Hexaxim® Clinical PEARLS

TAKE YOUR BEST SHOT! towards infant care

Hexaxim®

A Highly Immunogenic Choice for Primary Vaccination Series in Infants

Kim *et al.*, in 2017, conducted a phase III non-inferiority study in >300 Korean infants, that evaluated the immunogenicity and safety of Hexaxim® vaccine in 148 infants.[1]

Group 1	Group 2
Infants vaccinated with HepB vaccine alone at birth and hexavalent vaccine at 2, 4, and 6 months of age	Infants vaccinated with a standalone HepB vaccine at birth and at 1 and 6 months of age and a pentavalent vaccine at 2, 4, and 6 months of age

Higher GMC reported in group 1 (1068 mIU/mL) compared to group 2 (827 mIU/mL)[1]

No immediate adverse events were reported[1]

An RTU vaccine simplifies vaccine delivery, reduces the risk of handling errors, increases efficiency, is well- tolerated, and ultimately provides good immunization coverage.[2]

Hexaxim®

- Highly immunogenic and provides a long-term immune response[3]
- No vaccine-related severe adverse events[3]

Ab: Antibodies; CI: Confidence interval; GMC: Geometric mean concentrations; HepB: Hepatitis B; RTU: Ready-to-use.

References: 1. Kim YK, Vidor E, Kim HM, et al; A3L31 Study Group. Immunogenicity and safety of a fully liquid DTaP-IPV-HB-PRPT hexavalent vaccine compared with the standard of care in infants in the Republic of Korea. Vaccine. 2017 Jul 13;35(32):4022–4028. **2.** Wiedenmayer KA, Weiss S, Chattopadhyay C, *et al.* Simplifying paediatric immunization with a fully liquid DTP–HepB–Hib combination vaccine: Evidence from a comparative time-motion study in India. *Vaccine.* 2009;27(5):655–659. **3.** Cho HK, Park SE, Kim YJ, *et al.* Recommendation for use of diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b conjugate, and hepatitis B vaccine in infants. Clin Exp Pediatr. 2021;64(12):602–607.

Hexaxim®
Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed).
6-IN-1 READY TO USE VACCINE

TAKE YOUR BEST SHOT!
towards infant care

Hexaxim®

Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed).

6-IN-1 READY TO USE VACCINE

- High immunogenicity with high geometric mean titers in Indian schedule[1]
- Can be co-administered with other primary series* vaccine without clinical interference[3]
- The ready-to–use hexavalent DTaP vaccine ensuring complete dose delivery[2]
- Ensures high immunogenicity with or without Hep B birth dose[1,4]

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:

Components[1]	Quantity per dose (0.5 mL)
Active Ingredients:	
Diphtheria toxoid	30 Lf (≥ 20 IU[2])
Tetanus toxoid	10 Lf (≥ 40 IU[2])
Bordetella pertussis antigens	
Pertussis toxoid	25 µg
Filamentous haemagglutinin	25 µg
Poliovirus (inactivated)[3]	
Type 1 (Mahoney)	40 DU[4]
Type 2 (MEF-1)	8 DU[4]
Type 3 (Saukett)	32 DU[4]
Hepatitis B surface antigen[5]	10 µg
Haemophilus influenzae type b polysaccharide (polyribosylribitol 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	1.528 mg
Potassium dihydrogen phosphate	1.552 mg
Essential amino acids	1.115 mg
Trometamol	0.1515 mg
Saccharose	10.625 mg
Water for injections	Up to 0.5 mL

[1] NaOH, acetic acid or HCl can be used for pH adjustment. These components are only present in trace amount.
[2] As lower confidence limit (p=0.95)
[3] Produced on Vero cells
[4] Or equivalent antigenic quantity determined by a suitable immunochemical method
[5] Produced in yeast Hansenula polymorpha cells by recombinant DNA technology
[6] Essential amino acids including L-phenylalanine

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 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.

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) – 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.

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

Date of update: Dec 2021

Source: SMPC version 2 and CCDS version 6

*6,10,14 week.

References:

1. Chhatwal J, Lalwani S, Vidor E. Immunogenicity and Safety of a Liquid Hexavalent Vaccine in Indian Infants. *Indian Pediatr.* 2017;54(1):15–20.
2. De Coster I, Fournie X, Faure C, *et al.* Assessment of preparation time with fully-liquid versus non-fully liquid paediatric hexavalent vaccines. A time and motion study. *Vaccine.* 2015;33(32):3976–3982.
3. Hexaxim®–Summary of product characteristics.
4. Madhi SA, Mitha I, Cutland C, *et al.* Immunogenicity and safety of an investigational fully liquid hexavalent combination vaccine versus licensed combination vaccines at 6, 10, and 14 weeks of age in healthy South African infants. *Pediatr Infect Dis J.* 2011;30(4):e68–e74.

MAT-IN-2202315_0822

For full prescribing information. visit: www.sanofi.in(https://bit.ly/HexaximPI).

For the use of registered medical practitioner only.

Sanofi Healthcare India Pvt. Ltd.,
Sanofi House, CTS no. 117-B, L&T Business Park,
Saki Vihar Road, Powai, Mumbai-400072.

sanofi