

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 in next column), 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.
- 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.

Manufactured by **GlaxoSmithKline Biologicals**

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