

COVID-19 Vaccine Information Brief

June 20, 2022

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

Effective Immediately- Iowa Healthcare Providers May Begin Administering:

- **Pediatric Pfizer COVID-19 vaccine to children 6 months-4 years**
- **Pediatric Moderna COVID-19 vaccine to children 6 months-5 years**

IMPORTANT/NEW COVID-19 Vaccine Information

- Emergency Use Authorization of Moderna COVID-19 Vaccine for Children 6 Months Through 11 Years of Age
- ACIP recommends COVID-19 Vaccine for Young Children
- Pediatric Schedule: People Who Are NOT Moderately or Severely Immunocompromised
- Pediatric Schedule: People Who ARE Moderately or Severely Immunocompromised
- Vaccine Dosage
- Mixed Series For Children Ages 6 months Through 4 Years
- Moderna Pediatric Vaccine Information
- Pfizer Pediatric Vaccine Information
- Pfizer COVID-19 Medical Updates
- COVID-19 Vaccine Interchangeability and Vaccine Administration
- Patient and Parent/Guardian Counseling: Side Effects
- COVID-19 Vaccine Administration Errors
- V-Safe After Vaccination Health Checker

Emergency Use Authorization of Moderna COVID-19 Vaccine for Children 6 Months Through 11 Years of Age

On June 17, 2022, the [Emergency Use Authorization of Moderna COVID-19 Vaccine](#) was expanded to include use as a primary series in individuals 6 months through 17 years of age. **Moderna COVID-19 vaccine for children 6 years through 11 years of age is NOT available.**

Clinical considerations for the Moderna COVID-19 vaccine for children 6 years through 11 years of age will be discussed at the ACIP meeting June 22-23, 2022. At this time, healthcare providers should continue to vaccinate 6-17 year olds with the Pfizer COVID-19 vaccine.

ACIP recommends COVID-19 Vaccine for Young Children

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted June 18, 2022 to recommend all children 6 months through 5 years of age should receive a COVID-19 vaccine. This expands eligibility for vaccination and means all Americans ages 6 months and older are now eligible for vaccination. All children, including those who have already had COVID-19, should get vaccinated.

The CDC director has approved ACIP's recommendations. Iowa healthcare providers can begin administering the pediatric Pfizer COVID-19 vaccine for children 6 months through 4 years and a Moderna COVID-19 vaccine for children 6 months through 5 years of age.

Effective immediately, CDC recommends:**Pfizer-BioNTech COVID-19 Vaccine**

- **Children ages 6 months–4 years:** Should receive a 3-dose primary series. The first and second doses are separated by 3-8 weeks and the second and third doses are separated by at least 8 weeks. Currently, a booster is not authorized for this age group.
- **Children ages 5–11 years:** Should receive a 2-dose primary series separated by 3-8 weeks and 1 booster dose at least 5 months after completion of the primary series.

Moderna COVID-19 Vaccine

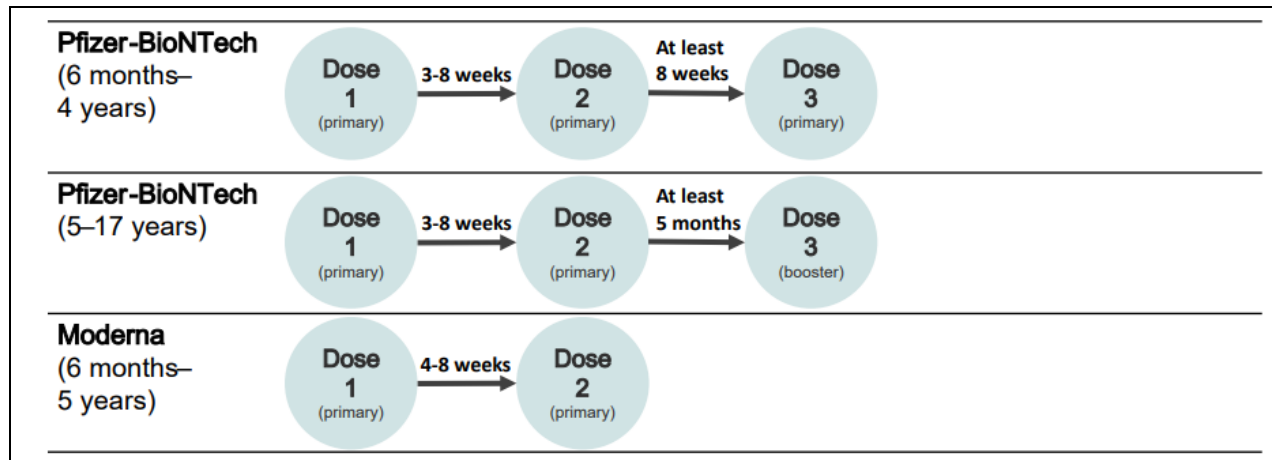
- **Children ages 6 months–5 years:** Should receive a 2-dose primary series separated by 4-8 weeks. Currently, a booster dose is not authorized for children in this age group who receive a Moderna primary series.

All children 6 months through 5 years of age should receive COVID-19 vaccine, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity. COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.

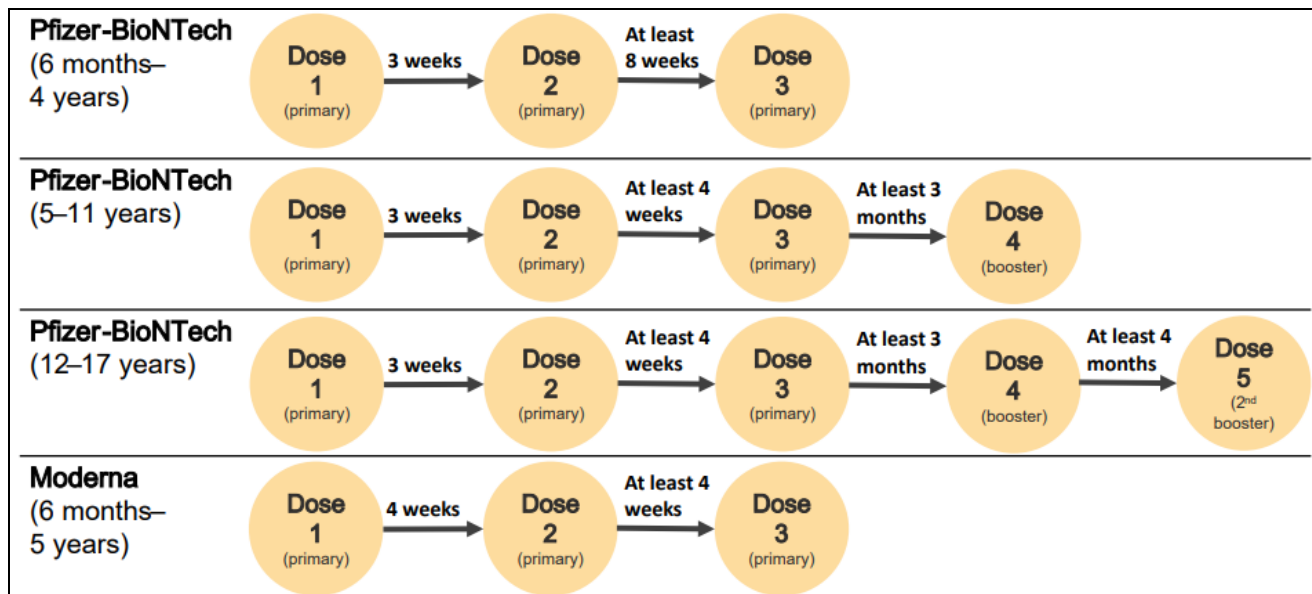
Resources

- [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](#)
-

Pediatric Schedule: People Who Are NOT Moderately or Severely Immunocompromised



Pediatric Schedule: People Who ARE Moderately or Severely Immunocompromised

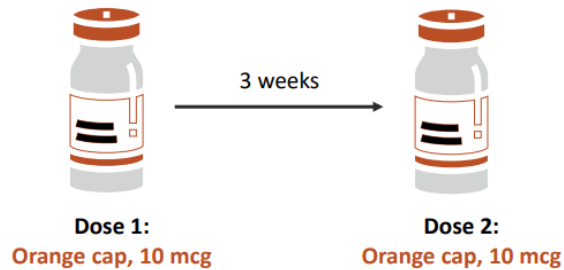


Vaccine Dosage

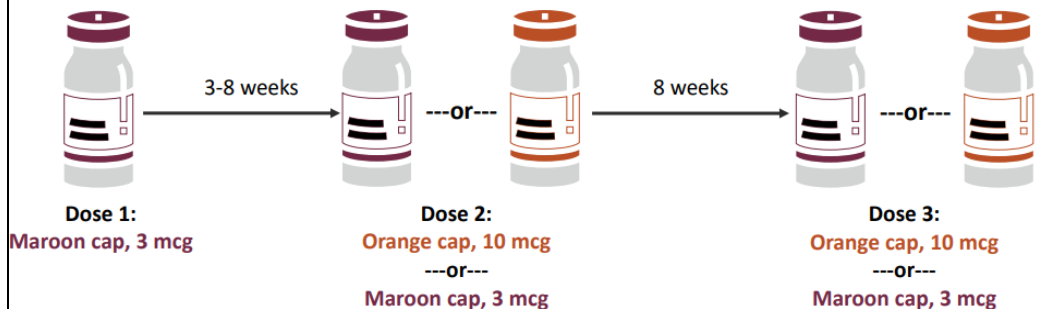
Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight.

- 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.

- **Scenario 1:** A 2-dose primary series using the formulation for people ages 5–11 years (orange cap)

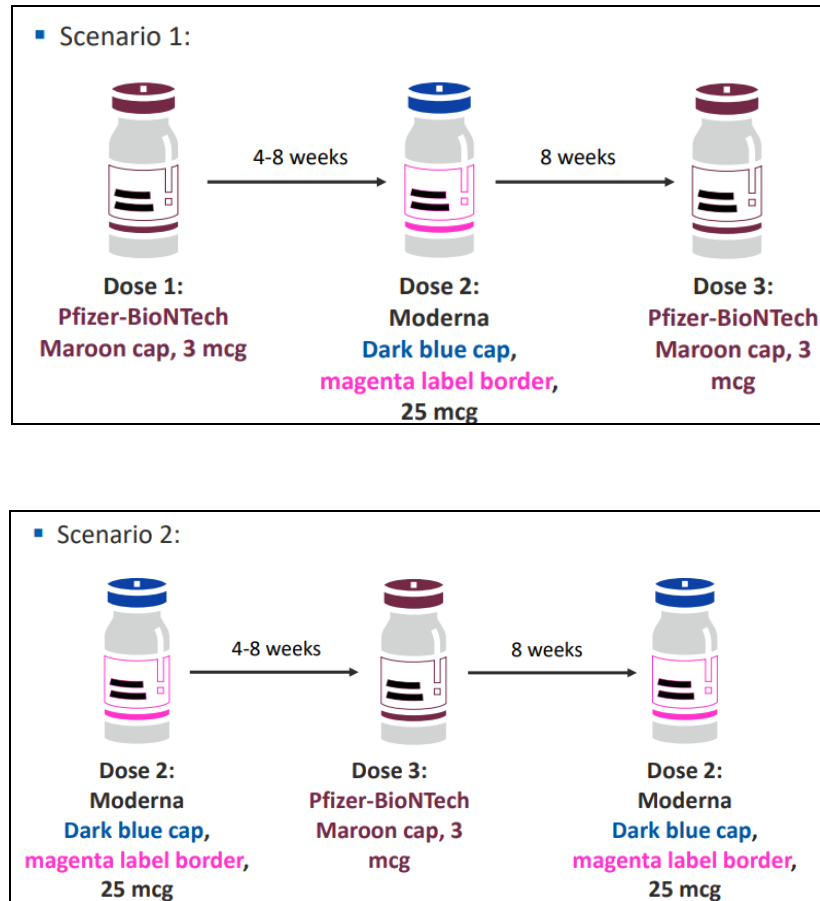


- Scenario 2:** A 3-dose primary series initiated with the formulation for ages 6 months–4 years. Dose 2 and 3 may be with: the formulation for ages 6 months–4 years or the formulation for ages 6–11 years.



Mixed Series For Children Ages 6 months Through 4 Years

Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should receive a third dose of either mRNA vaccine 8 weeks after the second dose to complete the 3-dose primary series.



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 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 vial with a dark blue cap and a label with a magenta border is supplied as a frozen suspension that does not contain a preservative and must be thawed prior to administration.
 - Verify that the vial of Moderna COVID-19 Vaccine has a dark blue cap and a label with a magenta border.
 - Each multiple-dose vial with a dark blue cap and a label with a magenta border contains 10 primary series doses of 0.25 mL each
 - Each dose must contain 0.25 mL of vaccine
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.25 mL, discard the vial and content
 - Thaw each vial before use following the instructions below.

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.

Moderna COVID-19 Vaccine Presentations

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.	 www.modernatx.com/covid19vaccine-eua	 www.modernatx.com/covid19vaccine-eua	 www.modernatx.com/covid19vaccine-eua	 www.modernatx.com/covid19vaccine-eua

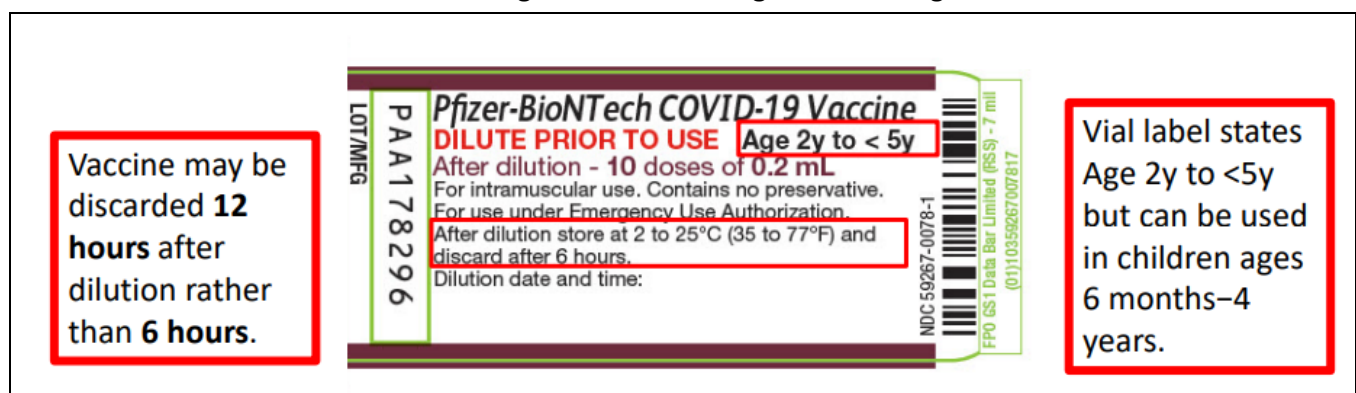
Resources:

- [Moderna Letter of Authorization](#)
- [Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) - 6 months through 5 years of age
- [Moderna EUA Fact Sheet for Recipients and Caregivers](#) - 6 months through 5 years of age
- [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](#)
- [Vaccine Resource Chart for Healthcare Providers](#)

Pfizer Pediatric Vaccine Formulation for Children Aged 6m–4 years

- The FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 months through 4 years of age.
- Pfizer-BioNTech COVID-19 Vaccine is supplied in a multiple dose vial with a maroon cap and a label with a maroon border is authorized for use to provide a 3-dose primary series to individuals 6 months through 4 years of age. **VACCINE MUST BE DILUTED PRIOR TO USE.**
- The vial labels may state “Age 2y to < 5y” or “Age 6m to < 5y” and carton labels may state “For age 2 years to < 5 years” or “For age 6 months to < 5 years”. Vials with either printed age range can be used for individuals 6 months through 4 years of age.

Pfizer COVID-19 Vaccine Formulation for Ages 6 months through 4 Years of Age



Pfizer COVID-19 Vaccine Storage and Handling

- **Shipping**
 - The Pfizer-BioNTech vaccine for children aged 6m–4 years ships at -80°C, like all current Pfizer COVID-19 vaccines in thermal containers with dry ice.
- **Ultra-Cold Storage**
 - Frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) for up to 12 months from the date of manufacture. **Do not store vials at -25°C to -15°C (-13°F to 5°F).** Once vials are thawed, they should not be refrozen.
- **Refrigerated Storage**
 - If cartons of Pfizer-BioNTech COVID-19 vaccine multiple dose vials with maroon caps and labels with maroon borders are received at 2°C to 8°C (35°F to 46°F), they can be stored at 2°C to 8°C (35°F to 46°F) for up to 10 weeks.
 - Check that the carton has been updated to reflect the 10 week refrigerated expiry date.
 - Regardless of storage condition, the vaccine should not be used after 12 months from the date of manufacture printed on the vial and cartons.









- **Dose Preparation for Administration**

- Each vial **MUST BE DILUTED** before administering the vaccine.
- *Prior to Dilution*
 - The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial with a maroon cap and a label with a maroon border contains a volume of 0.4 mL, and is supplied as a frozen suspension that does not contain preservative.
 - Each vial must be thawed before dilution.
 - Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)].
 - Refer to thawing instructions in the panels below.
- *Dilution*
 - Dilute the vial contents using 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP to form the Pfizer-BioNTech COVID-19 Vaccine.
 - ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and is included with the ancillary supply kits. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 2.2 mL of diluent.
- After dilution, 1 vial contains 10 doses of 0.2 mL.

- **Dosing and Schedule**

- Vaccine is administered intramuscularly as a primary series of 3 doses (0.2 mL each)
- The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose in individuals 6 months through 4 years of age.
- Individuals who will turn from 4 years to 5 years of age between any doses in the primary series may receive:
 - A 2-dose primary series with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 mcg modRNA, supplied in multiple dose vials with orange caps and labels with orange borders)
 - OR**
 - A 3-dose primary series initiated with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (each 0.2 mL dose containing 3 mcg modRNA, supplied in multiple dose vials with maroon caps). Each of Doses 2 and 3 may be with:
 - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age (supplied in multiple dose vials with maroon caps), or
 - Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 years through 11 years of age (supplied in multiple dose vials with orange caps and labels with orange borders).

Pfizer COVID-19 Vaccine Presentations

Age Group	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
Vial Cap Color and Label Border Color	MAROON 	ORANGE 	PURPLE** 	GRAY** 
Is Dilution Needed?	Dilute Before Use	Dilute Before Use	Dilute Before Use	Do Not Dilute
Amount of Diluent* Needed per Vial	2.2 mL	1.3 mL	1.8 mL	NO DILUTION
Dose Volume	0.2 mL	0.2 mL	0.3 mL	0.3 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

** The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

Resources

- [Pfizer Letter of Authorization](#)
- [Pfizer COVID-19 EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) - 6 months through 4 years of age
- [Pfizer COVID-19 EUA Fact Sheet for Recipients and Caregivers](#) - 6 months through 4 years of age

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

Pfizer has expanded its training sessions to address questions about currently recommended COVID-19 vaccine products as well as vaccines for children. The COVID-19 vaccine medical updates and site training webinars aim to educate providers and immunization staff on the proper use of the Pfizer-BioNTech COVID-19 Vaccines. Daily training (Monday through Friday) will begin Monday, June 20, 2022, and continue through July 8, 2022 (with no training on July 4th). For details, see [dates and links for upcoming training sessions](#).

COVID-19 Vaccine Interchangeability and Vaccine Administration**Vaccine Interchangeability**

COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series.

Children ages 6 months–4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine should be administered at least 8 weeks after the second dose to complete the 3-dose primary series.

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
-

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.

COVID-19 Vaccine Administration Errors

Error	Recommended Action
<ul style="list-style-type: none"> If the incorrect formulation is administered, resulting in a higher-than-authorized dose 	<ul style="list-style-type: none"> Do NOT repeat dose.^{†‡}
<ul style="list-style-type: none"> If the incorrect formulation is administered, resulting in a lower-than-authorized dose 	<ul style="list-style-type: none"> Repeat dose immediately (no minimum interval) with the age-appropriate formulation. Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccine, especially in males ages 12–39.^{†‡}

[†]If the administration error resulted in a higher-than-authorized vaccine dose, in general a subsequent dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the subsequent dose, this dose might be delayed, but this decision should be assessed on a case-by-case basis.

[‡]If the dosing is in accordance with the FDA EUA, it is not considered an error and VAERS reporting is not indicated.

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 \(VAERS\)](#)