

**PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### PEDIACEL®

#### Suspension for injection in pre-filled syringe

**Diphtheria, tetanus, pertussis, (acellular, component), poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed)**

**Read all of this leaflet carefully before your child is vaccinated because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed only for your child. Do not pass it on to others.
- If your child gets any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What PEDIACEL is and what it is used for
2. What you need to know before PEDIACEL is given to your child
3. How and when PEDIACEL is given
4. Possible side effects
5. How to store PEDIACEL
6. Contents of the pack and other information

### **1 What PEDIACEL is and what it is used for**

PEDIACEL is a vaccine. Vaccines are used to protect against infectious diseases.

PEDIACEL helps to protect against diphtheria, tetanus, pertussis, poliomyelitis and serious diseases caused by *Haemophilus influenzae* type b. PEDIACEL is given to children between the ages of 6 weeks and 4 years of age.

The vaccine works by causing the body to produce its own protection (antibodies) against the bacteria and viruses that cause these different infections:

- Diphtheria is an infectious disease that usually first affects the throat. In the throat, the infection causes pain and swelling which can lead to suffocation. The bacteria that cause the disease also make a toxin (poison) that can damage the heart, kidneys and nerves.
- Tetanus (often called lock jaw) is usually caused by the tetanus bacteria entering a deep wound. The bacteria make a toxin (poison) that causes spasms of the muscles, leading to inability to breathe and the possibility of suffocation.
- Pertussis (often called whooping cough) is a bacterial infection of the airways that can occur at any age but mostly affects infants and young children. Increasingly severe coughing spells that can last for several weeks are a characteristic of the disease. Coughing spells may be followed by a whooping noise.
- Poliomyelitis (often just called polio) is caused by viruses that affect the nerves. It can lead to paralysis or muscle weakness most commonly of the legs. Paralysis of the muscles that control

breathing and swallowing can be fatal.

- *Haemophilus influenzae* type b infections (often just called Hib) are serious bacterial infections and can cause meningitis (inflammation of the outer covering of the brain), infections of the blood, inflammation of the tissue under the skin, inflammation of the joints and inflammation of part of the back of the throat, causing difficulty in swallowing and breathing.

### **Important information about the protection provided**

PEDIACEL will only help to prevent these diseases if they are caused by the bacteria or viruses targeted by the vaccine. Your child could get diseases with similar symptoms if they are caused by other bacteria or viruses.

The vaccine does not contain any live bacteria or viruses and it cannot cause any of the infectious diseases against which it protects.

Remember that no vaccine can provide complete, life long protection in all people who are vaccinated.

## **2 What you need to know before PEDIACEL is given to your child**

To make sure that PEDIACEL is suitable for your child, it is important to tell your doctor or nurse if any of the points below apply to your child. If there is anything you do not understand, ask your doctor or nurse to explain.

### **Do not use PEDIACEL if your child**

- is allergic (hypersensitive) to
  - diphtheria, tetanus, pertussis, poliomyelitis or Hib vaccines
  - any of the other ingredients listed in section 6
  - any residual component carried over from manufacture (including neomycin, streptomycin, polymyxin B, glutaraldehyde, formaldehyde, and bovine serum albumin).
- has had a severe reaction affecting the brain within one week after a previous dose of any vaccine protecting against whooping cough.
- has a progressive condition or severe illness affecting the brain and nervous system or uncontrolled epilepsy.
- has an acute illness with or without a high temperature at the moment. Vaccination with PEDIACEL may need to be delayed until your child is better.

### **Warnings and precautions**

Tell your doctor or nurse before vaccination if your child:

- has had a vaccine that protects against whooping cough in the past and any of the following occurred soon afterwards:
  - had a temperature of 40°C or above, not due to another identifiable cause, within 48 hours of having the vaccine.
  - became floppy, unresponsive or unconscious after the previous vaccination, within 48 hours of having the vaccine.
  - cried continuously and could not be comforted for more than 3 hours within 48 hours of having the vaccine.
  - had a fit (convulsion) within 3 days of having the vaccine.
- is receiving steroids, chemotherapy or radiotherapy or has any other illness that may reduce the

ability to fight infections. If possible, vaccination should be postponed until the end of such disease or treatment.

Children with long standing problems with their immune system due to any reason (including HIV infection) may still be given PEDIACEL but the protection against infections after having the vaccine may not be as good as in children whose immune system is healthy.

- has any problems with the blood that cause easy bruising or bleeding for a long time after minor cuts. Your doctor or nurse will advise you whether your child should have PEDIACEL.
- has had Guillain-Barré syndrome (temporary loss of movement and feeling) or brachial neuritis (loss of movement, pain and numbness of the arm and the shoulder) following a previous injection with a tetanus containing vaccine. Your doctor or nurse will decide whether to give PEDIACEL to your child.

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2 - 3 days after vaccination.

A persistent hard lump or nodule may be felt under the skin at the injection site, especially if the injection was not very deep. An abscess may develop. These abscesses are not usually infected.

### **Other medicines or vaccines and PEDIACEL**

PEDIACEL can be given at the same time as other vaccines such as meningococcal group C vaccine, hepatitis B vaccine, 7-valent pneumococcal vaccine, measles, mumps and rubella (MMR) vaccine and varicella vaccine. Your doctor or nurse will give the two injections at different sites and will use separate syringes and needles for each injection.

Tell your doctor, nurse or pharmacist if your child is taking or has recently taken any other medicines.

### **Important information about some of the ingredients of PEDIACEL**

PEDIACEL may contain trace amounts of formaldehyde, glutaraldehyde and bovine serum albumin as well as the following antibiotics: neomycin, streptomycin and polymyxin B.

## **3 How and when PEDIACEL is given**

The vaccination should be given by medical or healthcare professionals who are trained in the use of vaccines and who are equipped to deal with any uncommon severe allergic reaction to the injection. Please refer to Section 4.

Your doctor or nurse will inject PEDIACEL into a muscle in the upper part of your child's leg (infants from the age of 6 weeks) or arm (older children up to four years).

### **Dosage**

#### **First Course of Vaccination (Primary Vaccination)**

Your child will receive two or three injections of half a millilitre given at least one month apart according to the local vaccination schedule.

#### **Booster**

When indicated by the local vaccination schedule, your child should receive a booster dose at least 6 months after the last dose of the primary vaccination. Your doctor or nurse will tell you when this dose should be given.

PEDIACEL is not suitable after a child has reached their fourth birthday.

### **If You Forget One Dose of PEDIACEL**

If your child misses a scheduled injection, your doctor will decide when to give the missed dose.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

## **4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Serious allergic reactions**

**If any of these symptoms occur after leaving the place where your child received his/her injection, you must consult a doctor IMMEDIATELY.**

Serious allergic reactions are a very rare possibility (may affect up to 1 in 10,000 people) after receiving any vaccine. These reactions may include:

- difficulty in breathing
- blueness of the tongue or lips
- a rash
- swelling of the face or throat
- low blood pressure causing dizziness or collapse.

When these signs or symptoms occur they usually develop quickly after the injection is given and while the child is still in the clinic or doctor's surgery.

### **Other side effects**

Very common reactions (may affect more than 1 in 10 people) are:

- loss of appetite
- irritability
- abnormal crying
- vomiting
- less active
- fever (temperature 38°C or higher)
- pain, redness, swelling

Common reactions (may affect up to 1 in 10 people) are:

- diarrhoea
- bruising and bleeding at the injection site

Uncommon (may affect up to 1 in 100 people) are:

- a fit (convulsion) with or without fever
- extensive limb swelling (from the injection site to beyond the joint)

The following additional side effects have been reported during the commercial use of PEDIACEL:

- allergic reactions, hives, swollen face
- high-pitched crying
- a period of floppiness and decreased responsiveness that gets better without treatment and has no after effects
- sleepy or drowsy (somnolence)
- paleness
- temporary absence of breathing
- rash
- pain in the vaccinated limb
- high fever (temperature 40.5°C or higher)
- injection site mass
- tiredness or lack of energy (asthenia)
- lethargic (listlessness)
- rarely skin reactions have been reported that may include rashes (which may be itchy), swelling of the lower limbs, blueness, redness, severe crying and sometimes a purple spotted rash of the legs that gets better without treatment.

#### **Reporting of side effects in the UK**

If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine."

#### **5 How to store PEDIACEL**

Keep this medicine out of the sight and reach of children.

Store in a refrigerator between 2°C and 8°C. Do not freeze. Keep the vaccine in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6 Contents of the pack and other information**

**Each 0.5 mL dose of PEDIACEL contains the following:**

**Active substances**

diphtheria toxoid	not less than 30 international units
tetanus toxoid	not less than 40 international units
acellular pertussis antigens	
pertussis toxoid	20 micrograms
filamentous haemagglutinin	20 micrograms
pertactin	3 micrograms
fimbriae types 2 and 3	5 micrograms
poliovirus (inactivated)	
type 1 (Mahoney)	40 D antigen units
type 2 (MEF-1)	8 D antigen units
type 3 (Saukett)	32 D antigen units
<i>Haemophilus influenzae</i> type b polysaccharide	
(polyribosylribitol phosphate)	10 micrograms
conjugated to tetanus toxoid	18-30 micrograms
adsorbed on aluminum phosphate	1.5 milligrams (0.33 milligram aluminum)

**Other ingredients**

Phenoxyethanol, polysorbate 80 and water for injections.

**What PEDIACEL looks like and contents of the pack**

PEDIACEL, suspension for injection, is provided in a pre-filled syringe.

Pack size of 1, 10 or 20 pre-filled syringes without attached needle.

Pack size of 1 or 10 pre-filled syringes with two separate needles.

Not all pack sizes may be marketed.

The normal appearance of the vaccine is a cloudy, white to off-white suspension, which may sediment during storage.

**Marketing Authorisation Holder**

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France

**Distributed by**

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**Manufacturer**

The manufacturer responsible for batch release is  
Sanofi Pasteur  
14 Espace Henry Vallée  
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**This medicinal product is authorised in the Member States of the EEA under the following names:**

<b>Member state</b>	<b>Name</b>
Cyprus, Czech Republic, Finland, France, Malta, Norway, Spain and the United Kingdom	PEDIACEL

**This leaflet was last revised in 10/2017**