



To Learn More About Childhood Immunization

- Ask your doctor or nurse
- Call your local or state health department's immunization program
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636
 - Visit the CDC Vaccines & Immunizations Web site at <http://www.cdc.gov/vaccines>

Please see Important Safety Information and Patient Information inside.

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Distributed by GlaxoSmithKline, Research Triangle Park, NC 27709

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GlaxoSmithKline Vaccines

www.PEDIARIX.com
1-866-PEDIARIX (1-866-733-4274)



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Childhood Immunization

What Parents Need to Know

Why Immunize Kids?

Vaccines Help Protect

Ever wonder why your baby gets so many shots in the first few years of life? The answer is simple – to protect against serious diseases. Here's how vaccines work.

Vaccines prompt a baby's body to produce antibodies, which help protect against disease. Should exposure to the actual disease occur later in life, these antibodies can ward off infection. In fact, the shots that many children receive in the first few years of life may help prevent 14 serious diseases, many of which could cause complications, and even death, if not prevented.

It may be difficult to imagine the panic that diseases such as polio once caused. Before polio vaccines, children could get polio from everyday activities such as swimming in a public pool. Polio caused some children to have to spend the rest of their lives in a wheelchair. Today, vaccines help protect children against polio.

Vaccines are developed through a rigorous process of research and testing. The federal government runs a stringent approval system. Even after approval, every vaccine batch is further safety-tested by the manufacturer. Side effects from most childhood vaccines are usually mild, and most often include soreness where the shot is given or a low fever. However, more serious side effects, though rare, do occur, and you should talk with your child's healthcare provider about any concerns you may have. If you notice any problems after your child has a shot, please inform your child's healthcare provider.

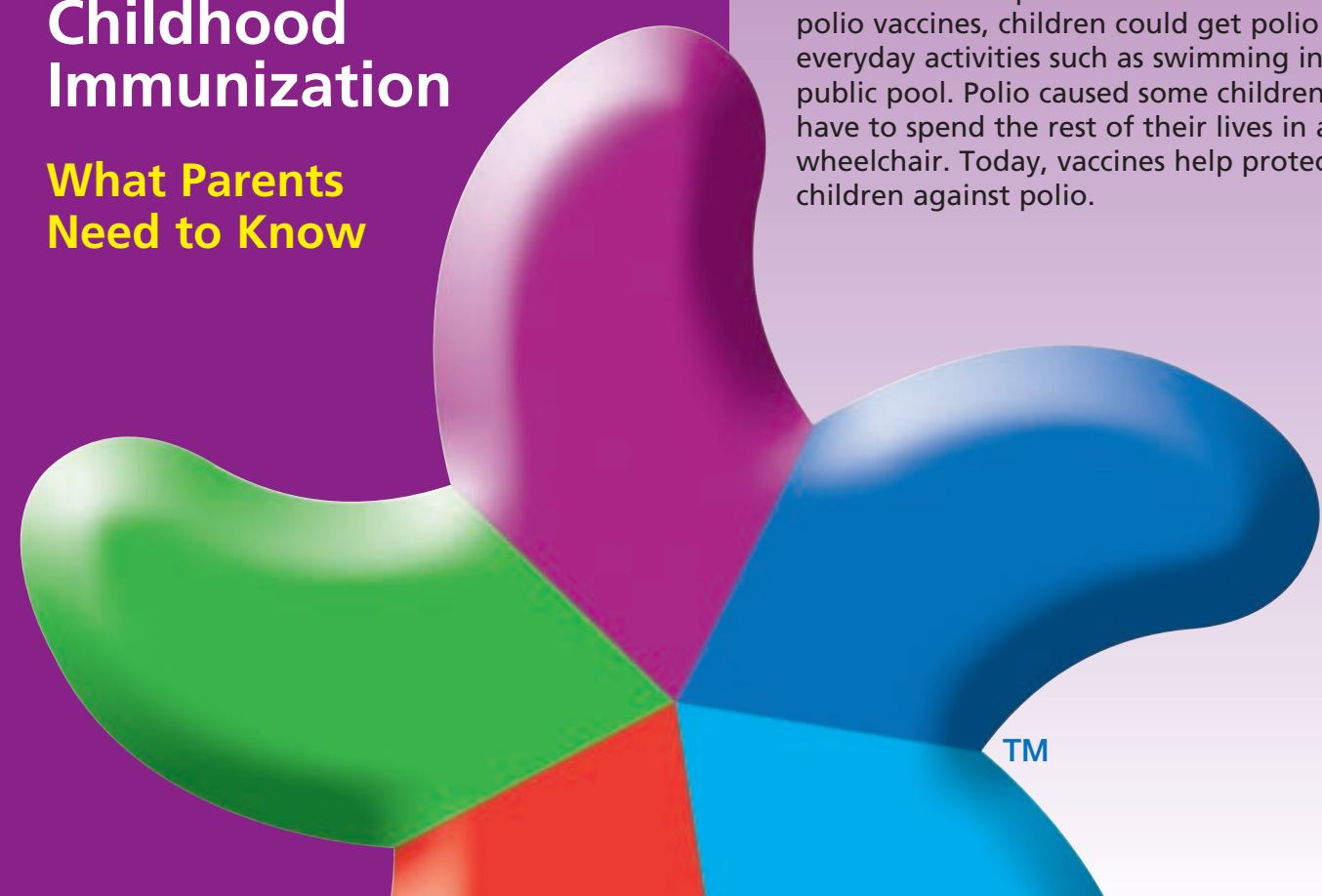
Experts Recommend Vaccination

The Office of the U.S. Surgeon General has stated that immunizations save more lives and prevent more illnesses than any other medical treatment. Thanks to vaccines, preventable infectious illnesses in this country are at an all-time low.

In addition, public health and medical experts from organizations devoted to children's health recommend a complete schedule of immunizations in early childhood. These groups include the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).



Please see Important Safety Information and Patient Information inside.



TM

Keep this information posted in a handy place.

Your Baby's Doctor

Doctor's Name	Hospital Affiliation
Practice	Office Hours
Address	
Telephone	Who to Call After Hours
E-mail	Insurance Information
Poison Control Center Phone Number	




Take this with you to each doctor visit.

Well-Baby Checkups

Regular exams are a vital part of keeping your baby healthy. Your doctor will measure your baby's growth and check development, and can give any necessary immunizations. To stay up-to-date, keep track of each visit here. (After age three, your baby will likely be checked once a year.)

Recommended Visit	Date	Issues to Discuss	Height	Weight
2-4 days to 2 weeks				
2 months				
4 months				
6 months				
9 months				
12 months				
15 months				
18 months				
24 months				

Immunization schedule with PEDIARIX

	Birth	1 mo	2 mos	4 mos	6 mos
Diphtheria, Tetanus, Pertussis			 DTaP	 DTaP	 DTaP
Polio					
Hepatitis B	Hep B		Hep B IPV	Hep B IPV	Hep B IPV

Please talk to your child's healthcare provider about other vaccines that may be needed.

IMPORTANT SAFETY INFORMATION

- In clinical studies, adverse events in infants receiving PEDIARIX included injection-site reactions (pain, redness, or swelling), fever, and fussiness
- PEDIARIX is contraindicated in infants with known hypersensitivity to any component of the vaccine including yeast, neomycin, and polymyxin B. Encephalopathy within 7 days of administration of a previous pertussis-containing vaccine or a progressive neurologic disorder is a contraindication
- Administration of PEDIARIX was associated with higher rates of fever relative to separately administered vaccines
- The decision to give PEDIARIX should be based on potential benefits and risks if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, or if adverse events have occurred in temporal relation to receipt of a pertussis-containing vaccine
- Vaccination with PEDIARIX may not protect 100% of susceptible individuals

PATIENT INFORMATION

PEDIARIX® (Pe-de-a-rix)
Diphtheria and Tetanus Toxoids and Acellular Pertussis
Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined

Read this information carefully before your child receives this vaccine.

- This information does not take the place of talking with your doctor, nurse, or other healthcare professional.
- Ask your healthcare professional for a copy of the Centers for Disease Control and Prevention's (CDC) Vaccine Information Sheets prior to immunization.

What is PEDIARIX and what is it used for?

PEDIARIX is a vaccine given to children to prevent five serious diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough), hepatitis B, and poliomyelitis (polio). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases. The vaccine cannot cause any of these diseases.

- **Diphtheria:** Diphtheria causes a thick covering in the back of the throat. It can lead to breathing problems, paralysis, heart failure, and even death.
- **Tetanus (Lockjaw):** Tetanus enters the body through cuts, scratches, or wounds in the skin. Tetanus can cause muscle stiffness, painful muscle spasms, seizures, and even death. The painful tightening of the muscles of the jaw, called "lockjaw," can prevent a person from opening his/her mouth or swallowing.
- **Pertussis (Whooping cough):** Pertussis is a highly infectious illness that causes severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a "whooping" sound, and so pertussis is often called "whooping cough." The cough may last for weeks. Pertussis can also cause pneumonia, seizures, brain damage, and even death.
- **Hepatitis B:** The hepatitis B virus can cause short-term (acute) illness that leads to loss of appetite, tiredness, pain in muscles, joints, and stomach, vomiting, and jaundice (yellow skin and/or eyes). It can also cause long-term (chronic) infection that can lead to serious consequences including liver damage (cirrhosis), liver cancer, and death.
- **Poliomyelitis (Polio):** Polio often causes only a mild illness but in some people it causes permanent damage or even death. In its most serious form, polio infection causes paralysis of the muscles, including those muscles needed for breathing and walking.

Vaccination is the best way to protect against these diseases. As with any vaccine, PEDIARIX may not protect 100% of individuals receiving the vaccine (especially those with immune system disorders), and is not recommended for treatment of these diseases.

How is PEDIARIX given?

Infants born to HBsAg-negative mothers should receive a total of 3 shots given in the thigh or arm typically at 2, 4, and 6 months of age. If your child misses a scheduled dose, talk to your doctor and arrange another visit as soon as possible. Make sure your child receives all 3 doses.

Who should not be given PEDIARIX?

Before your child receives PEDIARIX, you must tell your doctor or other healthcare professional if your child:

- is younger than 6 weeks of age or is 7 years old or older.
- previously had any allergic reaction to PEDIARIX, any ingredient contained in this vaccine, including yeast and the antibiotics, neomycin and polymyxin B (see list of ingredients below), or latex. Signs of a severe allergic reaction may include hives, difficulty breathing, and swelling of the throat.
- previously had an allergic reaction to any vaccine that protects against diphtheria, tetanus, pertussis, hepatitis B, or polio diseases.
- experienced symptoms of brain or nervous system disorder within 7 days after receiving a pertussis-containing vaccine.
- has an ongoing brain or nervous system disorder.

Also, tell your doctor if your child:

- had any of the following problems after a dose of PEDIARIX or a pertussis-containing vaccine:
 - A high temperature (105°F or higher) within 48 hours of vaccination.
 - A collapse or shock-like state within 48 hours of vaccination.
 - Persistent crying lasting 3 hours or more within 48 hours of vaccination.
 - Seizures with or without a fever within 3 days of vaccination.
- had Guillain-Barré syndrome after a vaccine containing tetanus toxoid.
- has a bleeding problem or bruises easily.
- has a moderate or severe illness with or without fever. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- is taking any other medicine or has recently received any other vaccine.
- has a tendency to have seizures due to fever or if there is a family history of seizures.

What are the possible side effects of PEDIARIX?

Any vaccine may have some side effects but it is possible that your child will have no side effects from vaccination. Side effects with PEDIARIX included pain, redness, or swelling at the injection site, fever, and fussiness. Fever occurred more often with PEDIARIX than when separately administered vaccines were given. Fever most commonly occurred on the day of vaccination and the day after vaccination and typically resolved within a 4-day period following the shot.

Other side effects that your child may experience include loss of appetite and drowsiness. These effects usually clear up within a few days. If these events continue or become severe, tell your doctor.

As with any vaccine, there is an extremely small risk of allergic reactions. Hives, swelling of the throat, and difficulty in breathing are signs of an allergic reaction. If any of these events occur, you should seek treatment immediately. Such rare reactions usually occur before leaving the doctor's office.

Brain or nervous system disease, collapse or periods of unconsciousness or lack of awareness, and seizures have occurred with other pertussis-containing vaccines. Other serious events, including death, have occurred after vaccinations; however, these risks are extremely small.

If you notice any other problems following vaccination, please inform your doctor.

What are the ingredients in PEDIARIX?

PEDIARIX contains a noninfectious protein from diphtheria, tetanus, and pertussis bacteria, hepatitis B virus, and inactivated polio viruses. The vaccine also contains sodium chloride (NaCl), and aluminum salts. Low levels of formaldehyde, polysorbate 80, neomycin sulfate and polymyxin B (antibiotics), and yeast protein are present. PEDIARIX is formulated without preservatives.

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1 Vaccine for 5 Diseases



**Diphtheria and Tetanus Toxoids
and Acellular Pertussis Adsorbed,
Hepatitis B (Recombinant) and
Inactivated Poliovirus Vaccine Combined**

How Many Shots and When?

While it's great news that new vaccines are being developed to prevent more and more diseases, the net result is lots of shots for kids. Today, in fact, children can receive up to 24 shots in the first two years of life. It can take several doses of a vaccine to achieve protection against some diseases, and some vaccines require a booster shot years later to maintain immunity.

The correct timing of children's shots is important in making sure protection

is achieved on time. Finally, new vaccines continue to be added to the schedule as they are developed, adding to the number of shots recommended for kids.







None of us enjoys seeing our children receive shots. The CDC recommends the use of combination vaccines – those that combine multiple vaccines into one shot – whenever possible to reduce the number of shots, and help improve on-time vaccination.



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Preparing for Your Baby's Checkups

Make the most of your time at your baby's checkups. Plan ahead by doing the following:

	Write down your questions and concerns. Bring the list with you to the visit.
	Be prepared for possible waits. Bring activities, snacks, and extra diapers for the waiting room.
	Know the office routine. Arrive early to complete paperwork.
	Remind yourself that this is one of the best things you can do for your baby.
	Learn about immunization choices.
	Be an active partner with your baby's healthcare providers.

