

## PFIZER VACCINE FOR CHILDREN AGES 5 TO 11 FACTS

On November 2, 2021, the U.S. Food and Drug Administration 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.

Key points for parents and caregivers:

- Effectiveness: Immune responses of children 5 through 11 years of age were comparable to those of individuals 16 through 25 years of age. In addition, the vaccine was found to be 90.7% effective in preventing COVID-19 in children 5 through 11.
- Safety: The vaccine's safety was studied in approximately 3,100 children age 5 through 11 who received the vaccine and no serious side effects have been detected in the ongoing study.
- The Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age is administered as a two-dose primary series, three weeks apart, but is a lower dose than that used for individuals 12 years of age and older.
- In the U.S., COVID-19 cases in children 5 through 11 years of age makeup 39% of cases in individuals younger than 18 years of age. According to the CDC, approximately 8,300 COVID-19 cases in children 5 through 11 years of age resulted in hospitalization. As of Oct. 17, 691 deaths from COVID-19 have been reported in the U.S. in individuals less than 18 years of age, with 146 deaths in the 5 through 11 years age group.
- 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 the first dose. Side effects were generally mild to moderate in severity and occurred within two days after vaccination, and most went away within one to two days.
- Based on the totality of scientific evidence available, the known and potential benefits of the Pfizer-BioNTech COVID-19 vaccine in individuals down to 5 years of age outweigh the known and potential risks.
- It is mandatory for Pfizer Inc. and all vaccination providers to report any serious adverse events to the FDA.