



November 4, 2021

****Emergency Use Authorization (Expanded Use)****

Pfizer-BioNTech COVID-19 Vaccine authorized in children aged 5-11 years

Background & Current Status^{1,2:}

- On December 11, 2020, the U.S Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine for prevention for COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.
- On May 10, 2021, the FDA reissued and expanded the Pfizer-BioNTech COVID-19 Vaccine EUA to include individuals aged 12 to 15 years.
- On August 23, 2021, FDA approved the Pfizer-BioNTech COVID-19 Vaccine, now known as Comirnaty®, for the prevention of COVID-19 in individuals aged 16 years and older.
- **On October 29, 2021, the FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age.** The authorization was based on the FDA's thorough and transparent evaluation of the data that included input from independent advisory committee experts who overwhelmingly voted in favor of making the vaccine available to children in this age group. This action introduces the first authorized COVID-19 vaccine available in this pediatric population.
- *The Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age is supplied in a multiple dose vial with an orange cap and a label with an orange border, and is administered, after dilution, as a two-dose primary series, 3 weeks apart, but is a lower dose (10 micrograms) than that used for individuals 12 years of age and older (30 micrograms).*
- Of interest, Pfizer and BioNTech are also conducting a pediatric study evaluating the safety and efficacy of the vaccine in children aged 6 months to 11 years of age.

Vaccine Efficacy^{1:}

The effectiveness data to support the EUA in children down to 5 years of age is based on an ongoing randomized, placebo-controlled study that has enrolled ~4,700 children aged 5 through 11 years. The study is being conducted in the U.S., Finland, Poland and Spain. Children in the vaccine group received two doses of the Pfizer-BioNTech COVID-19 Vaccine containing 10 micrograms of messenger RNA per dose. The FDA analyzed data that compared the immune response of 264 participants from this study to 253 participants 16 through 25 years of age who had two higher doses of the vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. The immune responses of the younger age participants were comparable to the older participants.

The FDA also conducted a preliminary analysis of cases of COVID-19 occurring seven days after the second dose. In this analysis, among participants without evidence of prior infection with SARS-CoV-2, 3 cases of COVID-19 occurred among 1,305 vaccine recipients and 16 cases of COVID-19 occurred among 663 placebo recipients; the vaccine was 90.7% effective in preventing COVID-19.

Vaccine Safety^{1:}

The available safety data to support the EUA include more than 4,600 participants (3,100 vaccine vs. 1,538 placebo) ages 5 through 11 years enrolled in the ongoing study. In this trial, a total of 1,444 vaccine recipients were followed for safety for at least 2 months after the second dose.

Commonly reported side effects in the clinical trial included injection site pain (sore arm), redness and swelling, fatigue, headache, muscle and/or joint pain, chills, fever, swollen lymph nodes, nausea and decreased appetite. More children reported side effects after the second dose than after first dose. Side effects were generally mild to moderate in severity and occurred within two days after vaccination, and most went away within 1-2 days.

The FDA and CDC safety surveillance systems have previously identified increased risks of myocarditis and pericarditis following vaccination with Pfizer-BioNTech COVID-19 Vaccine, particularly following the second dose, and with the observed risk highest in males 12 through 17 years of age. Therefore, the FDA conducted its own benefit-risk assessment using modelling to predict how many symptomatic COVID-19 cases, hospitalizations, intensive care unit (ICU) admissions and deaths from COVID-19 the vaccine in children 5 through 11 years of age would prevent versus the number of potential myocarditis cases, hospitalizations, ICU admissions and deaths that the vaccine might cause. The FDA's model predicts that overall, the benefits of the vaccine would outweigh its risks in children 5 through 11 years of age.

Ongoing Safety Monitoring¹:

Pfizer has updated its safety monitoring plan to include evaluation of myocarditis, pericarditis and other events of interest in children 5 through 11 years of age. In addition, the FDA and the CDC have several systems in place to continually monitor COVID-19 vaccine safety and allow for the rapid detection and investigation of potential safety problems.

CDC Interim Clinical Considerations³: Summary of recent changes (last updated November 3, 2021):

- Recommendations and clinical guidance for use of Pfizer-BioNTech COVID-19 Vaccine in children aged 5–11 years including updated section on [Vaccination of children and adolescents](#)
- Updated guidance on [COVID-19 vaccine dosing and schedule](#)
- Updated guidance for myocarditis and pericarditis after mRNA COVID-19 vaccination in section on [Considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna](#)
- New guidance for people who received passive antibody products in section on [COVID-19 vaccination and SARS-CoV-2 infection](#)
- Updated guidance in section on [People who received COVID-19 vaccine outside the United States](#)
- Updated guidance in section on [People who received COVID-19 as part of a clinical trial in the United States](#)
- Updated guidance on [Considerations for COVID-19 vaccination in moderately and severely immunocompromised people](#)
- Updated guidance in section on [Contraindications and precautions](#)
- Updated Table in [Appendix A: Vaccine administration errors and deviations](#)
- Updated [Appendix B: Triage of people with a history of allergies or allergic reactions](#)
- Updated [Appendix C: Ingredients included in COVID-19 vaccines](#)
- Updated [Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination](#)

Current EUA Fact Sheets^{2,4}:

As a convenience, Fact Sheets for the Pfizer-BioNTech COVID-19 Vaccine (5-11 years) are accessible below:

- ❖ [Healthcare Providers](#)
- ❖ [Recipients and Caregivers](#)

Mandatory Requirements under the EUA²:

- Use Pfizer-BioNTech COVID Vaccine only in authorized patients described in the respective Fact Sheets.
- Communicate to recipients or caregivers, as age appropriate, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to receiving Pfizer-BioNTech COVID-19 Vaccine.
- Include vaccination information in the local jurisdiction’s Immunization Information System or other system.
- Mandatory reporting of the following to the [Vaccine Adverse Event Reporting System \(VAERS\)](#):
 - Vaccine administration errors whether or not associated with an adverse event,
 - Serious adverse events (irrespective of attribution to vaccination),
 - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
 - Cases of COVID-19 that result in hospitalization or death.
- Respond to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer BioNTech COVID-19 Vaccines to recipients.
- *Federal, Tribal, and Urban programs are all encouraged to put “IHS” into field #26 of the form.*

References:

1. Food and Drug Administration. FDA News Release. [FDA Authorize Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 Through 11 Years of Age](#). Published online on October 29, 2021.
2. Food and Drug Administration. [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE](#). Revised: 29 October 2021.
3. Centers for Disease Control and Prevention. [ACIP Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#). Updated November 3, 2021.
4. Food and Drug Administration. [FACT SHEET FOR RECIPIENTS AND CAREGIVERS](#). Revised: 29 October 2021.