IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PEDIACEL®

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

This leaflet is part III of a three-part "Product Monograph" published when PEDIACEL® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PEDIACEL®. Contact your doctor, nurse or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is 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.

What it does:

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.

When it should not be used:

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- Do not give PEDIACEL® to a child who has an allergy to any ingredient in the vaccine or has had an allergic reaction after receiving a vaccine that contained similar ingredients.
- Do not give PEDIACEL® to a person who 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.

What the medicinal ingredient is:

Each 0.5 mL dose of PEDIACEL® contains: diphtheria toxoid, tetanus toxoid, acellular pertussis vaccine (pertussis toxoid, filamentous haemagglutinin, fimbriae types 2 and 3, pertactin), inactivated polio vaccine, Hib conjugate vaccine.

What the non-medicinal ingredients are:

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

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

If your child has any of the following conditions, talk to your doctor or pharmacist BEFORE the child receives PEDIACEL®:

- **A 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.

INTERACTIONS WITH THIS VACCINE

DO NOT mix PEDIACEL® with other vaccines or medicinal products in the same syringe.

PROPER USE OF THIS VACCINE

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

In case of drug overdose, contact a health-care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose

If immunization is delayed for any reason – the recommended schedule is:

- 3 single doses of 0.5 mL with 2 months between doses
- a 4th dose given 6 to 12 months after the 3rd dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

HOW TO STORE IT

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 of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For Health Care Professionals:
If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:
Should your child experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: (1-866-844-0018)
By toll-free fax: (1-866-844-5931)
Email: caefi@phac-aspc.gc.ca

Web: http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

Mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
A/L 6502A
Ottawa, Ontario
K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health-care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.sanofipasteur.ca

You may also contact the vaccine producer, Sanofi Pasteur Limited, for more information. Telephone: 1-888-621-1146 (no charge) or 416-667-2779 (Toronto area).

Business Hours: 8 a.m. to 5 p.m. Eastern Time Monday to Friday.

This leaflet was prepared by Sanofi Pasteur Limited.

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