

A Parent's Guide to Kids' Vaccines

Vaccines have contributed to a significant reduction in many childhood diseases, such as diphtheria, polio, measles, and whooping cough. It is now rare for American children to experience the devastating effects of these illnesses. Infant deaths due to childhood diseases have nearly disappeared in the United States and other countries with high vaccination coverage. But the germs that cause vaccine-preventable diseases and death still exist, and can be passed on to people who are not protected by vaccines.

Ensuring the safety and effectiveness of vaccines is one of the Food and Drug Administration's top priorities. Vaccines are developed in accordance with the highest safety standards; they must be safe to give to as many people as possible.

Like any medicine, vaccination has benefits and risks, and no vaccine is 100% effective in preventing disease. Most side effects of vaccines are usually minor and short-lived. A child may feel soreness at the injection site or experience a low-grade fever. Serious vaccine reactions are extremely rare, but they can happen. For example, signs of severe allergic reaction can include swelling, itching, weakness, dizziness, and difficulty breathing.

"But parents should also know that the risk of being harmed by a vaccine is much smaller than the risk of serious illness that comes with infectious diseases," says Norman Baylor, Ph.D., Director of the Office of Vaccine Research and Review in FDA's Center for Biologics Evaluation and Research (CBER). "Vaccination is an important step to get children off to a healthy start."

Vaccines may contain live, attenuated (but weakened) or killed (inactivated) forms of disease-causing bacteria or viruses, or components of these microorganisms. They trigger a response by the body's immune system when injected or given by mouth. Vaccines stimulate the body



Associated Press

Nurse Mike Hart gives vaccines to Gino Pastore, at the Washington Neighborhood Health Clinic in San Jose, Calif.

to make antibodies—proteins that specifically recognize and target the disease-causing bacteria and viruses, and help eliminate them from the body.

CBER is the part of FDA that regulates vaccines in the United States. CBER works with other agencies to study and monitor vaccine safety and effectiveness.

Before your child receives a vaccine, tell your doctor if you, your child, or a sibling has ever had a bad reaction to a vaccine.

STEPS TO TAKE WHEN YOU VACCINATE

Review the vaccine information sheets. These sheets explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Health practitioners are required by law to provide them.

Talk to your doctor about the benefits and risks of vaccines. Learn the facts about the benefits and risks, along with the potential consequences of not vaccinating against certain diseases. Some parents are surprised to learn that children can die of measles, chicken pox, and other vaccine-preventable diseases.

Tell your doctor about bad reactions. Before your child receives a vaccine, tell your doctor if you, your child, or a sibling has ever had a bad reaction to a vaccine. If your child or a sibling has had an allergic reaction or other severe reaction to a dose of vaccine, talk with your health care provider about whether that vaccine should be taken again.

Ask about conditions under which your child should not be vaccinated. This might include being sick or having a history of certain allergic or other adverse reactions to previous vaccinations or their components. For example, eggs are used to grow influenza (flu) vaccines, so a child who is allergic to eggs should not get a flu vaccine.

Report adverse reactions. Adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting Sys-

tem, which is maintained by FDA and the Centers for Disease Control and Prevention. For a copy of the vaccine reporting form, call 1-800-822-7967, or report online to www.vaers.hhs.gov

COMMONLY USED VACCINES

Diphtheria, Tetanus, Pertussis (DTaP)

- **What it's for:** Protects against the bacterial infections diphtheria, tetanus (Lockjaw), and pertussis (whooping cough). Tripedia, Infanrix and DAPTACEL are licensed for children 6 weeks to 7 years old. Diphtheria can infect the throat, causing a thick covering that can lead to problems with breathing, paralysis, or heart failure. Tetanus can cause painful tightening of the muscles, seizures, and paralysis. Whooping cough causes severe coughing spells and can lead to pneumonia, seizures, brain damage, and death.

- **Common side effects:** Mild fever, redness, soreness or swelling at the injection site, fussiness or crying more than usual.

- **Tell your health care provider beforehand if:** Your child is moderately or severely ill, has had a severe reaction to a previous shot or has a known sensitivity to ingredients of the vaccine, including latex, which is used for the stopper vial.

Tetanus, Diphtheria, Pertussis (Tdap) Vaccine

- **What it's for:** Boostrix is licensed for use for people ages 10 to 18 years. Adacel is licensed for people ages 11 years and older, up to age 64. Protects against the bacterial infections diphtheria, tetanus (Lockjaw), and

pertussis (whooping cough).

- **Common side effects:** Mild fever, pain and redness at injection site, headache, tiredness.

- **Tell your health care provider beforehand if:** Your child has had any allergic reaction to any vaccine that protects against diphtheria, tetanus, or pertussis diseases, any ingredient contained in the vaccine, or to latex.

Haemophilus influenzae type b (Hib) vaccine

- **What it's for:** Protects against Hib disease, which can cause meningitis (an infection of the covering of the brain and spinal cord), pneumonia (lung infection), severe swelling of the throat, and infections of the blood, joints, bones, and covering of the heart. Approved for children who are at least 2 months old.

- **Common side effects:** Redness, warmth or swelling at site of injection, fever.

- **Tell your health care provider beforehand if:** Your child is moderately or severely ill, or has ever had a life-threatening allergic reaction to a previous dose of Hib vaccine.

Hepatitis A Vaccine

- **What it's for:** Protects against liver disease caused by the hepatitis A virus. Hepatitis A can cause mild "flu-like" illness, jaundice (yellow skin or eyes), severe stomach pains, and diarrhea. A person who has hepatitis A can easily pass the disease to others within the same household. Havrix and VAQTA are licensed for use in children ages 12 months and up.

- **Common side effects:** Soreness at

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the injection site, headache, loss of appetite, tiredness.

- **Tell your health care provider beforehand if:** Your child has ever had a severe allergic reaction to a previous dose of the vaccine.

Hepatitis B Vaccine

- **What it's for:** Protects against liver disease caused by the Hepatitis B virus. Hepatitis B can lead to liver damage, liver cancer and death. Recombivax HB and Engerix-B are licensed for use in babies at birth.
- **Common side effects:** Soreness at injection site and fever.
- **Tell your health care provider beforehand if:** Your child is moderately or severely ill or has ever had a life-threatening allergic reaction to baker's yeast used for making bread, or to a previous dose of the vaccine.

Human Papillomavirus (HPV) Vaccine

- **What it's for:** Gardasil is licensed for the prevention of cervical cancer, abnormal and precancerous cervical lesions, abnormal and precancerous vaginal and vulvar lesions, and genital warts in females ages 9 to 26.
- **Common side effects:** Pain, redness or swelling, itching at the site of injection, dizziness, fainting.
- **Tell your health care provider beforehand if:** Your child has had an allergic reaction to yeast or another component of HPV vaccine, or to a previous dose of the vaccine.

Influenza (Flu) Vaccine —Inactivated Shot

- **What it's for:** Protects children six months and older against the influenza virus strains contained in the

vaccine. Influenza is a contagious respiratory illness caused by the influenza virus. It can cause mild to severe illness, and at times can lead to death. The influenza viruses that cause disease in people may change every year, so yearly vaccination is needed to reduce the chances of getting sick.

- **Common side effects:** Soreness at the injection site, low-grade fever, and aches. The influenza vaccine is made from killed or inactivated influenza viruses, so your child can't get the flu from the flu shot.
- **Tell your health care provider beforehand if:** Your child is moderately or severely ill, has ever had an allergic reaction to eggs or to a previous dose of the flu vaccine, or has ever had Gullian-Barre Syndrome (GBS), a serious neurological disorder that can occur either spontaneously or after certain infections. The disorder typically involves weakness in the legs and arms that can be severe.

Influenza (Flu) Vaccine —Live Intranasal

- **What it's for:** FluMist is sprayed into both nostrils and protects against flu in healthy children and adolescents ages 5 to 17.
- **Common side effects:** Runny nose, headache, vomiting, muscle aches, low-grade fever. This vaccine, which contains weakened viruses, usually doesn't cause illness, because the viruses have lost their disease-causing properties.
- **Tell your health care provider beforehand if:** Your child is pregnant, moderately or severely ill, has a weakened immune system, has ever had an allergic reaction to eggs or to a previous dose of the

flu vaccine, has a history of asthma or any other history of coughing, wheezing, or shortness of breath, or has a history of Gullian-Barre Syndrome (GBS).

Measles, Mumps, Rubella (MMR) Vaccine

- **What it's for:** Protects against measles, mumps, and rubella in children ages 12 months and up. Measles is a respiratory infection that causes skin rash and flu-like symptoms. It can cause severe disease leading to ear infection, pneumonia, seizures, and brain damage. Mumps causes fever, headache and swollen glands, especially salivary glands. It can also lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries. Rubella, also called German Measles, is an infection of the skin and lymph nodes and can cause arthritis. Rubella infection during pregnancy can lead to birth defects.
- **Common side effects:** Fever and mild rash. In rare cases, swelling of the glands in the cheeks or neck.
- **Tell your health care provider beforehand if:** Your child is ill or has ever had an allergic reaction to gelatin, the antibiotic neomycin, or a previous dose of the MMR vaccine.

Meningococcal Disease Vaccine

- **What it's for:** Menactra is licensed for use in people ages 11 years and older, up to age 55. Menomune is licensed for use in children 2 years and older. These vaccines protect against meningococcal disease, a serious illness caused by a bacteria. It is a leading cause of bacterial meningitis in children 2-18 years

old in the United States. Meningitis is an infection of fluid surrounding the brain and the spinal cord.

- **Common side effects:** Sore arm, headache, fatigue.
- **Tell your health care provider beforehand if:** Your child has had a severe allergic reaction to a previous dose of meningococcal vaccine, has a known sensitivity to vaccine components or latex, which is used in the vial stopper, or has bleeding disorders or a history of Guillain-Barre Syndrome (GBS), a serious neurological disorder that can occur either spontaneously or after certain infections. The disorder typically involves weakness in the legs and arms that can be severe.

Pneumococcal Conjugate Vaccine

- **What it's for:** Prevnar (Pneumococcal 7-valent Conjugate Vaccine) protects infants and toddlers against serious pneumococcal disease, such as meningitis and blood infections, and some ear infections.
- **Common side effects:** Redness, tenderness, swelling at injection site, fever, fussiness, drowsiness, loss of appetite.
- **Tell your health care provider beforehand if:** Your child is moderately or severely ill, or has ever had an allergic reaction to a previous dose.

Pneumococcal Vaccine Polyvalent

- **What it's for:** Pneumovax 23 is licensed for use in children with certain health conditions who are 2 years or older for the prevention of the 23 most prevalent types of pneumococcal bacteria. Pneumococcal disease can lead to serious infections of the blood, the lungs, such as pneumonia, and the covering of the brain (meningitis).
- **Common side effects:** Soreness, warmth, redness, swelling at the site of injection.
- **Tell your health care provider beforehand if:** Your child is allergic to any component of the vaccine,

has a respiratory illness or other active infection, or has severely compromised cardiovascular and/or pulmonary function.

Polio Vaccine

- **What it's for:** The inactivated poliovirus vaccine (IPV) protects against the virus that causes polio, an illness that can cause paralysis or death. For children at least 2 months old.
- **Common side effects:** Soreness at injection site, muscle aches, low-grade fever.
- **Tell your health care provider beforehand if:** Your child has ever had a severe allergic reaction to a previous shot or an allergic reaction to the antibiotics neomycin, streptomycin, or polymyxin B.

Rotavirus Vaccine

- **What it's for:** RotaTeq is a live vaccine given by mouth to prevent rotavirus gastroenteritis in infants. This viral infection of the stomach and intestines can cause severe diarrhea, vomiting, and fever, which may lead to serious dehydration. For children who are at least 6 weeks old, but younger than 32 weeks.
- **Common side effects:** Mild, temporary diarrhea or vomiting.
- **Tell your health care provider beforehand if:** Your child has a known or weakened immune system, is allergic to any of the ingredients of the vaccine, or has ever had an allergic reaction after getting a dose of the vaccine.

Varicella (Chicken Pox) Vaccine

- **What it's for:** Varivax (varicella virus vaccine live) protects against chicken pox in people 1 year and older. Chicken pox, which is caused by the varicella-zoster virus, causes itchy blisters and fever. Complications of chicken pox can include skin infection, scarring, brain swelling, and pneumonia.
- **Common side effects:** Soreness or swelling at the injection site, fever, mild rash.

- **Tell your health care provider beforehand if:** Your child is moderately or severely ill, or has ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or a previous dose of chicken pox vaccine. [FDA](#)

For More Information

FDA's Web Page on Vaccines
www.fda.gov/cber/vaccines.htm

Immunization Schedules
www.cdc.gov/vaccines/recs/schedules/default.htm

Vaccines Licensed for Distribution in the United States
www.fda.gov/cber/vaccine/licvacc.htm

The Vaccine Adverse Event Reporting System
www.fda.gov/cber/vaers/vaers.htm

CDC's Web Page on Vaccines
www.cdc.gov/vaccines/