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

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

	Components[1]	**Quantity per dose (0.5 mL)**
	Active Ingredients:	
	Diphtheria toxoid	30 Lf (≥ 20 IU[2])
	Tetanus toxoid	10 Lf (≥ 40 IU[2,3])
	Bordetella pertussis antigens Pertussis toxoid Filamentous haemagglutinin	 25 µg 25 µg
	Poliovirus (Inactivated)[4] Type 1{Mahoney) Type2 (MEF-1) Type 3 (Saukett)	 40 DU[5] 8 DU[5] 32 DU[5]
	Hepatitis B surface antigen[6]	10 µg
	Haemophilus influenzae type b polysaccharide (polyriobosylribitol phosphate) conjugated to Tetanus protein (PRP-T)	12 µg 22-36 µg
	Inactive Ingredients	
	Aluminium hydroxide, hydrated	0.6 mg Al^{3+}
	Buffers Disodium hydrogen phosphate Potassium dihydrogen phosphate Essential amino acids[7] Trometamol Saccharose	 1.528 mg 1.552 mg 1.115 mg 0.1515 mg 10.625 mg
	water for injections	Up to 0.5 ml

[1] NaOH, acetic acid or HCI can be used for pH adjustment. These Components are only present in trace amount.

[2] As lower confidence limit (p = 0.95)

[3] Or equivalent activity determined by an immunogenicity evaluation

[4] Produced on Vero cells

[5] Or equivalent antigenic quantity determined by a suitable immunochemical method.

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

[7] Essential amino acids including L-phenylalanine

The vaccine may contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin and polymyxin B.

Excipient with known effect

Phenylalanine……85 micrograms

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).

POSOLOGY AND METHOD OF ADMINISTRATION:

Primary Vaccination: Three injections at an interval of one to two months (at least 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 Hexaxim. Encephalopathy 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.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: 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.

Special populations:

Immunogenicity data are available for 105 preterm infants support the use of Hexaxim in preterm infants. The potential risk of apnoea and the need for respiratory monitoring for 48 to 72 hours should be considered when administering the primary immunization series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.

Immunogenicity data in HIV-exposed infants (infected and uninfected) showed that Hexaxim is immunogenic in the potentially immunodeficient population of HIV-exposed infants whatever their HIV status at birth. No specific safety concern was observed in this population.

DRUG INTERACTIONS:

Hexaxim can be administered simultaneously with a pneumococcal polysaccharide conjugate vaccine, measles, mumps, rubella (MMR) containing vaccines, rotavirus vaccines, a meningococcal C conjugate vaccine or a meningococcal group A, C, W-135 and Y conjugate vaccine, as no clinically relevant interference in the antibody response to each of the antigens have been shown. There may be a clinically relevant interference in the antibody response of Hexaxim and a varicella vaccine and these vaccines should not be administered at the same time. If co-administration with another vaccine is considered, immunization should be carried out on separate injection sites. Hexaxim must not be mixed with any other vaccines or other parenterally administered medicinal products.

PREGNANCY AND LACTATION:

Not applicable. This vaccine is not intended for administration to women of child-bearing age.

UNDESIRABLE EFFECTS: - 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, diarrhea, induration
- Uncommon side effects (may affect up to 1 in 100 people) – Allergic reaction, 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.

OVERDOSE:

No cases of overdose have been reported.

PHARMACODYNAMIC PROPERTIES

Pharmaco-therapeutic group: Vaccines, Bacterial and viral vaccines combined, ATC code: J07CA09

No pharmacokinetic studies have been performed.

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

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