

Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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Centers for Disease Control and Prevention (CDC) Recommends Pediatric COVID-19 Vaccine for Children 5 through 11 Years Old

On Tuesday, November 2, 2021, the CDC's Director, Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC's Advisory Committee on Immunization Practices's (ACIP) unanimous recommendation to extend the Pfizer-BioNTech's Emergency Use Authorization (EUA) to include all children 5 through 11 years of age, regardless of underlying conditions or prior COVID infection. This follows the Food and Drug Administration's (FDA) decision on October 26, 2021 to amend Pfizer-BioNTech's EUA for administration of their COVID-19 mRNA vaccine to children 5 through 11 years of age as a 2-dose series (10µg each dose, 3 weeks apart) based on the recommendation of its Vaccine Related Biologic Product Advisory Committee (VRBPAC).

After a thorough review, both committees felt that the totality of evidence demonstrated clearly that the benefits of vaccinating this population outweighed any potential risks. The studies performed showed that the main side effects were soreness at the injection site, fatigue, and headache. COVID-19 disease has significantly affected children in this age group, including hospitalization, intensive care admission, and even death. Although most of these severely affected children had underlying medical conditions, around a third did not.

The committees also felt that vaccinating children from 5 through 11 years of age could make a significant contribution in reducing the pandemic across the entire population by preventing future infections, both in and out of the school setting. Importantly, monitoring for potential, but very rare vaccine-related side effects will continue through the systems already in place, such as v-safe, the Vaccine Adverse Event Reporting System (VAERS), and the Vaccine Safety Datalink (VSD).

The Alabama Department of Public Health will proactively work with vaccine providers and Alabama's medical societies to ensure that this vaccine is available to all of Alabama's eligible children, especially the most vulnerable. Parents of eligible individuals desiring the vaccine should visit a participating local vaccine site. Those with questions or concerns should discuss the risks and benefits with their trusted provider.

Vaccine Storage and Handling

According to the FDA, the Pfizer-BioNTech COVID-19 vaccine will be distributed in multiple dose vials with orange caps and labels with orange borders and must be diluted before use. If received frozen at ultra-cold conditions of -25°C to -15°C (-13°F to 5°F), the vials can be stored in an ultra-low temperature freezer at 90°C to -60°C (-130°F to -76°F) for up to 6 months. The date printed on the vial is the date of manufacture, not the expiration date. The expiration will be

6 months after the date of manufacture. The vials may not be frozen at -25°C to -15°C (-13°F to 5°F). The vials can immediately be transferred to a refrigerator at 2°C to 8°C (35°F to 46°F) for thawing. Thawed vials may be kept at 2°C to 8°C (35°F to 46°F) for up to 10 weeks but may not be refrozen. 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. The information in the Updated FDA Fact Sheet link below supersedes the number of hours printed on vial labels and cartons.

Of note, any child who receives the 10µg dose at age 11 but then turns 12 years of age between the first and second doses, either the 10µg dose or the 30µg dose may be given as the subsequent dose.

Complete instructions, including dose volume and diluent can be found at <https://www.fda.gov/media/153714/download>

Interim Clinical Considerations (CDC)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Emergency Use Authorization

<https://webfiles.pfizer.com/Letter-Of-Authorization>