

***Haemophilus type b conjugate vaccine (I.P.)*****Peda HibTM****DESCRIPTION**

Peda HibTM - *Haemophilus* type b conjugate vaccine consisting of polysaccharide (PRP) of *Haemophilus* type b conjugated to Tetanus toxoid protein. This stimulates T-Cell dependent antibody synthesis in infants and young children with a booster response primarily of IgG class of antibodies. Peda HibTM is manufactured as per Indian Pharmacopoeia. The manufacturing facilities meets the requirements as per cGMP guidelines of revised schedule 'M' from the Drugs and Cosmetic Act, Government of India.

COMPOSITION

Each single dose lyophilisate contains:

10µg polysaccharide of *Haemophilus* type b conjugated to 20 µg Tetanus toxoid protein.

Lactose(I.P.) 2 mg

Sucrose(I.P.) 42.5 mg

Thiomersal (I.P.) (Preservative) 0.05 mg

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.

In case vaccine have not been stored in proper cold chain and or crack in vial, the integrity of pellet/powder of vaccine could change. Before using the vaccine check for powder/pellet integrity and discard vaccine if pellet is not visible/shrunk/deformed.

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 vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone & antihistaminics should also be available in addition supportive measures such as oxygen inhalation.

CONTRA-INDICATIONS

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

INDICATIONS

Peda HibTM is indicated for the prevention, in children from 6 weeks to 5 years age, of invasive diseases caused by *Haemophilus* type b e.g. meningitis, cellulitis epiglottitis. In no case the tetanus protein contained in Peda HibTM can replace the routine tetanus vaccine

DOSAGE : Age at first immunization

- (A) **Before 6 months :** Peda HibTM 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 a booster (4th injection) at 15-18 months.
- (B) **Between 6 to 12 months :** Two injections at interval of one or two months, followed by a booster (3rd injection) at 15-18 months.
- (C) **Between 1 to 5 years :** One single injection.

POSSIBLE SIDE EFFECTS

As in the case of any active product, there may be more or less moderate and temporary side effects. Mild local pain, redness, induration 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 HibTM is administered after reconstituting with D.P.T. vaccine.

PACK SIZE

One dose in glass vial with appropriate diluent.

STORAGE

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

Manufactured & Marketed by :

Bio-Med
PRIVATE LIMITED
AN ISO 9001, 14001
GMP CERTIFIED CO.

C-96, Site No. 1, B.S. Road. Indl. Area,
Ghaziabad-201009, (U.P.) INDIA
Phone : 0120-4204862, 4157534
Fax : 0120-4340219
Email : bmvaccine@yahoo.com
Website : www.biomed.co.in