Summary of Product Characteristics of Haemophilus type b conjugate Vaccine

Brand Name: Peda Hib™

Manufactured By:

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Summary of Product Characteristics

(As per Annexure C of Module 1 of Guidance for industry by CDSCO)

1. Name of the Medicinal product :-

Haemophilus type b conjugate vaccine
Brand Name: Peda Hib™

2. Qualitative & Quantitative Compositions :-

Each Single dose (0.5 ml)l yophilisate contains:
10 µg polysaccharide of Haemophilus type b conjugated to 20 µg
Tetanus toxoid protein.
Lactose (I.P)……..2mg
Sucrose (I.P)……..……42.5mg
Thiomersal (I.P.)(preservative)…….0.05mg

3. Pharmaceutical Form :-

Lyophilised vaccine with vaccine diluent for reconstitution.

4. Clinical Particulars :-

4.1 Therapeutic Indications:-

Peda Hib™ is indicated for prevention, in children from 6 weeks to 5 years age, of invasive disease caused by Haemophilus type b e.g. meningitis, cellulitis epiglotitis. In no case the tetanus protein contained in Peda Hib™ can replace the routing tetanus vaccine.

4.2 Physiology and method of administration:-

Reconstitute the lyophilisate with the entire content of the vaccine diluent provided. Shake gently for full reconstitution. Administer 0.5 ml by intramuscular injection. It should under no circumstances be administered intravenously.

Age at first immunization

A) Before 6 months :

Peda Hib™ can be administered to infants from the age of 1.5 months with three injections of one dose (0.5 ml) at intervals of one or two months, followed by booster (4th injection) at 15 – 18 months.

B) Between 6 to 12 months:

Two injections at interval of one or two months, followed by booster (3rd injection) at 15 – 18 months.

C) Between 1 to 5 Years:

One single injection.

4.3 Contra-indications:-

- ❖ Hypersensitivity to any of the vaccine component
- ❖ Acute infection or febrile illness.

4.4 Special warnings and precaution for use:-

The vaccine should be shaken gently and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either of the above, being observed, discard the vaccine.

As with other vaccines, in rare cases anaphylactic shock may occur in susceptible individual. The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be life saving. It should be used at the first suspicion of anaphylaxis. The vaccines should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone & antihistaminic should also be available in addition to supportive measures such as oxygen inhalation.

4.5 Interaction with other medicinal products and other forms of interaction:-

No adverse reaction is known to occur when used in combination with DPT and/or Hepatitis B

4.6 Pregnancy & Lactation:-

Not applicable

4.7 Effects on ability to drive and use machines:-

Not Applicable

4.8 Undesirable effects:-

As in the case of any active product, there may be more or less moderate and temporary side effects. Mild local pain, redness, in duration or fever may occur during the 48 hours following injection.

D.P.T. vaccine causes more or less moderate temporary side effects, similar side effects may be observed when Peda Hib™ is administered after reconstituting with D.P.T. vaccine.

4.9 Over dose:-

Not Applicable

5. Pharmacological Properties :-

5.1 Pharmacodynamic Properties :-

Not applicable for vaccines as immunizing doses are too less for Pharmacodynamics studies.

5.2 Pharmacokinetic Properties:-

Evaluation of Pharmacokinetic properties is not required for vaccine.

5.3 Preclinical Safety Data :-

In the preclinical safety Data the Peda Hib™ vaccine is found safe.

6. Pharmaceutical Particulars :-

6.1 List of excipients:-

Lactose (I.P)……..2mg
Sucrose (I.P)…….……42.5mg
Thiomersal (I.P.) (preservative)……..…….0.05mg

6.2 Incompatibilities:-

Not applicable

6.3 Shelf life:-

Use the product within 36 months from the date of manufacture.

6.4 Special precaution for storage:-

Store between 2°C to 8°C in the refrigerator.

6.5 Nature & contents of container:-

Materials used for the containerization of vaccine are as follows:

- Glass Vials :-

  USP Type-I clear tubular 2 ml glass vials.

- Rubber closures :-

  13 mm Grey Butyl Slotted Rubber Stopper (Sterile ready for use).

- Aluminium Seals :-

  13 mm flip off PK-1 aluminium seals.

Materials used for the containerization of vaccine diluent are as follows:

- Glass vial :-

  2 ml clear tubular glass vial (USP type I)

- Rubber Closures: -

  13 mm non slotted Grey butyl, 'Unister RFU' sterile Rubber stopper.

- Aluminium Seals :-

  13 mm flip off white (WE1) aluminium seal.

6.6 Special precautions for disposal:-

No special requirements

7. Marketing authorization Holder :-

BIO-MED (P) LTD.
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8. Marketing authorization number :-

Form 46 permission No. MF-1350 dated 14/06/2004.

9. Date of first authorization/Renewal of the authorization:-

a) Additional item license No. vide letter No. XXF/837/2198 dated 20/03/2004.

b) Additional item license No. vide letter No. 20F/837/9826 dated 17/07/2004.

c) Renewal of authorization on Form 26-H dated 21 May 2014.

10. Date of Revision of the text :-

January 2024