PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PENTACEL®

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

Read this carefully before your child receives PENTACEL®. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your child's medical condition and treatment and ask if there is any new information about PENTACEL®.

What is PENTACEL® used for?

PENTACEL® is a vaccine that is used to help prevent against 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 PENTACEL® will produce enough antibodies to help protect them against these 5 diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

How does PENTACEL® work?

PENTACEL® 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 PENTACEL®?

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

Non-medicinal ingredients: Aluminum phosphate (adjuvant), 2-phenoxyethanol, polysorbate 80, water for injection, Tris (hydroxymethyl) aminomethane and sucrose. Residual formaldehyde, glutaraldehyde, bovine serum albumin, neomycin, polymyxin B sulphate, streptomycin sulphate are present in trace amounts.

PENTACEL® comes in the following dosage forms:

PENTACEL® is supplied in two vials: one vial of freeze-dried Act-HIB® vaccine and one vial of liquid dose of 0.5 mL QUADRACEL® vaccine which are then combined for injection into a muscle.

Do not use PENTACEL® if:

- Do not give PENTACEL® 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 PENTACEL® 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.

To help avoid side effects and ensure proper use, talk to your healthcare professional if your child has any of the following conditions BEFORE the child receives PENTACEL® :

- **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 (AW) 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 your child takes, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

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

PENTACEL® may be given at the same time but at separate sites with Hepatitis B vaccine, 7-valent pneumococcal conjugate vaccine, MMR and Varicella vaccines.

How to take PENTACEL®:

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 PENTACEL®, contact a healthcare professional, 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

What are possible side effects from using PENTACEL®?

These are not all the possible side effects your child may experience when receiving PENTACEL®. If your child experiences 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 PENTACEL® 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 have 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 PENTACEL®.

Serious side effects are extremely rare.

If your child has a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your child's 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/aefi-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 PENTACEL®:

- 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 Sanofi Canada website (https://www.sanofi.com/en/canada) or by contacting the vaccine producer, Sanofi Pasteur Limited at 1-888-621-1146 (no charge).

This leaflet was prepared by Sanofi Pasteur Limited.

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