

## COVID-19 PEDIATRIC PFIZER-BIONTECH VACCINE KEY MESSAGES

### TOPLINES

- **CDC now recommends the Pfizer COVID-19 Vaccine for children ages 5 through 11 years.**
  - The recommendation now paves the way for 28 million children to receive the vaccine.
  - Providers can start vaccinating as soon as possible with the vaccination program fully up and running the week of November 8th.
- **The Pfizer COVID-19 Vaccine is over 90% effective at preventing COVID-19 in children ages 5 through 11 years.**
  - Getting your child vaccinated can help protect them against COVID-19, as well as reduce disruptions to in-person learning and group activities by helping curb community transmission.
- **COVID-19 vaccines have undergone—and continue to undergo—the most intensive safety monitoring in U.S. history.**
  - In clinical trials of about 3,000 children, serious side effects were rare and self-limiting.
- **After getting a COVID-19 vaccine, children may have some side effects similar to those seen in adults and with other vaccines.**
  - These are normal signs that their body is building protection, but they should go away in a few days.
- **We are following the science.**
  - This recommendation was made based on in-depth review of available safety, immunogenicity, and efficacy data.

### BACKGROUND

- The CDC's Advisory Committee on Immunization Practices (ACIP) recommended children ages 5 through 11 years receive a Pfizer-BioNTech COVID-19 Vaccine.
  - There are about 28 million children between the ages of 5 and 11 in the U.S.
  - Nearly 2 million cases of COVID-19 have involved children in this age group since the start of the pandemic.
- With many children back in school and participating in extracurricular activities, and cases of COVID-19 still high across the U.S., vaccinating children ages 5 through 11 years is critical to preventing infections and therefore possible severe disease, as well as reducing COVID-19 transmission.
- The decision by FDA and CDC to expand and recommend the use of the vaccine among children followed an in-depth review of available safety, immunogenicity, and efficacy data.
  - Safety data was reviewed from about 3,000 children who received the vaccine and found no severe adverse events with reported post-vaccine symptoms, including soreness at the site, headaches, muscle aches and low-grade fevers, which are common in the adult population.
  - Similar to what we saw in the adult clinical trials, vaccination was nearly 91% effective in preventing COVID-19 among children ages 5 through 11 years.
- While children are at a lower risk of becoming severely ill with COVID-19 compared to adults, [children can be infected with the virus](#) and there is no way to tell in advance if a child will get a severe or mild case.
  - Some children have developed a rare but serious disease that is linked to COVID-19 called [multisystem inflammatory syndrome \(MIS-C\)](#).
- Getting your child vaccinated can help protect them against COVID-19, as well as reduce disruptions to in-person learning and group activities by helping curb community transmission.
- Widespread vaccination is critical to helping us end this unprecedented pandemic.

### SAFETY

- It's important to note that COVID-19 vaccines have undergone – and will continue to undergo – the most intensive safety monitoring in U.S. history.
  - Robust clinical trials featuring thousands of children were conducted to evaluate the safety and immune response to a COVID-19 vaccine in this population.
  - Because young children are still growing and developing, researchers assessed the need for different doses of vaccines already used for adolescents and adults.
  - As a result, children ages 5 through 11 years will receive an age-appropriate dose of the Pfizer-BioNTech Vaccine that is one-third the dose that adolescents and adults receive.
  - Smaller needles, specifically designed for children, will also be used to give the vaccine to children.
  - The Pfizer-BioNTech Vaccine for children ages 5 through 11 has the same active ingredients as the vaccine given to adults and adolescents. However, the vaccine for children comes in a different vial with a different color cap. The Pfizer-BioNTech Vaccine that is given to adults and adolescents cannot be used for children ages 5 through 11 years.
- Cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) have been reported following COVID-19 vaccination in children ages 12 through 17 years.
  - While these conditions are rare, the available evidence suggests a link with mRNA COVID-19 vaccination.
  - Most cases have been in young males and most occur after the second vaccine dose.
  - In general, people who developed these conditions following COVID-19 vaccination respond well to medical treatment and rest and recover.
- Children may have some [side effects](#) from COVID-19 vaccination, which are normal signs that their body is building protection. These side effects may affect your child's ability to do daily activities, but they should go away in a few days.
  - [Serious side effects are rare](#), but may occur.
  - However, the benefits of COVID-19 vaccination outweigh the known and potential risks.
- Parents/caregivers can enroll their child in [v-safe](#), a free, easy-to-use smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins. Through v-safe, you can report how your child is feeling after vaccination.

#### TOUGH Q&A - GENERAL

**Q: Do children younger than 12 years old need to be vaccinated? Are they at increased risk of getting sick from COVID-19?**

**A:** With many children back in school and participating in extracurricular activities, COVID-19 vaccination among children ages 5 through 11 years is critical to preventing infection and possible severe disease, as well as reducing the spread of COVID-19. There are approximately 28 million children between the ages of 5 and 11 in the United States, and there have been nearly 2 million cases of COVID-19 within this age group during the pandemic. While fewer children have been sick with COVID-19 compared to adults, [children can be infected with the virus](#), and there is no way to tell in advance if a child will get a severe or mild case. Some children have developed a rare but serious disease that is linked to COVID-19 called [multisystem inflammatory syndrome \(MIS-C\)](#).

**Q: Are COVID-19 vaccines safe for children in this age group?**

**A:** Based on data from the clinical trial, children may have some [side effects](#) from COVID-19 vaccination, which are normal signs that their body is building protection. These side effects may affect your child's ability to do daily activities, but they should go away in a few days. [Serious side effects are rare](#), but may occur.

**Q: Where will vaccines for younger children be available?**

**A:** Finding available COVID-19 vaccines for anyone 5 years and older is convenient. Pharmacies and HRSA sites, including Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), and Community Health Centers are being leveraged to administer COVID-19 vaccine to children who may not seek service in a pediatric practice. FQHCs, pharmacies, public health, and pediatric provider networks can partner with schools, districts, and communities to host pediatric vaccination clinics. These vaccine providers can encourage school-based and extracurricular vaccination for younger school-aged children to hold targeted programs to ensure equity and coverage.

Later this week and into next week, [vaccines.gov](https://www.vaccines.gov) will list doctor's offices, local pharmacies, healthcare clinics, and local health departments where vaccine is available. This free resource provides accurate and up-to-date information about vaccination services in your area. You can also text your ZIP code to 438829, or call 1-800-232-0233 to find locations near you in the U.S.

**Q: How does dosage work for children? What should a parent do if a child turns 12 after they get their first dose of the pediatric vaccine but before the second dose is due?**

**A:** As opposed to many medications, vaccine dosages are based on age and not size or weight. If a child turns from 11 to 12 years of age in between their first and second dose and receives the pediatric Pfizer-BioNTech COVID-19 Vaccine for their second dose, they do not need to repeat the dose.

**Q: Is this Pfizer vaccine the same one that's given to adolescents and adults?**

**A:** The Pfizer-BioNTech Vaccine for children ages 5 through 11 has the same active ingredients as the vaccine given to adults and adolescents. However, the vaccine for children comes in a different vial with a different color cap. The Pfizer-BioNTech Vaccine that is given to adults and adolescents cannot be used for children ages 5 through 11 years. Children ages 5 through 11 will receive an age-appropriate dose that is one-third of what adolescents and adults receive. Smaller needles, designed specifically for children, are used for children ages 5 through 11 years. COVID-19 vaccine dosage does not vary by patient weight but by age on the day of vaccination. Children are still required to get two doses three weeks apart to be considered fully vaccinated.

**Q: Is there a fertility/development concern with vaccinating children before they reach puberty?**

**A:** No. There is no evidence that any vaccines, including COVID-19 vaccines, can cause female or male fertility problems.

**Q: Does a parent or guardian have to give consent before a child can receive a COVID-19 vaccine?**

**A:** No. There is no federal legal requirement for a parent, guardian, or caregiver to consent for COVID-19 or any other vaccination. However, this **does not mean** that consent is not required for select age groups. State or local laws and policies, as well as vaccine provider policies, around minor consent for vaccination have existed for a long time and will also apply to COVID-19 vaccination of children. COVID-19 vaccine providers should follow current state/jurisdictional policies and practices for other routine immunizations in this age group.

**Q: How will vaccine safety be monitored in this age group?**

**A:** COVID-19 vaccines have undergone – and will continue to undergo – the most intensive safety monitoring in U.S. history. CDC and FDA will continue to monitor safety using our established and new safety monitoring systems. Parents/caregivers can enroll their child in [v-safe](#), a free and easy-to-use smartphone-based app, where they can complete health check-ins after COVID-19 vaccination and report how their child is feeling after vaccination. Additionally, patients, caregivers, and vaccine providers are also asked to report adverse events after vaccination to the [Vaccine Adverse Event Reporting System \(VAERS\)](#), even if it is not clear that

the vaccine caused the adverse event. CDC reviews all of the information and reports any serious adverse reactions.

**Q: Is the federal government worried about myocarditis or pericarditis after vaccination in children?**

**A:** Cases of [myocarditis](#) (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) have been reported after Pfizer-BioNTech COVID-19 vaccination of children ages 12–17 years. These reactions are rare; in one study, the risk of myocarditis after the second dose of Pfizer-BioNTech in the week following vaccination was around 54 cases per million doses administered to males ages 12–17 years.

**Q: Is it safe to co-administer COVID-19 vaccines with other vaccines, like flu?**

**A:** Yes, if a patient is eligible, both flu and COVID-19 vaccines can be administered at the same visit, as [recommended by CDC and ACIP](#). In addition to flu vaccine, COVID-19 vaccine can be given with other vaccines as well.

**Q: Will COVID-19 vaccines for children be free?**

**A:** Yes, COVID-19 vaccines are available for everyone at no cost, including the Pfizer-BioNTech Vaccine for children ages 5 through 11 years. COVID-19 vaccines will continue to be given to all eligible people living in the United States, regardless of insurance or immigration status.

**Q: Will children younger than 12 receive a vaccine card?**

**A:** Yes, all vaccine recipients, including children ages 5 through 11 years, will receive a CDC vaccination card upon initial vaccination.