



Health Alert Network Message 21-78 Update: CDC Approval of Pfizer COVID-19 Vaccine for Children 5-11 Years

Origination Date:
November 3, 2021

Revision Dates (List All Revision Dates):
November 5, 2021

UPDATED: Pediatric COVID-19 Vaccine for Children 5 to 11 Years

On 11/03/2021, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine. CDC now expands vaccine recommendations to about 28 million children in the United States in this age group and allows providers to begin vaccinating them as soon as possible. Enrolled COVID-19 vaccination providers can now place orders for the Pfizer-BioNTech pediatric vaccine in LINKS.

COVID-19 cases in [children](#) can result in hospitalizations, deaths, MIS-C (multi-inflammatory syndrome in children) and long-term complications, such as "long COVID," in which symptoms can linger for months. The spread of the Delta variant resulted in a surge of COVID-19 cases in children throughout the summer. During a 6-week period in late June to mid-August, COVID-19 hospitalizations among children and adolescents [increased fivefold](#). Vaccination, along with other preventative measures, can protect children from COVID-19 using the safe and effective vaccines already recommended for use in adolescents and adults in the United States. Similar to what was seen in adult vaccine trials, vaccination was nearly 91 percent effective in preventing COVID-19 among children aged 5-11 years. In clinical trials, vaccine side effects were mild, self-limiting, and similar to those seen in adults and with other vaccines recommended for children. The most common side effect was a sore arm.

COVID-19 vaccines have undergone – and will continue to undergo – the most intensive safety monitoring in U.S. history. Vaccinating children will help protect them from getting COVID-19 and therefore reducing their risk of severe disease, hospitalizations, or developing long-term COVID-19 complications. Getting your children vaccinated can help protect them against COVID-19, as well as reduce disruptions to in-person learning and activities by helping curb community transmission.

Fact Sheet For Healthcare Providers Administering Vaccine To 5 to 11 Year Olds:

<https://www.fda.gov/media/153714/download>

Important differences between the adult and pediatric Pfizer COVID-19 Vaccines:

- The pediatric formulation is for children aged 5-11.
- The pediatric formulation will come with an orange vial cap.
- The dose for children aged 5-11 is 10mcg.
- The injection volume is 0.2ml.
- The fill volume of the vial is 1.3ml.
- The amount of diluent needed is 1.3ml.

- There will be 10 doses per vial after dilution.
- The pediatric vaccine can be stored in ULT freezer for 6 months.
- Once unfrozen, the vaccine should not be refrozen.
- The vaccine can be refrigerated for up to 10 weeks.
- **Update: The vial must be used within 12 hours of opening, after which it must be discarded.**

Please see attached comparison chart (HAN 21-78 Update Attachment) for storage, handling, and dosage differences between Pfizer vaccine for 5-11 year old children and the existing adult/adolescent Pfizer vaccine.

Update: Vial Storage During Use:

- If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.
- Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may be stored at 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to dilution. After dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution.
- Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. This is outdated information. The information in this Full EUA Prescribing Information supersedes the number of hours printed on vial labels and cartons. After initial puncture providers have 12 hours to use this product before it must be discarded.

The following is attributable to Dr. Walensky:

“Together, with science leading the charge, we have taken another important step forward in our nation’s fight against the virus that causes COVID-19. We know millions of parents are eager to get their children vaccinated and with this decision, we now have recommended that about 28 million children receive a COVID-19 vaccine. As a mom, I encourage parents with questions to talk to their pediatrician, school nurse or local pharmacist to learn more about the vaccine and the importance of getting their children vaccinated.”

The Updated Pfizer COVID-19 Pediatric Emergency Use Authorization (EUA) fact sheet for recipients and caregivers can be found at:

<https://www.fda.gov/media/153717/download>

Where and how can families get their children vaccinated?

Families should contact their local vaccine provider to confirm they have the COVID-19 pediatric vaccine. Vaccine is in the process of being shipped and some providers may not receive their initial shipments until later in the week or next week. Currently families can call 211 or the COVID-19 Vaccine Hotline at 1-855-453-0774 with general questions or to find a vaccination

location near them that has ordered COVID-19 pediatric vaccine. In the coming days the federal vaccine finder Vaccines.gov will be updated with pediatric vaccine search capability.

For a person younger than age 18, parental/caregiver consent is needed to get the shot. Parental consent may be given verbally or via signed form. LDH has developed a consent form providers may use if they choose to; it can be found at ldh.la.gov/Covid-19K-12.

If you have questions, please contact la.immunization@la.gov