SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT: PENTAXIM
   (Diphtheria, Tetanus, Pertussis (Acellular, Component), Poliomyelitis (Inactivated) Vaccine
   (Adsorbed) and Haemophilus Influenza Type b Conjugate Vaccine)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

   Diphtheria toxoid ................................................................. ≥ 30 I.U.
   Tetanus toxoid ................................................................. ≥ 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.

   For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

   Powder and a suspension for injection

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

   The usual recommended schedule includes primary vaccination, consisting of three injections at an interval of one to two months from the age of 2 months, followed by a booster injection within the second year of life.
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 is allergic to one of the vaccine’s components, to any manufacturing process residues (glutaraldehyde, neomycin, streptomycin and polymyxin B) that may be present as traces, or of a pertussis vaccines (acellular or whole cells), or if your child experienced an allergic reaction after injection of a vaccine containing the same substances,
- if your child suffers from evolving encephalopathy (cerebral lesions),
- if your child suffered from encephalopathy (cerebral lesions) within 7 days of a previous dose of a pertussis vaccine (acellular or whole cells pertussis),
- if your child has a fever or an acute disease (the vaccination must be postponed).

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) nor by the intradermal route,
- If your child suffers from thrombocytopenia or clotting problems as there is a risk of bleeding during intramuscular administration,
- If your child suffers from hypersensitivity to glutaraldehyde, neomycin, streptomycin and polymyxin B, as these substances are used during the manufacturing process,
- if your child already presented with febrile convulsions, not related to a previous vaccine injection; in this case it is particularly important that temperature be monitored in the 48 hours following vaccination and that antipyretic treatment be regularly administered to help reduce fever, for 48 hours,
- if any of the following events are known to have occurred in temporal relation to receipt of vaccine (the decision to give further doses of pertussis-containing vaccine should be carefully considered):
  • Fever ≥ 40°C within 48 hours not due to another identifiable cause.
  • Collapse or shock-like state with hypotonic-hyporesponsive episode (drop in energy) within 48 hours of vaccination.
  • Persistent, inconsolable crying lasting ≥ 3 hours, occurring within 48 hours of vaccination.
  • Convulsion with or without fever, occurring within 3 days of vaccination.
- if your child suffers/suffered from medical problems or allergic reactions, especially allergic reactions following injection of PENTAXIM,
- if your child presented Guillain-Barre syndrome (abnormal sensitivity, paralysis) or brachial neuritis (paralysis, diffuse pain in the arm and shoulder) following receipt of a prior vaccine containing tetanus toxoid (vaccine against tetanus), the decision to give any further vaccine containing tetanus toxoid should be evaluated by your doctor,
- if your child presented oedematous reactions (or swelling) occurring in the lower limbs after injection of a vaccine containing the Haemophilus influenzae type b valence, the two vaccines, diphtheria - tetanus - pertussis – poliomyelitis vaccine and the
Haemophilus influenzae type b conjugate vaccine should be administered in two separate injection sites and on two 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 decreased. It is then recommended to wait until the end of the treatment or disease before vaccinating. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response may be limited.
- PENTAXIM dose not protect against invasive diseases caused by serotypes other than Haemophilus influenzae type b, nor against meningitis due to other micro-organisms.

Important information about some of the ingredients of PENTAXIM
List of excipients with recognised effect: formaldehyde

4.5 Interaction with other medical products and forms of interaction

In case your child should receive PENTAXIM simultaneously with other vaccines than those already mentioned, please ask your doctor or 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 medicines, PENTAXIM can cause side effects. The most common reactions are: irritability, local reactions at the injection site such as redness and induration greater than 2 cm. These signs and symptoms usually occur within 48 hours following the vaccination and may continue for 48 – 72 hours. They resolve spontaneously without requiring specific treatment. The following side effects have been reported:
- Erythema, induration, pain at the injection site; redness and oedema (swelling) ≥ 5 cm at the injection site; fever sometimes above 40°C.
- Oedema (swelling) > 5 cm that may spread over the entire limb where the vaccine has been administered. This reaction occurs within 24 – 72 hours after vaccination and resolves spontaneously within 3 – 5 days. The risk seems to be dependent on the number of prior doses of acellular pertussis – containing vaccines, with a greater risk following the 4th and 5th doses.
- Diarrhoea; vomiting
- Loss of appetite.
- Somnolence; convulsion with or without fever, hypotonic-hyporesponsive episodes (hypotonic episodes – drop in energy – hyporesponsiveness – drop in awareness).
- Nervousness, irritability; insomnia or sleep disturbances; abnormal crying, prolonged inconsolable crying.
- Allergy – like symptoms, such as skin eruptions, erythema, and urticaria, face oedema, sudden face or neck swelling (Quincke’s oedema) or generalized reaction: sudden and serious malaise with drop in the blood pressure, accelerated heart rhythm associated with respiratory disorders and digestive disorders (anaphylactic reaction, shock).
Furthermore, during the administration of *Haemophilus influenzae* type b containing vaccines, edematous reactions (swelling) affecting the lower limbs have been reported. These reactions are sometimes accompanied by fever, pain and crying. They are not accompanied by cardio-respiratory signs.

Potential side effects (i.e. they have not been reported directly with PENTAXIM, but with other vaccines containing one or more of the antigenic constituents of PENTAXIM) are the following:

- Guillain – Barre syndrome (abnormal sensitivity, paralysis) and brachial neuritis (paralysis, diffuse pain in the arm and shoulder) following administration of a vaccine containing tetanus toxoid.
- 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 vaccinations.

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

4.9 Overdose

5. PHARMAKOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

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

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
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.

Do not use PENTAXIM if you notice an abnormal colour or the presence of foreign particles.
Do not use after the expiry date stated on the label, the box.

7. MARKETING AUTHORITY
Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORITY NUMBER(S)
2C 22/47 (N)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
18 June 2004

10. DATE OF REVISION OF THE TEXT
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