Diphtheria-Tetanus-Acellular Pertussis-Polio-*Haemophilus influenzae* type b Conjugate Combined Vaccine Biological Page (DTaP-IPV-Hib)

Section 7:	**Biological Product Information**		**Standard #: 07.211**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
Approval Date:	September 10, 2012	**Revised:**	August 3, 2022

	INFANRIX™-IPV/Hib	**Pediacel®**
Manufacturer	GlaxoSmithKline Inc.	Sanofi Pasteur Limited
Biological Classification	Inactivated	

Indications for Provincially Funded Vaccine	• Primary immunization for children **2 months up to and including 59 months of age** when diphtheria, tetanus, acellular pertussis, polio and Hib vaccines are indicated.
	  ○ Primary immunization at 2, 4 and 6 months of age with a booster dose at 18 months of age.
	• Children **5 years up to and including 6 years of age** who are presenting with no immunization or an incomplete primary series when diphtheria, tetanus, acellular pertussis and polio vaccines are indicated and who require the first, second, third or fourth dose in that series.
	  ○ Note: These children need higher concentrations of diphtheria (designated as "D") and pertussis (designated as "P") for the first, second, third or fourth dose of diphtheria, tetanus, acellular pertussis and polio.
	• Children **younger than 7 years of age** who sustain a wound injury that have not received the recommended number of tetanus toxoid doses for their age and need higher concentrations of diphtheria and pertussis (see Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard # 08.400).
	• Child recipients of hematopoietic stem cell transplant (HSCT) should have their immunization schedules restarted post-transplant (see #08.304 Standard for Immunization of Transplant Candidates and Recipients).
	• Child solid organ transplant (SOT) candidates and recipients **who are 5 years up to and including 6 years of age** and require tetanus, diphtheria, pertussis, polio and Hib containing vaccine (see #08.304 Standard for Immunization of Transplant Candidates and Recipients).
	Notes:
	• It is acceptable to give additional doses of diphtheria, tetanus, pertussis, polio and Hib combined vaccine for children who are delayed in their immunization series.
	• Children who have received 4 previous doses of DTaP-IPV±Hib presenting for their pre-school immunization at 4 years up to and including 6 years of age (or the equivalent of the pre-school immunization) would receive dTap-IPV. This dose may not be necessary if the 4th dose was given at 4 years of age or older.
	• Child solid organ transplant (SOT) candidates and recipients may need to be immunized using minimum intervals (see #08.304 Standard for Immunization of Transplant Candidates and Recipients).	

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Serology	**Pre-Immunization and Post immunization** • There are no serological tests available for pertussis, polio or *Haemophilus influenza type b*. • Serological testing is not typically recommended to assess levels of immunity to diphtheria or tetanus. For additional information see the Alberta Health DAT/TAT Interpretation tables at: https://open.alberta.ca/publications/aefi-policy-for-alberta-immunization-providers	
Schedule	**Children 2 months up to and including 6 years of age:** • Dose 1 – 2 months of age • Dose 2 – 4 months of age and minimum 4 weeks after dose 1 • Dose 3 – 6 months of age and minimum 4 weeks after dose 2 • Dose 4 – 18 months of age and minimum 6 months after dose 3 • Dose 5 – 4 to 6 years of age given as dTap-IPV, with a minimum of 6 months after dose 4. See Diphtheria Tetanus-Acellular Pertussis-Polio Combined Vaccine Biological Page #07.213. **Individual 5 years of age and older:** • For recipients of HSCT see #08.304 Standard for Immunization of Transplant Candidates and Recipients for specific scheduling information. • For SOT candidates and recipients **5 years up to and including 6 years of age** requiring Hib vaccine see #08.304 Standard for Immunization of Transplant Candidates and Recipients for specific scheduling information. **Spacing Considerations:** • Children who are delayed for any dose should be immunized using minimum intervals to allow for more rapid protection. • Dose five given as diphtheria, tetanus, acellular pertussis, polio (dTap-IPV), is recommended at 4 years up to and including 6 years of age (see dTap-IPV Vaccine Biological Page - #07.213). • When dose four is administered at 4 years of age or older, the fifth dose is not necessary. • Children who have had pertussis infection should continue to receive pertussis-containing vaccines. History of disease may not confer long-term immunity. • Children in whom invasive Hib disease develops under 2 years of age should receive Hib vaccine as recommended because natural disease may not induce long term protection. At time of administering vaccine, there should be a 1 month interval from invasive Hib disease. **Note:** Individuals travelling to countries currently exporting and/or infected with polio may need special immunization documentation verifying polio immunization. These individuals should consult with a Travel Clinic to determine what documentation is required.	
Preferred Use	N/A	
Dose	0.5 mL **Note:** For INFANRIX™-IPV/Hib, add the entire contents of the syringe to the vial containing the powder. Once reconstituted withdraw the 0.5 mL dose for administration. Any vaccine remaining in the vial should be discarded.	
Route	IM	

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Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of the vaccine. • Anaphylactic or other allergic reaction to a previous dose of a vaccine containing tetanus, diphtheria, pertussis, polio or Hib. • Encephalopathy of unknown etiology (e. g., coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis-containing vaccine. **Precautions:** • Capsular polysaccharide antigen (Hib antigen) can be detected in the urine of vaccine recipients for up to two weeks following immunization with conjugate vaccines. This phenomenon could be confused with antigenuria associated with invasive Hib infections. • Hib vaccines should never be given 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). • Children who have invasive Hib disease after completing the immunization series at 2, 4 and 6 months of age should be evaluated for evidence of an underlying immune deficiency. • Children with neurologic conditions should be assessed carefully. • 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 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 • Increased crying, irritability/fussiness, restlessness • Decreased activity, fatigue • Decreased appetite, diarrhea, vomiting **Uncommon:** • Diffuse swelling of injected limb, sometimes involving the adjacent joint • Lymphadenopathy • Rash, urticaria • Upper respiratory tract infection, cough, bronchitis, rhinorrhea **Rare:** • Anaphylaxis • Arthus-type injection site reaction • Persistent nodule at the site of injection • Pruritus, dermatitis • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	This vaccine generally will not be administered to individuals over 7 years of age, with the exception of HSCT recipients. Adequate data is not available for the use of this vaccine during pregnancy and therefore will not routinely be recommended in Alberta for pregnant women. However, use of this vaccine during pregnancy may be considered in consultation with your MOH if the individual is at high risk of disease.	

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Lactation	This vaccine generally will not be administered to individuals over 7 years of age, with the exception of HSCT recipients. If indicated this vaccine can be administered to eligible breastfeeding women.	

Composition	**Active Ingredients:**
	• Diphtheria toxoid – 25 Lf
	• Tetanus toxoid – 10 Lf
	• Acellular pertussis:
	  ○ Pertussis toxoid (PT) – 25 mcg
	  ○ Filamentous haemagglutinin (FHA) – 25 mcg
	  ○ Pertactin (PRN) – 8 mcg
	• Inactivated poliomyelitis vaccine
	  ○ Type 1 (Mahoney) – 40 DU
	  ○ Type 2 (MEF1) – 8 DU
	  ○ Type 3 (Saukett) – 32 DU
	• Purified polyribosyl-ribitol-phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus toxoid – 10 mcg
	Non-medical Ingredients:
	• Lactose
	• Sodium chloride
	• Aluminum salts
	• Medium 199 – as stabilizer including amino acids, mineral salts and vitamins
	• Water for injection
	• **Manufacturing residuals:**
	  ○ Formaldehyde
	  ○ Polysorbate 80
	  ○ Potassium chloride
	  ○ Disodium phosphate
	  ○ Monopotassium phosphate
	  ○ Glycine
	  Trace amounts of:
	  ○ Neomycin sulphate
	  ○ Polymyxin sulphate
		Active Ingredients:
		• Diphtheria toxoid – 15 Lf
		• Tetanus toxoid – 5 Lf
		• Acellular pertussis:
		  ○ Pertussis toxoid (PT) – 20 mcg
		  ○ Filamentous haemagglutinin (FHA) – 20 mcg
		  ○ Pertactin (PRN) – 3 mcg
		  ○ Fimbriae types 2 and 3 (FIM) – 5 mcg
		• Inactivated poliomyelitis vaccine
		  ○ Type 1 (Mahoney) – 40 DU
		  ○ Type 2 (MEF1) – 8 DU
		  ○ Type 3 (Saukett) – 32 DU
		• Purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to tetanus protein – 10 mcg
		Non-medical Ingredients:
		• **Excipients:**
		  ○ Aluminum phosphate (adjuvant) – 1.5 mg
		  ○ 2-phenoxyethanol – 0.6% v/v
		  ○ Polysorbate 80 – ≤ 0.1% w/v
		• **Manufacturing residuals:**
		  Trace amounts of:
		  ○ Bovine serum albumin
		  ○ Neomycin
		  ○ Polymyxin B
		  ○ Streptomycin
		  ○ Formaldehyde
		  ○ Glutaraldehyde

Blood/Blood Products	Animal blood (including equine-derived blood) is used as a raw material in the manufacturing process. Does not contain human blood or blood products.	Does not contain human blood or blood products.
Bovine/Porcine Products	Ingredients of animal origin, including bovine, equine and porcine derived materials, are used as raw materials in the manufacturing process.	• Contains trace amounts of bovine serum. • Porcine-derived products are used as raw materials in the early stages of the manufacturing process.
Latex	Does not contain latex.	

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Interchangeability	The first three doses of the immunization series should be completed, whenever possible, with the same combination product. However, if the original vaccine is not known or not available an alternate combination product may be used to complete the primary series. Either Pediacel® or Infanrix™-IPV/Hib may be used interchangeably for the fourth dose.	
Administration with Other Products	• Can be given at the same time as other inactivated and live vaccine using a separate needle and syringe for each vaccine. • The same limb may be used if necessary, but different sites on the limb must be chosen.	
Appearance	• The Hib component will appear as a lyophilized white powder. • The DTaP-IPV component is supplied as a turbid white suspension.	Uniform, cloudy white to off-white suspension.
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 when possible to protect from light	
Vaccine Code	DTaP-IPV-Hib	
Antigen Code	Tetanus – T Diphtheria – D Acellular pertussis – P Inactivated polio vaccine – POL *Haemophilus influenzae* type b - Hib	
Licensed for	• Children 6 weeks up to and including 4 years of age. • Off-license use has been recommended by AH for children 5 years up to and including 6 years of age. • Off-license use has been recommended by AH for eligible HSCT clients 5 years of age and older and SOT candidates and recipients up to and including 6 years of age.	• Children 2 months up to and including 6 years of age. • Off-license use has been recommended by AH for children 6 weeks of age and older and eligible HSCT clients 7 years of age and older.

Program Notes:

- 2012 Fall: Infanrix™-IPV/Hib became available in the routine Alberta Immunization Program.
- 2007 December: Pediacel® was introduced into the routine Alberta Program.
- 1997 July 1: Pentacel®, containing the acellular pertussis component, became available in the routine Alberta Immunization Program.
- 2016 September 14: Pediacel® became available to use off-license in children 6 weeks of age and older.
- 2017 June 1: Pediacel® and Infanrix™-IPV/Hib implemented for use in place of DTaP-IPV as Quadracel® and Infanrix®-IPV are unavailable.
- 2017 November: Infanrix-hexa® replaces Pediacel® and Infanrix®-IPV/Hib in routine infant schedule for infants born March 1, 2018 or after.
- 2022 August 3: Removal of reference to Td as product no longer available in Alberta.

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Related Resources:

- Diphtheria, Tetanus, Acellular Pertussis, Polio and *Haemophilus influenzae* type b Conjugate Vaccine Information Sheet (104512).

References:

1. Alberta Health. (2022 June). Alberta Immunization Policy. *Diphtheria-Tetanus-Acellular Pertussis-Polio-Haemophilus influenzae type b Conjugate Combined Vaccine.*
2. Alberta Health. (2019, April 1). Alberta Immunization Policy. *Adverse Event Following Immunization (AEFI) Policy for Alberta Health Services Public Health*. Alberta Health.
3. American Academy of Pediatrics. (2015). *Red Book: 2015 Report of the Committee on Infectious Diseases.* Elk Grove, IL: American Academy of Pediatrics.
4. Centers for Disease Control and Prevention. (2011). Chapter 7: *Haemophilus influenzae* type b. In *Epidemiology and Prevention of Vaccine Preventable Diseases* (12th Edition ed.).
5. Centers for Disease Control and Prevention. (2011). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. *Morbidity and Mortality Weekly Report, 60* (2), 36-39.
6. GlaxoSmithKline. (2015, July). Product Monograph. *Infanrix-IPV/Hib: Combined diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, Haemophilus influenzae type b vaccine*.
7. National Advisory Committee on Immunization. (2012). Canadian Immunization Guide (Evergreen Edition). Ottawa, ON: Public Health Agency of Canada.
8. Sanofi Pasteur Limited. (2012, February 28). Product Monograph. *Pediacel: Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine and Haemophilus Influenzae b Conjugate Vaccine*.