

## **Health Advisory**

### **COVID-19 Pfizer-BioNTech Single Booster for Children between 5 to 11 years May 23, 2022**

#### **SUMMARY POINTS**

- Children between ages 5 through 11 years should receive the Pfizer-BioNTech single booster at least 5 months after completing the primary series.
- FDA has evaluated the safety and effectiveness data and determined that the Pfizer-BioNTech single booster outweighs its known and potential risks.
- Common side effects profiles of the Pfizer-BioNTech single booster are similar to the side effects from the primary series.
- If children are eligible to receive other vaccinations, they may receive the COVID-19 and other vaccines during the same visit.

The CDC and FDA recommend a single booster dose of Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age **at least 5 months** after completing the primary series or the additional dose for those who are immunocompromised. The CDC and the FDA have determined that benefits will outweigh any known and potential risks.

Emerging data suggests that vaccine effectiveness against COVID-19 wanes with increasing time after the second dose of vaccine in all populations who are eligible to receive the COVID-19 vaccines.

Support for authorization is based on immune response data from a subset of study participants (children between ages 5 to 11 years) who received a Pfizer-BioNTech booster dose 7 to 9 months after completing the two-dose primary series. Antibody level against COVID-19 one month after the booster dose was compared to the level before the booster dose and found to be increased.

In addition to efficacy data, FDA gathered the safety information from 400 children who received a booster dose at least 5 months (ranging from 5 to 9 months) after completing a two-dose primary series. The most common side effects were injection site pain/redness/swelling, fatigue, headache, muscle/joint pain, chills, and fever.

Pfizer-BioNTech is the only COVID-19 vaccine authorized for children between 5 to 11 years of age. There is no second booster dose authorized for this age group. Children less than 5 years of age are not eligible for any COVID-19 vaccines.

People who are 5 years and older may receive the COVID-19 vaccines and other vaccines (i.e., a flu shot) during the same visit. If the child is eligible to receive multiple vaccines at the same visit, each injection should be separated by 1 inch or more.

#### Resources:

- [COVID-19 Vaccine Recommendations for Children and Teens](#)
- [COVID-19 Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years](#)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#)