 11 years of age
- [Moderna EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) - 12 years and older and booster doses for 18 years of age and older
- [Moderna EUA Fact Sheet for Recipients and Caregivers](#) - 12 years and older
- [Moderna COVID-19 Vaccine](#)
- [Dear Healthcare Provider Letter](#)
- [Vaccine Resource Chart for Healthcare Providers](#)

## COVID-19 Vaccine Administration

COVID-19 vaccines may be administered without regard to timing of other vaccines. Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. In accordance with [general best practices](#), routine administration of all age appropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the healthcare visit.

When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers and parents/guardians may consider:

- Whether a child is behind or at risk of becoming behind
  - Likelihood of the child returning for another vaccination
  - Their risk of vaccine-preventable diseases
  - The reactogenicity profile of the vaccines
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## Patient and Parent/Guardian Counseling: Side Effects

Children may experience fewer side effects than adolescents or young adults. Local side effects may include:

- Pain, swelling, and redness at the injection site,
- Axillary or inguinal lymphadenopathy

Systemic side effects may include:

- Fever, fatigue, headache, chills, myalgia, arthralgia
- Irritability, crying, sleepiness, loss of appetite in infants and younger children

## Febrile Seizures

Febrile seizures were rare in COVID-19 vaccine clinical trials for young children. The impact of coadministration with COVID-19 vaccines on risk of febrile seizures has not been specifically studied. Febrile seizures are not uncommon generally and can occur in infants and young children with any condition that causes a fever, including COVID-19. Nearly all children who have a febrile seizure recover quickly and do not have any permanent neurological damage. CDC will closely monitor for febrile seizures following COVID-19 vaccination in young children.

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## V-Safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
  - [V-safe after vaccination health checker website](#)
  - [V-Safe Print Resources](#)
  - [Vaccine Adverse Event Reporting System \(VAERS\)](#)
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