

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PEDIACEL®

Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine and Haemophilus b Conjugate Vaccine (Tetanus Protein – Conjugate)

Read this carefully before you start taking **PEDIACEL®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PEDIACEL®**.

What is PEDIACEL® used for?

PEDIACEL® is a vaccine that is used to help prevent diphtheria, tetanus (lock jaw), pertussis (whooping cough), polio and invasive *H. influenzae* type b (Hib) infections. This vaccine may be given to children aged 2 months or older. It may also be given as a booster to children up to age 7.

The majority of children who are vaccinated with PEDIACEL® will produce enough antibodies to help protect them against these 5 diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

How does PEDIACEL® work?

PEDIACEL® causes the body to produce its own natural protection against diphtheria, tetanus, pertussis (whooping cough), poliomyelitis and invasive Hib infections. After your child receives the vaccine, the body begins to make substances called antibodies. Antibodies help the body to fight disease. If a vaccinated person comes into contact with one of the germs that cause these diseases, the body is usually ready to destroy it

What are the ingredients in PEDIACEL®?

Medicinal ingredients: diphtheria toxoid, tetanus toxoid, acellular pertussis vaccine (pertussis toxoid, filamentous haemagglutinin, fimbriae types 2 and 3, pertactin), inactivated polio vaccine, Hib conjugate vaccine.

Non-medicinal ingredients: 2-phenoxyethanol, Aluminum phosphate, bovine serum albumin, glutaraldehyde, neomycin, polymyxin B, polysorbate 80, streptomycin and trace amounts of formaldehyde

PEDIACEL® comes in the following dosage forms:

PEDIACEL® is a liquid vaccine that is injected into a muscle. A single dose is 0.5 mL.

Do not use PEDIACEL[®] if:

- a child has an allergy to any ingredient in the vaccine or has had an allergic reaction after receiving a vaccine that contained similar ingredients.
- a person has had a serious nervous system disorder within 7 days after a previous pertussis vaccine. In case of progressive nervous system disorder or uncontrolled epilepsy, vaccination may be considered only after a treatment has been established and the condition is stabilized.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child get PEDIACEL[®]. Talk about any health conditions or problems you or your child may have or have had, including:

- high fever or serious illness. Wait until the child is better to give the vaccination.
- an allergy to any component of the vaccine or the container.
- a serious nervous system adverse event following a previous pertussis vaccination.
- diseases of the immune system or who are taking a medical treatment that affects the immune system. The vaccine may provide your child with a lower level of protection than it does for people with healthy immune systems. If possible, try to postpone the vaccination until after your child has completed the treatment.
- a bleeding disorder or take blood-thinning medications. Tell the person giving the injection about your child's condition. The injection must be done carefully to prevent excessive bleeding.
- a higher risk of seizure than the general population. A fever-reducing medication may be given to your child.
- Fainting can occur following, or even before, any needle injection. Therefore, tell your doctor or nurse if your child fainted with a previous injection

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take PEDIACEL[®]:

Usual dose:

A single dose of 0.5 mL is recommended for routine immunization of infants at 2, 4, 6 and 18 months of age and in children up to their 7th birthday.

The vaccination should be given in the muscle, preferably in the thigh for children up to 1 year-old. In children >1 year of age, the shoulder is the preferred site since use of the thigh results in limping due to muscle pain

Overdose:

If you think you, or a person you are caring for, have taken too much PEDIACEL[®], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to go back to the healthcare professional at the scheduled time, ask the healthcare professional for advice.

What are possible side effects from using PEDIACEL[®]?

These are not all the possible side effects you may have when taking PEDIACEL[®]. If you experience any side effects not listed here, tell your healthcare professional.

A vaccine, like any medicine, may cause side effects. Up to one third of children who receive PEDIACEL[®] may have mild side effects such as redness, swelling or tenderness around the injection site. Other common reactions include fever, increased crying, fussiness, being less active and decreased eating. These side effects are usually mild and last no more than 3 to 4 days. Severe reactions, such as high fever, swelling and redness of the entire arm or leg, or a serious allergic reaction are very rare.

Tell your doctor, nurse or pharmacist as soon as possible if your child is not feeling well after receiving PEDIACEL[®].

Serious side effects are extremely rare.

This is not a complete list of side effects. For any unexpected effects while taking PEDIACEL[®], contact your doctor, nurse or pharmacist.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur Limited cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). Do not freeze. Throw the product away if it has been exposed to freezing.

Do not use after the expiration date.

Keep out of reach and sight of children.

If you want more information about PEDIACEL®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofipasteur.ca, or by calling 1-888-621-1146 (no charge) or 416-667-2779 (Toronto area).

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