Infanrix Hexa vaccine

Newborn use only

2021

Alert	Ensure the pre-filled syringe containing the diphtheria, tetanus and pertussis toxoid is mixed with the vial containing the HIB component of the vaccine. Parental consent to be obtain prior administration. Preterm infants should receive vaccines according to the recommended schedule at their chronological age, without correction for prematurity, provided they are medically stable and there are no contraindications to vaccination.(1)
Indication	1. Primary immunisation against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type B in infants at 6 weeks/2 months, 4 and 6 months from the date of birth. (1,2) 2. Catch-up vaccination schedules in children < 10 years of age.
Action	Induces the production of antibodies against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type B infection.
Drug type	Combination vaccine - DTPa-hepB-IPV-Hib — diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-Haemophilus influenzae type b combination vaccine.
Trade name	INFANRIX hexa
Presentation	The vaccine consists of both a 0.5 mL monodose pre-filled syringe and a vial containing a lyophilised pellet.(1)
Dose	0.5 mL
Dose adjustment	Not applicable
Maximum dose	Not applicable
Total cumulative dose	Not applicable
Route	IM
Preparation	See below
Administration	1. May administer oral sucrose 2 minutes prior to injection (observe local pain policy). 2. Gently shake the pre-filled syringe. 3. Add its contents to the vial of Hib pellet and shake until pellet is completely dissolved. 4. Administer 0.5 mL of reconstituted suspension by intramuscular injection (IMI) to the anterolateral aspect of the thigh (slowly to reduce pain). 5. Administer on the opposite limb from other concurrently administered vaccines (e.g. Prevenar 13).
Monitoring	Observe for 15 minutes after vaccination for any Adverse Event Following Immunisation (AEFI). Pain: Refer to local pain relief policy. Apnoea and bradycardia in premature infants for up to 48 hours. Infants with a history of febrile convulsions should be closely followed up as such adverse events may occur within 2 to 3 days post-vaccination.
Contraindications	Anaphylaxis following a previous dose of any DTPa vaccine. Hypersensitivity to any vaccine component. Lack of parental consent
Precautions	Significant acute illness or temperature greater than 38.5°C – postpone vaccine until neonatologist approves. If the infant has experienced an encephalopathy of unknown aetiology occurring within 7 days after previous vaccination with a pertussis containing vaccine. The following reactions to a previous dose may preclude further doses: - Convulsions within 3 days. - Persistent, severe, inconsolable crying for three or more hours within 48 hours. - Unexplained temperature > 40.5°C within 48 hours. Immunosuppressed patients Thrombocytopaenia or bleeding disorders. Children who have had a hypotonic/hyporesponsive episode (HHE) within 48 hours of vaccination with a DTPa containing vaccine should receive further doses as advised by the Adverse Events after Immunisation Clinics.
Drug interactions	Tetanus Immune Globulin or Diphtheria Antitoxin, if used, should be given at a separate site, with a separate needle and syringe. Should not be given to infants or children on anticoagulant therapy unless the potential benefit clearly outweighs the risk of administration.

	Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines.
Adverse reactions	Common: Pain, inflammation, redness, injection site mass persisting for up to a few days. Uncommon: Headache, fever, lethargy, malaise, myalgia. Rare: Anaphylaxis, urticaria and peripheral neuropathy. Any serious or unexpected adverse event following immunisation should be reported promptly. Providers should use clinical judgment in deciding which adverse events to report and parents/carers should be encouraged to notify the immunisation service provider or health authorities of any untoward medical occurrence that follows immunisation. Each State/Territory has its own contact details for notification. Contact telephone number for NSW Public Health Unit is 1300 066 055.
Compatibility	Not applicable
Incompatibility	Do not mix with any other vaccines in the same syringe.
Stability	After reconstitution, the vaccine should be injected promptly. However, the vaccine is stable for up to eight hours at room temperature.
Storage	Store between +2 and +8°C. Do NOT freeze. Discard if the vaccine has been frozen. Protect from light.
Excipients	Lactose, medium 199 (as stabiliser containing amino acids, mineral salts, vitamins and other substances), sodium chloride, aluminium hydroxide, aluminium phosphate and water for injections. The vaccine also contains the following residues: potassium chloride, polysorbate 20 and 80, formaldehyde, glycine, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, neomycin sulfate and polymyxin B sulfate.
Special comments	
Evidence	**Efficacy** Infanrix hexa was highly immunogenic for the vaccine antigens diphtheria and tetanus toxoids, poliovirus type 1, 2 and 3 antigens, pertussis antigens (PT, FHA and PRN), HBsAg and the Hib antigen (polyribosylribitol phosphate [PRP]) both as primary and booster vaccination in healthy infants aged < 2 years, with antibodies against these antigens persisting in the long term.(3) Seroprotective titres against these antigens were achieved in 95–100% of Infanrix hexa recipients. (3) Well-established serological correlates of protection exist for antibodies against tetanus, diphtheria, hepatitis B, polio and Hib.(4) Infanrix hexa was administered concomitantly with a rotavirus vaccine (Rotarix) in a randomised, double-blind, placebo-controlled trial and with a 13-valent-pneumococcal vaccine (Prevenar-13) in several studies. Limited data from these studies suggest that co-administration of these vaccines with Infanrix hexa does not affect the immunogenicity of either co-administered vaccine. (3) Infanrix hexa can be co-administered with other live or inactivated vaccines without interference with the immune response.(4) **Safety** Available clinical data from more than 10 years' experience with the vaccine suggest that Infanrix hexa as primary and booster vaccination is a safe and useful option for providing protection against the common childhood diseases of diphtheria, tetanus, poliomyelitis, pertussis, hepatitis B and invasive Hib disease. (1,3) A course of injections with Infanrix hexa was as effective at producing protective levels of antibodies as giving separate vaccines containing the same active substances. Overall, between 95 and 100% of the children had antibodies to diphtheria, tetanus, pertussis, hepatitis B virus, polioviruses, and Hib, 1 month after the vaccination course.(5) In 2007 the Committee for Medicinal Products for Human Use reviewed cases of apnoea in preterm infants following vaccination and concluded that the apnoea occurred due to immaturity of the immune system. Hence, their recommendation is to monitor very preterm infants for up to 48–72 hours after vaccination.(4) Historical concerns about potential temporal association between sudden unexpected death (SUD) and hexavalent vaccines has been extensively investigated and in 2003 the European Medicines Agency concluded absence of a cause-effect relationship and no change in the benefit-risk profile of then available hexavalent vaccines.(4)

Practice points	1. Do not give INFANRIX hexa at birth. 2. Preterm infants should be vaccinated according to their chronological age from birth. 3. Immune response to some Hib conjugate vaccines has been reduced in infants born prematurely. 4. The first dose of INFANRIX hexa can be given at 6 weeks of age due to the high morbidity and occasional mortality associated with pertussis in very young infants. If the first dose is given at 6 weeks of age, the next scheduled doses should still be at 4 and 6 months. 5. Paracetamol may be prescribed (15 mg/kg/dose) for administration at 4 hourly intervals after immunisation (maximum of 4 doses in a 24 hour period) for a fever > 38.5°C or significant pain if the child is miserable. Prophylactic administration of paracetamol at the time of, or immediately after, vaccination to reduce the risk of fever is not routinely recommended, with the exception of children < 2 years of age receiving meningococcal B vaccine and whole cell pertussis (DTPa). 6. The vastus lateralis muscle in the anterolateral thigh is the recommended site for IM vaccination in infants < 12 months of age. The deltoid muscle or ventrogluteal area is the recommended site for IM vaccination in children > 12 months of age. 7. Children with congenital limb malformation(s) should receive their vaccines in an unaffected limb where possible. The ventrogluteal area can also be considered. 8. NSW Health has provided free antenatal pertussis vaccinations for every woman during every pregnancy. 9. There is currently no evidence to suggest infants require an extra DTPa vaccine at 18 months of age if their mother received antenatal pertussis vaccine. 10. Interruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved with Infanrix hexa. Refer to The Australian Immunisation Handbook (1) for catch-up schedule.
References	1. Australian Immunisation Handbook. Infanrix hexa. Accessed on 12 April 2021. 2. New South Wales Immunisation schedule July 2020. Accessed on 12 April 2021. 3. Dhillon S. DTPa-HBV-IPV/Hib Vaccine (Infanrix hexa): A Review of its Use as Primary and Booster Vaccination. Drugs 2010; 70(8): 1021-58. 4. Baldo V, Bonnani P, Castro M & et al. Combined hexavalent diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-Haemophilus influenzae type b vaccine – Infanrix hexa. Human Vaccines & Immunotherapeutics 2014; 10 (1): 129-137. 5. European Medicines Agency. Infanrix hexa: summary of product characteristics [online].

VERSION/NUMBER	DATE
Original 1.0	**15/11/2016**
Current 2.0	**15/04/2021**
REVIEW	15/04/2026

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