

Fact Sheet

COVID-19 Vaccine for Children 5-11 Years Old

The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) have authorized, under emergency use, the first COVID-19 vaccine for children under age 12 years. The new **Pfizer-BioNTech COVID-19 vaccine pediatric formulation for children ages 5-11** years is now available at children's hospitals, pharmacies, local health departments and some pediatric and primary care practices in all Ohio counties.

While children are less likely than adults to get severely ill from COVID-19, they are not invincible. Children most certainly can, and do, become ill. Just like adults, when children become sick from COVID-19, they can spread it to others and suffer severe health outcomes, including hospitalization or even death.

According to the American Academy of Pediatrics, as of Oct. 28, 2021, nearly 6.4 million Americans younger than 18 years had been infected with COVID-19, and 791 had died. In Ohio, nearly 206,000 children have contracted COVID-19, and 15 Ohio residents under age 18 years have died.

COVID-19 can cause otherwise healthy children to suffer multisystem inflammatory syndrome in children (MIS-C), a potentially life-threatening condition causing inflammation of multiple vital organs. Pediatric hospitals have reported an increase in cases of MIS-C in Ohio.

ABOUT THE VACCINE

The Pfizer-BioNTech vaccine for 5-11-year-olds is a new product configuration of the existing Pfizer-BioNTech COVID-19 vaccine that has been successfully administered to millions of people ages 12 years and older across the country.

The new pediatric formulation is a lower dose that has been clinically tested for administration in young children. It is safe and highly effective at preventing symptomatic infections. Healthy volunteers participate in clinical studies to receive the vaccine so it can be tested for safety and possible side effects. Clinical trials in children ages 5-11 years found the vaccine to be 90.7% effective in preventing symptomatic COVID-19. To compare, the flu shot is typically between 40% to 60% effective.

Before vaccines can be authorized for use, their safety and effectiveness are thoroughly evaluated by scientists, researchers, medical professionals, the U.S. Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). Vaccine safety is continuously monitored by many systems and agencies, including the CDC's Vaccine Adverse Event Reporting System (VAERS).

The 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 (10 micrograms) than that used for individuals 12 years of age and older (30 micrograms). Full protection is achieved two weeks after the second shot. This means it would take five weeks for your child to achieve full protection.

The current Pfizer/Comirnaty product for adults and adolescents should not be used in children younger than 12 years of age.

ABOUT EMERGENCY USE AUTHORIZATION

An Emergency Use Authorization (EUA) allows the use of an unapproved medical product, or unapproved use of an approved medical product, for use during a public health emergency if the benefits of its use outweigh any known or potential risks. The Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines have been granted EUA following rigorous review. The Pfizer vaccine has also received full approval from the FDA for use in people 16 years and older.

In the past, EUAs have been issued for products, devices, and drugs related to Ebola, H1N1, Zika, and others. The EUAs are valid until the pandemic is over, the FDA revokes the EUAs, or the products are approved for traditional licensure by the FDA. The FDA closely

monitors each vaccine for safety after the EUA is issued. Drug manufacturers are encouraged to obtain traditional FDA licensed vaccine approval as soon as possible.

PARENT/GUARDIAN CONSENT

Consent from a parent or guardian is required before youth under age 18 years can be vaccinated. Emancipated teens may sign their own consent.

WHEN AND WHERE TO BE VACCINATED

There will be many opportunities to be vaccinated in your community, whether you walk in or make an appointment with a nearby provider. The vaccine will be available at select pharmacies, local health departments, children's hospitals, and select pediatric and primary care offices across the state.

State law allows those ages 7 years and older to receive a COVID-19 vaccine at a pharmacy. Pharmacists in Ohio may vaccinate children younger than age 7 years if the pharmacist has met certain federal requirements as specified in the PREP Act. The Ohio Department of Health is encouraging Ohioans to check with their pharmacy regarding minimum age for vaccination and availability.

Ohioans can check gettheshot.coronavirus.ohio.gov for the latest eligibility information and to find a vaccine provider close to home offering the Pfizer vaccine for those 5-11 years old.

The vaccine can be administered at the same time as a flu shot or other childhood immunizations.

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For additional information, visit coronavirus.ohio.gov. For answers to your COVID-19 questions, call 1-833-4-ASK-ODH (1-833-427-5634).

Your mental health is just as important as your physical health. If you or a loved one are experiencing anxiety related to the coronavirus pandemic, help is available 24 hours a day, seven days a week. Call the COVID-19 CareLine at 1-800-720-9616.