Diphtheria-Tetanus-Acellular Pertussis-Hepatitis B-Polio-*Haemophilus Influenzae* type b Conjugate Combined Vaccine (DTaP-IPV-Hib-HB)

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.214**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	September 1, 2016	**Published**	August 15, 2025

	INFANRIX hexa
Manufacturer	GlaxoSmithKline Inc.
Classification	Non-live: DT (toxoid), aP (subunit), IPV (inactivated), Hib (conjugate), HB (recombinant)
Indications for Provincially Funded Vaccine	• Primary immunization for children **2 months up to and including 23 months of age** when diphtheria, tetanus, acellular pertussis, polio, Hib and hepatitis B vaccines are indicated for non-hyporesponsive individuals. **Note:** Hepatitis B containing vaccine is indicated for: ○ Infants born to hepatitis B infected mothers or whose primary caregiver is hepatitis B infected (acute cases or carriers) ○ Infants born March 1, 2018 or later ○ Infants who are household contacts of a hepatitis B case or carrier. Infants whose families have immigrated to Canada from areas where there is a high prevalence (8% or higher) of hepatitis B. See Hepatitis B Endemic Countries List. **Note:** INFANRIX hexa contains only a regular strength dose of hepatitis B vaccine and is **not indicated for infants and children requiring a double dose** of hepatitis B vaccine.
Serology	• There are no serological tests available for pertussis, polio or *Haemophilus influenzae* type b. • Serological testing is not typically recommended to assess levels of immunity to diphtheria or tetanus. For additional information see the AH Interpretation of DAT/TAT Level tables within the Adverse Event Following Immunization Policy for Alberta Immunization Providers. **Hepatitis B Post-Immunization Serology** **Infants born to mother with hepatitis B infected mothers:** • HBsAg and Anti-HBs serology is recommended 1–6 months following primary series of INFANRIX hexa and when the infant is at least 9 months of age. • If the infant is negative for Anti-HBs (antibodies) after the first series, administer a second hepatitis B vaccine series with repeat serology testing 1 month later. **Household contacts of a hepatitis B case or carrier:** • Send infant/child for HBsAg and Anti-HBs serology 1–6 months following the primary series of INFANRIX hexa and at least 6 months after HBIG. • If the infant/child is negative for Anti-HBs (antibodies) after the first series, administer a second hepatitis B vaccine series, with repeat serology testing 1 month later.

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Schedule
(See schedule below for infants born to hepatitis B infected mothers)
	Children 2 months up to and including 23 months of age
	Primary Series:
	• Dose 1: 2 months of age
	• Dose 2: 4 months of age
	• Dose 3: 6 months of age
	Note:
	• For a 3 dose primary series the minimal interval between the first and second dose of vaccine is 4 weeks; the minimal interval between the second and third dose of vaccine is 8 weeks; and the minimal interval between the first and third dose is 16 weeks.
	• Do not administer the third dose in the series to infants before 24 weeks (6 months) of age.
	• Complete the first 3 doses of an immunization series with the same combination product whenever possible. If this is not possible an alternative combination may be used.
	  ○ Ideally, a series started with INFANRIX hexa will be completed with INFANRIX hexa.
	  ○ Ideally, a series started with DTaP-IPV-Hib and single antigen hepatitis B vaccine should be completed with DTaP-IPV-Hib and single antigen hepatitis B vaccine.
	  ▪ **Exception**: Infants given a dose of hepatitis B vaccine at birth, see details below.
	  ○ The schedule and spacing considerations for this vaccine vary slightly from those of the individual HBV and DTaP-IPV-Hib vaccines. Ensure the appropriate schedule is followed for the vaccine(s) that are being used.
	• Use DTaP-IPV-Hib containing vaccine for the routine 18 month booster.
	  ○ **Exception**: If the spacing between the first 3 doses is less than minimum intervals as detailed above, use INFANRIX hexa at the routine 18 month booster. This applies to all indications for vaccine.
	• Children who have had pertussis infection should continue to receive pertussis-containing vaccines.
	• Children in whom invasive Hib disease develops before 24 months of age should receive Hib vaccine as recommended because natural disease may not induce protection.
	• Children 7 months up to and including 23 months of age who are starting a primary series or who have an incomplete primary series of INFANRIX hexa should receive INFANRIX hexa.
	  ○ INFANRIX hexa can be offered up to and including 23 months of age. In children 24 months of age or older, use separate DTaP-IPV-Hib and hepatitis B vaccines to complete the series.
	  ○ Doses of INFANRIX hexa that have been administered to children 24 months to less than 7 years of age will be considered valid doses.
	  ○ These children may need fewer doses of the Hib component; however, it is acceptable to give the additional doses of Hib vaccine in this combination vaccine for convenience of administration.
	• Individuals travelling to countries currently exporting and/or infected with polio may need special immunization documentation verifying polio immunization. Advise to consult with a travel clinic to determine what documentation is required.

Schedule for infants born to hepatitis B infected Mothers	**Infants presenting at 2 months of age who received hepatitis B vaccine at birth:** • Dose 1: Birth use hepatitis B vaccine • Dose 2: 2 months of age INFANRIX hexa • Dose 3: 4 months of age INFANRIX hexa • Dose 4: 6 months of age INFANRIX hexa **Note:** • Do not administer the fourth dose in the series to infants before 24 weeks (6 months) of age. • Where a dose of hepatitis B vaccine is given at birth, INFANRIX hexa can be used for the subsequent doses. The infant would receive a total of 4 doses of hepatitis B vaccine.

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	• When a dose of hepatitis B vaccine is given at birth, INFANRIX hexa can be used for the second dose of hepatitis B vaccine if the infant is at least 6 weeks old.
	  ○ This spacing would only be used if early immunization is required due to increased risk of exposure to antigens other than hepatitis B contained in the vaccine.
	• Complete the routine 18 month booster with a DTaP-IPV-Hib containing vaccine.
	  ○ **Exception:** If the spacing between the 3 doses of INFANRIX hexa is less than minimum intervals, provide a fourth dose of INFANRIX hexa at the routine 18 month booster.
	• Infants with a birth weight of less than 2,000 grams:
	  ○ The response to hepatitis B vaccine may be diminished in these infants
	  ○ When these infants are born to hepatitis B infected mothers 4 doses of hepatitis B vaccine are required.
	  ○ The ideal schedule for hepatitis B containing vaccines is birth, 1 month, 2 months and 6 months. Due to operational considerations, the above alternate schedule is routinely used in Alberta.

Preferred Use	N/A
Dose	0.5 mL
Route	IM
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of INFANRIX hexa. • Anaphylactic reaction to a previous dose of vaccine containing diphtheria, tetanus, pertussis, polio, Hib or hepatitis B antigens. • Encephalopathy (for example, coma, decreased level of consciousness, or prolonged seizures) within 7 days of a previous dose of a pertussis-containing vaccine not attributable to another identifiable cause. **Precautions:** • Do not give INFANRIX hexa to child hematopoietic stem cell transplant (HSCT) recipients and children pre and post solid organ transplant, as INFANRIX hexa contains a regular strength dose of hepatitis B vaccine. • Capsular polysaccharide antigen (Hib antigen) can be detected in the urine of vaccine recipients for up to 2 weeks following immunization with conjugate vaccines. This phenomenon could be confused with antigenuria associated with invasive Hib infections. • Do not give Hib vaccines to a child younger than 6 weeks of age. Data suggest that Hib conjugate vaccines given before 6 weeks of age may induce immunologic tolerance (reduced response to subsequent doses). • Defer pertussis immunization in children with progressive neurological disorders (such as infantile spasms, uncontrolled epilepsy or progressive encephalopathy), until the condition is corrected or stable. The decision to give pertussis vaccine must be made on an individual basis after careful consideration of the risks and benefits. • If Guillain-Barré Syndrome (GBS) occurred within 6 weeks of immunization with a previous dose of vaccine containing tetanus toxoid, it is prudent to withhold subsequent doses of tetanus-containing vaccine. Those who develop GBS outside of this interval or have an alternative cause identified, may receive subsequent doses of tetanus-containing vaccine.
Possible Reactions	**Common:** • Pain, redness, swelling and induration at the injection site • Fever • Unusual crying, irritability/fussiness, restlessness, nervousness • Decreased appetite, diarrhea, vomiting • Pruritus

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	• Increased or decreased sleepiness. **Uncommon:** • Diffuse swelling of the injected limb sometimes involving the adjacent joint • Upper respiratory tract infection, cough • Fatigue. **Rare:** • Anaphylaxis • Bronchitis, bronchospasm • Convulsions (with or without fever) • Dermatitis • Urticaria • Rash. As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	N/A • Vaccine licensed for children 6 weeks up to 2 years of age.
Lactation	N/A • Vaccine licensed for children 6 weeks up to 2 years of age.

Composition	Each 0.5 mL dose contains:
	Active Ingredients:
	• Diphtheria toxoid – 25 Lf
	• Tetanus toxoid – 10 Lf
	• Acellular pertussis:
	  ○ Pertussis toxoid (PT) – 25 mcg
	  ○ Filamentous haemagglutinin (FHA) – 25 mcg
	  ○ Pertactin – 8 mcg
	• Hepatitis B surface antigen – 10 mcg
	• Inactivated poliomyelitis vaccine
	  ○ Type 1 - 40 D-antigen units (DU)
	  ○ Type 2 – 8 DU
	  ○ Type 3 – 32 DU
	• Adsorbed purified capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus toxoid – 10 mcg.
	Non-medical Ingredients:
	• Aluminum salts - 0.82 mg
	• Lactose - 12.6 mg
	• Medium 199 (as a stabilizer) – 1.15 mg
	• Sodium chloride – 4.5 mg
	• Water for injection.
	Manufacturing residuals:
	• Neomycin sulphate
	• Polymyxin B sulphate

Blood/Blood Products	Does not contain human blood or blood products.
Bovine/Porcine Products	Bovine Products: • Bovine milk-derived materials other than lactose are not used in the formulation of the vaccine; however, they are used as raw materials during the manufacturing process.

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	Porcine Products: • Porcine derived materials are not used in the formulation; however, they are used as raw materials during the manufacturing process. Various materials of animal origin are used during manufacturing. Presence of residual traces in the final product cannot be excluded.
Latex	Does not contain latex.
Interchangeability	• Complete the first 3 doses of the series with the same combination product. • If the original vaccine is not available or not known, use an alternate combination product to complete the primary series, with a separate dose of hepatitis B vaccine. ○ Either Pentacel, Pediacel or Infanrix-IPV/Hib may be used interchangeably for the fourth dose.
Administration with Other Products	May be given at the same time as other inactivated and live vaccine. • Use a separate needle and syringe for each vaccine. • The same limb may be used if necessary but use different sites on the limb.
Preparation	• Add entire contents of syringe DTaP-HB-IPV (PEDIARIX) to the vial containing the Hib powder. • Shake the mixture well until the powder is completely dissolved. • Withdraw the entire contents of the reconstituted vial for administration.
Appearance	• The Hib component appears as a lyophilized white powder. • The DTaP-HB-IPV (PEDIARIX) component is supplied as a turbid white suspension. • The reconstituted vaccine is slightly more cloudy than the liquid component alone.
Storage	• Store at +2^{0}C to +8^{0}C. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in original packaging to protect from light.
Vaccine Code	DTaP-IPV-Hib-HB
Antigen Code	Tetanus – T Diphtheria – D Acellular pertussis – P Hepatitis B – HB Inactivated polio vaccine – POL *Haemophilus influenzae* type b - Hib
Licensed for	Children 6 weeks up to 2 years of age.
Notes	• 2016 June: INFANRIX hexa introduced for children under 24 months of age for infants born to hepatitis B infected mothers/caregivers, household contacts of hepatitis B carriers and whose families come from endemic countries. • 2018 March: Expanded indications to include hepatitis B vaccine as Universal Infant Hepatitis B program for infants born on or after March 1, 2018. • 2024 July 1: Updated to reference Pentacel product, references to dTap changed to Tdap to align with national standards.
Related Resources	• Diphtheria, Tetanus, Acellular Pertussis, Hepatitis B, Polio and *Haemophilus influenzae* type b Conjugate Vaccine Information Sheet.

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