

**Registration No. :** 2C 22/47 (N)

**Importer / Manufacturer:** Sanofi Pasteur Ltd., Thailand/Sanofi Pasteur S.A., France

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICAL PRODUCT : PENTAXIM

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

*The active substances are:*

Diphtheria toxoid . . . . .  $\geq 30$  I.U.

Tetanus toxoid . . . . .  $\geq 40$  I.U.

*Bordetella pertussis* antigens:

Toxoid . . . . . 25 micrograms

Filamentous haemagglutinin . . . . . 25 micrograms

Type 1 poliomyelitis virus (inactivated) . . . . . 40 D.U.\*†

Type 2 poliomyelitis virus (inactivated) . . . . . 8 D.U.\*†

Type 3 poliomyelitis virus (inactivated) . . . . . 32 D.U.\*†

Polysaccharide of *Haemophilus influenzae* type b Conjugated  
to the tetanus protein . . . . . 10 micrograms  
for one dose 0.5 ml after reconstitution

\* D.U. : D antigen unit.

† or equivalent antigenic quantity determined by a suitable immunochemical method.

### 3. PHARMACEUTICAL FORM

PENTAXIM is presented in the form of a powder and a suspension for injection (0.5 ml in a pre-filled syringe with attached needle – box of 1 or 0.5 ml in a prefilled syringe with two separate needles – box of 1)

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

PENTAXIM is indicated to help protect your child against diphtheria, tetanus, pertussis and poliomyelitis and against invasive infections due to the *Haemophilus influenzae* type b bacterium (meningitis, blood infections, etc.) It is indicated in children from the age of 2 months.

It does not protect against infections caused by other types of *Haemophilus influenzae* or against meningitis due to other micro-organisms.

#### 4.2 Posology and method of administration

##### Posology:

The general recommended schedule includes a primary vaccination in 3 injections one or two month interval from two months of age, followed by a booster injection during the second year of life.

##### Method of administration:

For syringes without attached needles, the separate needle must be fitted firmly to the syringe, rotating it by a one-quarter turn.

Reconstitute the vaccine by injecting the suspension of the combined diphtheria, tetanus, acellular pertussis and poliomyelitis vaccine into the vial of the *Haemophilus influenzae* type b conjugate vaccine powder.

Shake until complete dissolution of the powder. The cloudy whitish appearance of the suspension after reconstitution is normal.

The vaccine must be administered immediately after reconstitution.

Administer by the intramuscular route.

Administration should preferably be performed in the anterolateral aspect of the thigh (middle third).

**If one dose of PENTAXIM is missed:**

Please inform your doctor.

### 4.3 Contraindication

**Do not use PENTAXIM:**

- if your child suffers from evolving encephalopathy with or without convulsions (a neurological disease),
- if your child experienced a strong reaction in the 48 hours following a previous vaccine injection: fever equal to or greater than 40°C, persistent crying syndrome, convulsions with or without fever, hypotonic-hypo-responsive syndrome,
- if your child experienced an allergic reaction to a previous vaccination against diphtheria, tetanus, pertussis and poliomyelitis and *Haemophilus influenzae* type b infections,
- if your child is allergic to the active substances, to any of the excipients, to neomycin, to streptomycin and to polymixin B.

### 4.4 Special warnings and precautions for use

**Take special care with PENTAXIM:**

- make sure the vaccine is not injected by the intravascular route (the needle must not penetrate a blood vessel) or by the intradermal route,
- If your child has a fever, suffers from an acute disease, especially an infectious disease, or an evolving chronic disease; vaccination should be postponed,
- If your child already presented with febrile convulsions, not related to a previous vaccine injection; in this case it is particularly important that body temperature be monitored in the 48 hours following vaccination and that antipyretic treatment be regularly administered to help reduce fever, for 48 hours,
- if your child experienced oedematous reactions (or swelling) of the lower limbs occurring after the injection of a vaccine containing *Haemophilus influenzae* type b valence: administration of the diphtheria - tetanus - pertussis – poliomyelitis vaccine and of the *Haemophilus influenzae* type b conjugated vaccine will have to be performed in two separate injection sites and on different days,
- If your child follows a treatment that suppresses her/his immune defences or if your child presents with immunodeficiency: in these cases the immune response to the vaccine may be lowered.

**List of excipients with recognised effects:**

Formaldehyde

### 4.5 Interaction with other medical products and forms of interaction

If your child is to be vaccinated with PENTAXIM and other vaccines at the same time, ask your doctor or your pharmacist for more information.

*Please inform your doctor or pharmacist if your child has recently taken any other medicines, even those not prescribed.*

#### **4.6 Pregnancy and lactation**

#### **4.7 Effects on the ability to drive and use machines**

#### **4.8 Undesirable effects**

*Like all medicinal products, PENTAXIM can cause side effects.*

Local reactions at the injection site such as pain, erythema (redness) and induration may occur within 48 hours following administration.

Systemic reactions: fever, sometimes greater than 40°C, irritability, drowsiness, sleeping and feeding disturbances, diarrhoea, prolonged inconsolable crying. More rarely urticaria, skin eruptions, convulsions with or without fever have been observed within 48 hours following administration. Hypotonic or hypotonic - hyporesponsive episodes have been reported.

Oedematous reactions (swelling) of the lower limbs have been reported following the administration of vaccines containing the *Haemophilus influenzae* type b valence.

These reactions are sometimes accompanied by fever, pain and crying.

*If you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.*

#### **4.9 Overdose**

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

#### **5.2 Pharmacokinetic properties**

#### **5.3 Preclinical safety data**

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

*The other ingredients are:* saccharose, trometamol, aluminium hydroxide, Hanks' medium without phenol red, acetic acid and/or sodium hydroxide for pH adjustment, formaldehyde, phenoxyethanol and water for injections.

#### **6.2 Incompatibilities**

#### **6.3 Shelf life**

3 years

#### **6.4 Special precautions for storage**

Keep out of the reach and sight of children.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Do not use after the expiry date stated on the label, the box.

### **6.5 Nature and contents of container**

Powder in vial (glass) + 0.5 ml of suspension in a prefilled syringe (glass): box of 1

Powder in vial (glass) + 0.5 ml of suspension in a prefilled syringe (glass) with two separate needles: box of 1

### **6.6 Special precautions for disposal and other handling**

Do not use PENTAXIM if you notice an abnormal colour or the presence of foreign particles.

## **7. MARKETING AUTHORISATION HOLDER**

Sanofi Pasteur Ltd., Bangkok, Thailand

## **8. MARKETING AUTHORISATION NUMBER(S)**

2C 22/47 (N)

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Conditional approval: 18 June 2004

Unconditional approval: 16 October 2006

## **10. DATE OF REVISION OF THE TEXT**

December 2005

Date of local approval: 12 March 2008

(The above information is based on the currently approved leaflet)

(The new version of leaflet is under variation)