

Pfizer/BioNTech COVID-19 vaccine – EUA granted for 6 months to 4 years

- On June 17, 2022, the [FDA announced](#) the emergency use authorization ([EUA](#)) of the [Pfizer/BioNTech COVID-19 vaccine](#) for the prevention of COVID-19 to include use in children down to 6 months of age.
 - The FDA amended the EUA to include use of the vaccine in individuals 6 months through 4 years of age. The vaccine had previously been authorized for use in individuals 5 years of age and older.
- The efficacy and safety of Pfizer/BioNTech COVID-19 vaccine for individuals 6 months to 4 years of age was established in an ongoing, randomized, blinded, placebo-controlled clinical study in the U.S. and internationally.
 - A total of 80 children 6 months to 23 months of age and 140 children 2 years to 4 years of age received a 3-dose primary series at 3 mcg. Immune response for both age groups was comparable to immune response seen with a higher dosage in 170 adults 16 – 25 years of age.
- Warnings and precautions for Pfizer/BioNTech COVID-19 vaccine include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine effectiveness.
- The most common adverse reactions with Pfizer/BioNTech COVID-19 vaccine use in children 6 months to 23 months of age were irritability, decreased appetite, fever and pain, tenderness, redness and swelling at the injection site. These side effects were also reported for the vaccine recipients 2 through 4 years age, in addition to fever, headache, and chills.
- The recommended dose of Pfizer/BioNTech COVID-19 vaccine in children 6 months to 4 years is given intramuscularly as a primary series of three doses (0.2 mL/3 mcg). The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose.
 - Refer to Pfizer/BioNTech COVID-19 vaccine [Fact Sheet](#) for additional administration guidelines.
- The Pfizer/BioNTech COVID-19 vaccine for children 6 months to 4 years of age will be distributed by the federal government.
 - The Pfizer/BioNTech COVID-19 vaccine for children 6 months to 4 years of age will be available as multiple dose vials with maroon caps and labels with maroon borders. (NDC 59267-0078-04).

What's Next?

- The CDC's [Advisory Committee on Immunization Practices \(ACIP\)](#) convened June 17 and 18 to make recommendations on appropriate utilization of the Pfizer/BioNTech COVID-19 vaccine in 6 months to 4 years of age.

- The CDC director will need to sign off on ACIP's recommendations prior to implementation.



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