

COVID-19 Vaccine Information Brief

November 3, 2021

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

Effective Immediately: Iowa Healthcare Providers May Begin Administering Pediatric Pfizer Vaccine to 5–11-Year Olds

IMPORTANT/NEW COVID-19 Vaccine Information

- **ACIP recommends Pfizer-BioNTech Pediatric COVID-19 vaccine for children ages 5 to 11**
- Pfizer Pediatric Vaccine Information- Vaccine Storage & Handling
- Pfizer COVID-19 Medical Updates
- V-Safe After Vaccination Health Checker

ACIP recommends Pfizer-BioNTech Pediatric COVID-19 vaccine for children ages 5 to 11

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted November 2, 2021 to recommend Pfizer's Pediatric COVID-19 vaccine for those 5-11 years of age under Emergency Use Authorization. The CDC director has also approved ACIP's recommendations. Iowa healthcare providers can begin administering the pediatric Pfizer vaccine to children 5-11 years of age once vaccine shipments have been received.

Effective immediately, CDC recommends:

A two-dose, primary vaccination series for everyone ages 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity. Pediatric Pfizer-BioNTech COVID-19 vaccine (2-doses, 10µg, IM) is recommended for children 5–11 years of age, under an Emergency Use Authorization. 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.

Formulation and Dosing for Pfizer COVID-19 Vaccine

	Formulation for ≥ 12 -year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Number of doses	2	2
Interval	3 weeks (21 days)	3 weeks (21 days)
Additional primary dose	Moderate and severe immunocompromise	Not recommended
Booster dose	Not recommended 12–17 years	Not recommended
	Recommended for certain groups ≥ 18 years*	

*Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underlying medical conditions, or who work or live in high-risk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021

- **Formulations of the Pfizer-BioNTech COVID-19 Vaccines are NOT interchangeable.**
 - If a child ages 5–11 years inadvertently receives a 30 μg dose for their first dose, they should receive a single age-appropriate 10 μg dose for their second dose 21 days later and should be considered as having a completed primary series.
 - If a child ages 5–11 years inadvertently receives a 30 μg dose for their second dose, they should be considered as having a completed primary series.
 - If an individual aged ≥ 12 years inadvertently receives a 10 μg dose, the dose should be repeated with the age appropriate 30 μg dose immediately.
 - Exception for children who turned from 11 to 12 years in between their first and second dose and receive a second 10 μg dose to complete their series.

Vaccine Dosage

- Children should receive the age-appropriate vaccine formulation regardless of their size or weight.
 - As opposed to many medications, vaccine dosages are based on age and not size or weight.
- The dosage should be based on the child’s age on the day of vaccination.
 - If a child turns from 11 to 12 years of age in between their first and second dose and receives 5–11 years 10 μg (orange cap) for their second dose, they do not need to repeat the dose and this is not considered an error per the EUA.

Current or Prior SARS-CoV-2 Infection

- People with known current SARS-CoV-2 infection should defer vaccination at least until the person has recovered from the acute illness (if the person had symptoms) AND they have met criteria to discontinue isolation.
 - (Isolation and precautions can typically be discontinued 10 days after positive test if asymptomatic or 10 days after symptom onset and after resolution of fever for at least 24 hours) Serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making.

Counseling: Expected Side Effects from PfizerBioNTech COVID-19 Vaccine

Children may experience fewer side effects than adolescents or young adults. Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection.

Expected side effects include:

- Local: pain, swelling, erythema at the injection site
- Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy

Routine antipyretic or analgesic medications can be taken for the treatment of post vaccination local or systemic symptoms, if medically appropriate. In general, Aspirin is not recommended for use in children and adolescents ≤18 years due to risk of Reye’s syndrome.

Resources:

- [Pfizer Fact Sheet for Healthcare Providers](#)
- [Pfizer Face Sheet for Recipients and Caregivers](#)
- [COVID-19 Vaccination for Children 5-11 Years Old - CDC](#)

Pfizer Pediatric Vaccine Information- Vaccine Storage & Handling

The Pfizer-BioNTech vaccine for 5–11-year-olds is a new product configuration with new packaging, new preparation, and a new national drug code (NDC). **The current product for adults and adolescents should not be used for children.** The Pfizer-BioNTech vaccine for 5–11-year-olds is a two dose series 21 days apart.

Vaccine Storage and Handling

- The product will be delivered in a newly updated product shipper at -80°C. The shipper is disposable and does not need to be returned to Pfizer. **The shipper CANNOT be used for vaccine storage.**
- The shipper box should be unpacked immediately upon receipt, as indicated on the carton.
- The contents must be placed in an ultra-cold freezer -90°C to -60oC or a refrigerator at 2°C to 8°C. **DO NOT PLACE THE PRODUCT IN THE REGULAR FREEZER.**
- Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2 to 8°C and 6 months at ultra cold temperatures of -90 to -60°C.
- Once open, doses in vials should be used within 6 hours. Clinics should consider vial size (10-doses) and 6-hour timeframe when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.

Shippers

Pfizer pediatric vaccines will be shipped on dry ice in smaller disposable shippers. Unlike the adult shippers,



these smaller shippers cannot be used for temporary storage. The contents **MUST** be removed and placed in a refrigerator or ultra-cold freezer as soon as the order is received. (See storage table below). **Do not store Pfizer pediatric COVID-19 vaccine in a standard freezer.** The shipper is disposable and does not need to be returned to Pfizer.

Controlant Temperature Monitoring

Shipping boxes will continue to contain the familiar Controlant temperature monitor. The shipper should be unpacked immediately upon delivery. Check the temperature monitor for any excursion warnings, turn the monitor off, and return it in the package provided.



Pediatric Vaccine Vials and Diluent

Pediatric vials come packaged in cartons of 10 vials each. Vials come with a distinctive orange cap, orange striping on the label, and orange striping on the carton. Each vial will be filled to 1.3mL before dilution. The pediatric formula will continue to require addition of 1.3mL of diluent (1:1 ratio) and will contain 10 doses per vial. Orders of Pfizer pediatric vaccine include ancillary kits that contain 10mL diluent vials. While these vials appear to contain sufficient diluent for multiple vials, they **must only be used once**.



● **Diluent vials are a one-time-use item and should be discarded with the remaining content after each use.**

- For each vial of vaccine, extract 1.3mL of diluent from a single-use vial to reconstitute 1.3mL of vaccine.
- Do not be tempted to puncture diluent vials more than once.

Storage and Handling

The table below indicates the length of time the pediatric vials can be stored at each temperature. Note, the 10 weeks in the refrigerator is **not** in addition to the 6 months in the freezer. All conditions for storage must be completed within the overall time frame for expiration. Once expired, the vaccine should be discarded regardless of storage conditions.

Storage Conditions	
Ultra Cold Freezer (-90°C to -60°C)	6 months
Freezer (-25°C to -15°C)	N/A
Refrigerator (2°C to 8°C)	10 weeks

Pfizer COVID-19 Medical Updates

Pfizer Vaccines US Medical Affairs will be hosting “Medical Updates” for its COVID-19 vaccine (with its partner BioNTech) on Tuesdays, at 5pm ET, and Thursdays, at 12pm ET, for the remainder of 2021.

These sessions will be continuously updated to reflect new information and changes that evolve. Such updates will be identified at the start of each session and further explained during each presentation.

November 2021 Sessions

Please click on the links below to join the sessions at the designated times.

Date & Time	Password
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Attendee link – November 4 – 12 PM ET	Y4ZkXdh2bz7
Attendee link – November 5 – 12 PM ET	rJSpNPts332

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 \(VAERS\)](#)