TAKE YOUR BEST SHOT! towards infant care

Hexaxim®

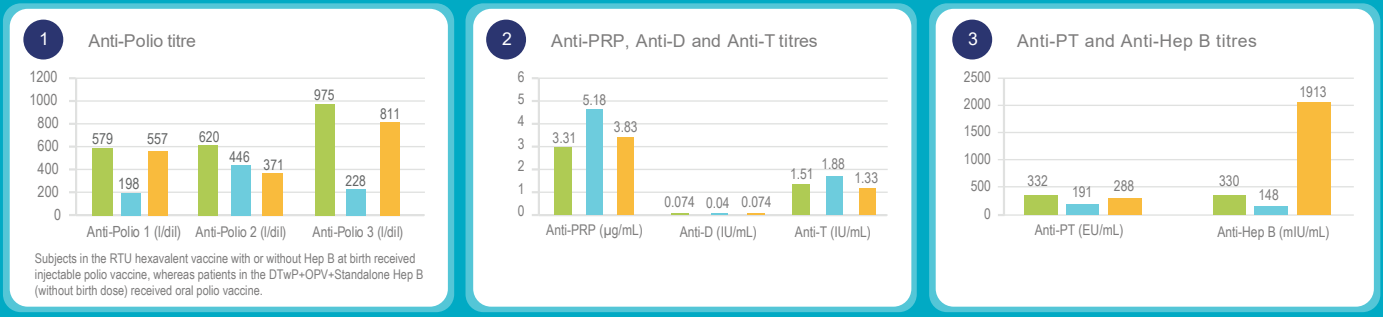
An appropriate fit for EPI schedule

Hexaxim® Clinical PEARLS

Pediatric combination vaccines are used routinely and have an enormous impact on childhood disease incidence.[1]

Madhi *et al.* compared the immunogenicity of the hexavalent vaccine with other licensed vaccines[1]

GMT 1 Month After the 3-Dose Primary Vaccination[1]



RTU hexavalent vaccine without Hep B at birth | DTwP+OPV+Standalone Hep B (without birth dose) | RTU hexavalent vaccine with Hep B at birth

- 2-fold higher Hep B GMT response for RTU hexavalent primary vaccine than standalone Hep B vaccine.[1]
- Approximately 6-fold higher Hep B GMT for group receiving RTU hexavalent primary vaccine + Hep B at birth compared to the group not receiving Hep B at birth.[1]

Reconstitution time and quality of administration of combination vaccines are major factors for successful immunisation.[2]

Coster *et al.* assessed the benefits of fully liquid vaccine over non-fully liquid vaccine to overcome these challenges.[2]

Fully liquid vaccine is better as it is:

Time saving
Leads to quicker vaccine delivery.[2]

5 Times lesser risk
Ensures enhanced safety by minimizing mishandling errors.[2]

Hence, preferred by ≈98% of HCPs.[2]

Anti-PRP: Anti-*Haemophilus influenzae* type b polysaccharide conjugated to tetanus protein. Anti-D: Anti-Diphtheria; Anti-T: Anti-Tetanus; Anti-PT: Anti-pertussis toxoid; D: Diphtheria; DTwP: Diphtheria, tetanus toxoid, and whole-cell pertussis; EPI: Expanded Program on Immunization; FHA: Filamentous hemagglutinin; GMT: Geometric mean titers; HBsAg: Sanofi Pasteur recombinant hepatitis B surface antigen; HCPs: Healthcare professionals; Hep: Hepatitis; OPV: Oral poliovirus vaccine; PRP-T: Haemophilus influenzae type b polysaccharide conjugated to tetanus protein. RTU: Ready–to–use.

References: 1. Madhi SA, Mitha I, Cutland C, *et al.* Immunogenicity and safety of an investigational fully liquid hexavalent combination vaccine versus licensed combination vaccine at 6, 10, and 14 weeks of age in healthy South African infants. *Pediatr Infect Dis J.* 2011;30(4):e68–74. **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.

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

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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 dose1 (0.5 ml) contains:

Components[1]	Quality per dose 0.5 mL)
Active Ingredients:	
Diphtheria toxoid	30 Lf (> 20 IU2)
Tetanus toxoid	10 Lf(>40 IU2)
Bordetella pertussis antigens	
Pertussis toxoid	25 mg
Filamentous haemagglutinin	25 mg
Poliovirus (inactiviated)[3]	
Type 1 (Mahoney)	40 DU4
Type 2 (MEF-1)	8 DU4
Type 3 (Saukett)	32 DU4
Hepatitis B surface antigen[5]	10 mg
Haemophilus influenzae type b polysaccharide (polyribosylribitol phosphate)	12 mg
conjugated to Tetanus protein (PRP-1)	22-36 mg
Inactive Ingredients:	
Aluminium hydroxide, hydrated	0.6 mg Al
Buffers	
Disodium hydrogen phosphate	1.528 mg
Potassium dihydrogen phosphate	1.552mg
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 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 quality 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-2201021_0522

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

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