

SUMMARY PRODUCT CHARECTERISTICS

**Diphtheria, Tetanus Pertussis (whole cell) Haemophilus influenza type b
conjugate vaccine**

DESCRIPTION	The vaccine is composed of Hib vaccine as a freeze dried powder which is reconstituted using liquid DTP as diluents. DPT vaccine is a sterile opaque uniform suspension of diphtheria toxoid, tetanus toxoid and killed <i>Bordetella pertussis</i> bacilli adsorbed on aluminium gel and suspended in isotonic sodium chloride solution. The Hib polysaccharide is prepared from capsular polysaccharide of H influenza type b strain and after activation is coupled to tetanus toxoid.
POTENCY	Each dose of 0.5ml contains: Diphtheria toxoid..... $\leq 25\text{Lf}$ ($\geq 30\text{IU}$) Tetanus toxoid..... $\geq 5\text{Lf}$ ($\geq 40\text{IU}$) B pertussis..... $\leq 16\text{OU}$ ($\geq 4\text{IU}$)
THERAPEUTIC INDICATIONS	It is indicated for active immunization of infants at or above the age of 6 weeks of birth and of children through 6 years of age against diphtheria, tetanus, whooping cough and hemophilus influenza.
DOSAGE & METHOD OF ADMINISTRATION	For active immunization of infants and preschool children, it is recommended that 3 intramuscular injections of 0.5ml be administered within an interval of 4 weeks between doses. Although the customary age for first dose of primary immunization is 2 months but is now recommended to be given at 6 weeks of age. A booster dose of DTP and Hib can be given at the age of 15 to 18 months. A reinforcing injection of DTP-Hib should be administered at 5 years of age.
CONTRAINDICATIONS	Known hypersensitivity to any component of the vaccine, or a severe reaction to previous dose of the combination vaccine or any of its constituents is an absolute contraindication to subsequent doses of the combination vaccine or the specific vaccine known to have provoked an adverse reaction.
SPECIAL WARNINGS & PRECAUTION FOR USE	Prior to injection of any vaccine all known precautions should be taken to prevent adverse reactions. Parents of a child with a family history of seizures should be informed that the child has an increase risk of seizures following DTP administration.
INTERACTION WITH OTHER MEDICINAL PRODUCTS & OTHER FORM OF INTERACTION	As with other intramuscular injection use with caution in patients on anticoagulant therapy, immunosuppressive therapy including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids may induce immune response to vaccines.
UNDESIRABLE EFFECTS	Adverse reaction with the use of this vaccine includes local redness, warmth edema and induration with or without tenderness as well as urticaria and rash. Systemic reactions such as fever, headache, nausea and weakness may appear in a few subjects.
STORAGE OF VACCINES	Vaccine should be stored between +2°C and +8°C. Protect from light.
PRESENTATION	1 dose vial plus diluent (0.5ml)
MARKETING AUTHORIZATION	Serum Institute of India Ltd

HOLDER	
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02701

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