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

Abridged Prescribing Information

DIPHTHERIA, TETANUS, PERTUSSIS (ACELLULAR, COMPONENT), HEPATITIS B (rDNA), POLIOMYELITIS (INACTIVATED) AND *HAEMOPHILUS INFLUENZAE* TYPE b CONJUGATE VACCINE (ADSORBED)

HEXAXIM® Suspension for injection in pre-filled syringe

COMPOSITION One dose[1] (0.5 ml) contains:

Active tngredi ent s:	
Diphtheria toxoid	30 LI (20 IU')
Tetanus toxoid	10 LI (40 IU[2])
*Bordetello pertussis*antigens Pertusss toxoid Filamentous haemagglutinin	 25 µg 25 µg
Poliovirus(inactivated)' Type1 (Mahoney) Type2 (MEF-1) Type3 (Saukett)	40 DU' 8 DU[4] 32 DU'
Hepatitis Bsurfaceantigens	10 µg
Hoemophilusinfluenzoe type b polysaccharide (polyribosylribitol phosphate) conjugated to Tetanusprotein (PRP-T)	12 µg 22-36 µg
Ina ctive Ingredients:	
Aluminiumhydroxide, hydrated 0.6 mg Al'•	
Buffers Disodium hydrogenphosphate Potassium dihydrogenphosphate Essential amino acids Trometamol Saccharose Watefor injections	 1.52Bmg 1.552 mg 1.115 mg 0.1515mg 10.625 mg Up to 0.5 ml

[1] Adsorbed on aluminium hydroxide, hydrated (0.6 mg Al^{3+})

[2] IU International unit

[3] Produced on Vero cells

[4] Equivalent antigenic quantity in Vaccine.

[5] Produced in yeast *Hansenula polymorpha* cells by recombinant DNA technology

THERAPEUTIC INDICATIONS

Hexaxim (DTaP-IPV-HB-Hib) is indicated for primary and booster vaccination of infants and toddlers from six weeks of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib).

DOSAGE AND ADMINISTRATION:

Primary Vaccination: Three injections at an interval of one to two months (atleast four weeks apart).

Booster: At least 6 months after the last dose of first course. This vaccine should be used according to the local vaccination programme.

Hexaxim should be administered intramuscularly. The recommended injection sites are generally the antero-lateral aspect of the upper thigh in infants and toddlers and the deltoid muscle in older children. The intradermal or intravascular route must not be used.; ensure that the needle does not penetrate a blood vessel. Separate syringes, separate injection sites and preferably separate limbs must be used in case of concomitant administration with other vaccines.

CONTRAINDICATIONS: History of an anaphylactic reaction after a previous administration of HexaximEncephalopathy within 7 days of administration of a previous dose of any vaccine containing pertussis antigens (whole cell or acellular pertussis vaccines). Uncontrolled neurologic disorder, uncontrolled epilepsy.

WARNINGS AND PRECAUTIONS: Vaccination must be postponed in cases of moderate or severe febrile and/or acute disease; the administration of Hexaxim must be carefully considered in individuals who have a history of serious or severe reactions within 48 hours following administration of a vaccine containing similar components. As with all injectable vaccines, the vaccine must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration. If any of the following events are known to have occurred after receiving any pertussis containing vaccine, the decision to give further doses of pertussis containing vaccine should be carefully considered:

- Temperature of ≥ 40°C within 48 hours not due to another identifiable cause;
- Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of vaccination;
- Persistent, inconsolable crying lasting ≥ 3 hours, occurring within 48 hours of vaccination;
- Convulsions with or without fever, occurring within 3 days of vaccination. Take special care in case of Guillain Barré Syndrome, Brachial neuritis, acute or chronic renal insufficiency, epilepsy.

SAFETY RELATED INFORMATION:- Serious Allergic reactions (anaphylactic reaction):-Difficulty in breathing, blueness of tongue/lips, a rash, swelling of face /throat, sudden and dizziness, loss of consciousness, accelerated heart rate with respiratory disorders. Serious allergic reactions are a rare possibility (may up to 1 in 1,000 people) after receiving this vaccine. Other side effects:

- Very common (more than 1 in 10 people)- Anorexia, crying, somnolence, vomiting, pain redness and swelling at injection site, irritability, Fever (≥38°C)
- Common side effects (may affect upto 1 in 10 people) – Prolonged crying, diarrhoea, induration
- Uncommon side effects (may affect up to 1 in 100 people) – Allergicreaction, lump at injection site, High fever (≥39°C).
- Rare side effect (may affect up to 1 in 1,000 people) – Rash, Large injection-site reactions (>5 cm), including extensive limb swelling from the injection site beyond one or both joints, have been reported in children. These reactions start within 24-72 hours after vaccination, may be associated with erythema, warmth, tenderness or pain at the injection site and resolve within 3-5 days without need of treatment. Fits (convulsions) with or without fever, Very Rare side effects (may affect up to 1 in 10,000 people) – hypotonic reactions, hypotonic hyporesponsive episodes.

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

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