For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Abridged Prescribing Information

Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component), Inactivated Poliomyelitis Vaccine And Haemophilus Type B Conjugate Vaccine I.P.
PENTAXIM®

QUALITATIVE & QUANTITATIVE COMPOSITION

The active substances are:
After reconstitution one dose (0.5 ml) contains:
Diphtheria toxoid [1] ≥ 30 IU [2] [3]
Tetanus toxoid [1] ≥ 40 IU [2] [3]
Bordetella pertussis antigens:
Pertussis toxoid [1]……...25 micrograms
Filamentous haemagglutinin [1]…...25 micrograms
Poliomyelitis virus (inactivated)
Type 1 poliomyelitis virus (Mahoney strain) [4] (inactivated)……40 DU [5] [6]
Type 2 poliomyelitis virus (MEF-1 strain) [4] (inactivated)……8 DU [5] [6]
Type 3 poliomyelitis virus (Saukett strain) [4] (inactivated)……...32 DU [5] [6]
Polysaccharide of *Haemophilus influenzae* type b 10 micrograms
conjugated to the tetanus protein..... 18-30 micrograms
[1] adsorbed on aluminium hydroxide, hydrated 0.3 mg Al3+
[2] IU: International Unit
[3] Or equivalent activity determined by an immunogenicity evaluation
[4] Produced on VERO cells.
[5] DU: D antigen unit.
[6] or equivalent antigenic quantity determined by a suitable immunochemical method.
The other components are:
Suspension for injection:
Hanks 199 medium without phenol red, acetic acid glacial and/or sodium hydroxide(for pH adjustment), formaldehyde, phenoxyethanol, Ethanol, anhydrous, water for injections.
Hanks 199 medium is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other components (such as glucose) diluted in water for injections.

THERAPEUTIC INDICATIONS

PENTAXIM® is indicated for the active immunization of children against Diphtheria, Pertussis, Tetanus, Polio and against invasive infections due to Haemophilus influenzae type b bacterium (such as meningitis, septicaemia, etc.) in children from the age of 2 months or according to local recommendations. This vaccine does not protect against infections caused by other types of Haemophilus influenzae nor against meningitis due to other micro-organisms.

DOSAGE AND ADMINSITRATION

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 or according to local recommendations, followed by one booster injection within the second year of life.

Method of administration

For syringes without attached needles, the 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 powder of the Haemophilus type b conjugate vaccine. Shake until complete dissolution of the powder. After reconstitution, the whitish-turbid appearance of the suspension is normal. The vaccine must be used immediately after reconstitution. Administer by the intramuscular route. Administration should preferably be performed in the anterolateral side of the thigh (middle third).

SAFETY RELATED INFORMATION

CONTRAINDICATIONS

- Allergy to one of the vaccine components, to any manufacturing process residues (glutaraldehyde, neomycin, streptomycin or polymyxin B) that may be present as traces or of a pertussis vaccine (acellular or whole cell) or history of allergic reaction after a vaccine containing the same substances.
- Evolving encephalopathy (cerebral lesions)
- Past history of encephalopathy (cerebral lesions) within 7 days of a previous dose of a pertussis vaccine (acellular or whole cell)
- Fever or an acute disease (vaccination must be postponed)

WARNING AND PRECAUTIONS

Do not inject by intravascular or intradermal route, Take special care in case of:

- thrombocytopenia or clotting
- hypersensitivity to glutaraldehyde, neomycin, streptomycin and polymyxin B,
- febrile convulsions, not related to a previous vaccine injectionthe decision to give further doses of pertussis-containing vaccine should be carefully considered allergic reactions, especially those following injection of PENTAXIM®,
- Guillain-Barre Syndrome or brachial neuritis following receipt of a prior vaccine containing tetanus toxoid, the decision to give any further vaccine containing tetanus toxoid should be evaluated. immunosuppressive therapy or immunodeficiency. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response may be limited.

ADVERSE REACTIONS

Very common reactions (may affect more than one in 10 children)

Loss of appetite, Nervousness, irritability, abnormal crying,Somnolence,Vomiting ,Injection-site redness (erythema), fever 38°C or higher, injection-site swelling (œdema), injectionsite pain.

Common reactions (may affect less than one in 10 children but more than one in 100 children)

Diarrhoea,Injection-site hardening (induration),Insomnia, sleep disorder.

Uncommon reactions (may affect less than one in 100 children but more than one in 1000 children) Injection site redness and swelling (oedema) of 5 cm or more,Fever 39°C or higher, Inconsolable and prolonged crying (for more than 3 hours).

Rare reactions (may affect less than one in 1000 children but more than one in 10 000 children)

-Fever over 40°C,Swelling in legs and feet (oedematous reactions affecting lower limbs) with a bluish discoloration of the skin (cyanosis) or redness, small transient red spots (purpura) occurring within hours of vaccination, and disappearing without treatment and without sequelae. Swelling may be accompanied with severe crying

For full prescribing information, please contact Sanofi Healthcare India Pvt. Ltd., Sanofi House, C.T.S No. - 117-B, L & T Business Park, Saki Vihar Road, Powai, Mumbai 400072.

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