Hexaxim® Clinical PEARLS

TAKE YOUR BEST SHOT! Towards infant care

Hexaxim®:

An Efficacious Ready-to-Use Hexavalent Vaccine for Primary Immunization in Infants

Hexaxim® has a good safety profile and provides immunity against all six diseases.[1]

Hexaxim® is a viable alternative to other hexavalent vaccines currently available on the market.[1]

- Provides long-term antibody persistence for all antigens at 3.5 and 4.5 years of age[2]
- Higher GMC reported in infants receiving Hexaxim® with Hep B vaccine alone at birth (1068 mIU/mL) compared to infants receiving the pentavalent vaccine with Hep B vaccine alone at birth (827 mIU/mL)[3]

Fully liquid vaccine is the preferred choice

Saves **~5 minutes** across three doses when compared to the hexavalent vaccine that needs reconstitution[4]

5 times less mishandlings compared to hexavalent vaccine that needs reconstitution[5]

Hexaxim® is the preferred RTU choice:

- Is immunogenic and safe[1]
- Is a fully liquid vaccine requiring no reconstitution[7]

- Provides sixfold high anti-Hep B GMT with Hep B at birth[6]
- Significantly improves and simplifies the vaccination process[7]

GMC: Geometric mean concentration; GMT: Geometric mean titer; HCPs: Healthcare professionals; Hep B: Hepatitis B; RTU: Ready-to-use.

References: 1. Dakin A, Borrow R, Arkwright PD. A review of the DTaP-IPV-HB-PRP-T hexavalent vaccine in pediatric patients. *Expert Rev Vaccines.* 2023;22(1):104–117. **2.** Madhi SA, López P, Zambrano B, *et al.* Antibody persistence in pre-school children after hexavalent vaccine infant primary and booster administration. *Hum Vaccin Immunother.* 2019;15(3):658–668. **3.** Kim YK, Vidor E, Kim HM, *et al.* Immunogenicity and safety of a fully liquid DTaP-IPV-HB-PRP~T hexavalent vaccine compared with the standard of care in infants in the Republic of Korea. *Vaccine.* 2017;35(32):4022–4028. **4.** Lloyd AJ, Nafees B, Ziani E, *et al.* What are the preferences of health care professionals in Germany regarding fully liquid, ready-to-use hexavalent pediatric vaccine versus hexavalent pediatric vaccine that needs reconstitution? *Patient Prefer Adherence.* 2015;9:1517–1524. **5.** 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. **6.** 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. **7.** Bakhache P, Virey B, Bienenfeld C. Knowledge and practices regarding infant vaccination: Results of a survey of French physicians. *Eur J Pediatr.* 2019;178(4):533–540.

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

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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 the Indian schedule[1]

Ensures **high immunogenicity with or without** Hep B birth dose[2]

Immunogenic and safe in pre-term infants[3-6]

Can be **co-administered with other primary** series* vaccine without clinical interference[3]

Assurance of complete dose delivery with the only Ready-to-Use DTaP vaccine[2]

For the use only of a Registered Medical Practitioner 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	25 µg
Filamentous haemagglutinin	25 µg
Poliovirus (Inactivated)[4]	
Type 1(Mahoney)	40 DU[5]
Type 2 (MEF-1)	08 DU[5]
Type 3 (Saukett)	32 DU[5]
Hepatitis B surface antigen[6]	10 µg
Haemophilus influenzae type b polysaccharide (polyriobosylribitol phosphate)	12 µg
conjugated to Tetanus protein (PRP-T)	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[7]	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]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 up to 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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Source: EU SmPC dt. 24.09.2020 (CCDS v8 and v10) and EU SmPC dt. 18.02.2021 (CCDS v10)

*6,10,14 week.

DTaP: Diphtheria, tetanus, and acellular pertussis; Hep B: Hepatitis B.

References:

1. Chhatwal J, *et al. Indian Pediatrics.* 2017 Jan;54(1):15-20; **2.** De Coster I, *et al. Vaccine.* 2015 Jul 31;33(32):3976-82; **3.** López P, *et al. The Pediatric Infectious Disease Journal.* 2017 36(11), pp.e272-e282; **4.** HEXAXIM® Summary of Product Characteristics; **5.** Boisnard F, *et al.* Use of Hexyon/Hexacima/Hexaxim in preterm infants in Europe. 16th World Congress on Public Health 2020, Online event, 12-16 October 2020, poster presentation; **6.** Martinelli D, *et al. Vaccine.* 2020;38:5148-5153.

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

For the use of registered medical practitioner only.

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