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

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.211**	
Created and approved by	Provincial Immunization Program Standards and Quality		
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	INFANRIX-IPV/Hib	PEDIACEL	PENTACEL
Manufacturer	GlaxoSmithKline Inc.	Sanofi Pasteur Limited	Sanofi Pasteur Limited
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. • 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. • Child and adult hematopoietic stem cell transplant (HSCT) recipients should have their immunization schedules restarted post-transplant. See Standard for Immunization of Transplant Candidates and Recipients • Child solid organ transplant (SOT) candidates and recipients. See Standard for Immunization of Transplant Candidates and Recipients **Note:** • 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 Tdap-IPV. This dose may not be necessary if the 4th dose was given at 4 years of age or older.		
Serology	**Pre-Immunization and Post immunization** • 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 Alberta Health Interpretation of DAT/TAT Levels tables in the Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers.		

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Schedule	**Children completing a primary series started with INFANRIX hexa:**
	• Dose 4: 18 months of age
	Children initiating or completing a primary series with DTaP-IPV-Hib:
	• Dose 1: Day 0
	• Dose 2: 8 weeks after dose 1
	• Dose 3: 8 weeks after dose 2
	• Dose 4: 12 months after dose 3
	Spacing Considerations:
	• Minimum spacing between doses 3 and 4 is 6 months as long as the child is over 15 months of age. For minimum intervals, see Standard For Recommended Immunization Schedules
	• Children may need fewer doses of the Hib component if they have received a dose of Hib vaccine at 15 months of age or older; however, it is acceptable to give additional doses of the Hib component using this combination vaccine.
	• When the fourth primary immunizing dose is administered at 4 years of age or older, the fifth dose (preschool booster) is not necessary.
	• Children receiving their fifth dose between four and six years of age should receive Tdap-IPV. See Tdap-IPV Vaccine Biological Page.
	Note:
	Children receiving their fifth dose may receive a lower concentration of diphtheria (designated as "d") and pertussis (designated as "p").
	Recipients of HSCT:
	• Should have their immunization schedules restarted post- transplant., See
	  ○ Immunization for Child HSCT Transplant Recipients
	  ○ Immunization for Adult HSCT Transplant Recipients
	Children expecting solid organ transplantation. See
	• Immunization for Children Expecting Solid Organ Transplant Before 18 Months of Age (Accelerated)
	• Immunization for Children Expecting Solid Organ Transplant After 18 Months of Age (Catch-up and Ongoing Schedule)
	Note:
	• Persons who have had pertussis infection should continue to receive pertussis-containing vaccines.
	• Children who develop invasive Hib disease before 24 months of age should receive Hib vaccine as recommended because natural disease may not confer immunity. Hib vaccine can be administered 4 weeks after invasive Hib disease onset.
	• 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	None • Available vaccines are safe and immunogenic in eligible age groups. • Offer the alternate product if a person has a medical contraindication to one product if supply is available.		
Dose	0.5 mL		
Route	IM		
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of the vaccine.		

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	• Anaphylactic or other allergic reaction to a previous dose of a vaccine containing tetanus, diphtheria, pertussis, polio or Hib. • 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. • Defer pertussis immunization in children with progressive neurological disorders, such as infantile spasms, uncontrolled epilepsy, 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. **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. • 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). • 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. See Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression *Neurologic Conditions*. • 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 • Swelling at injection site greater than 5cm • Fever >38℃ • Unusual/abnormal crying, irritability/fussiness, restlessness • Decreased activity, fatigue, somnolence (sleepiness) • Decreased appetite, diarrhea, vomiting **Uncommon:** • Fever >39.5℃ • Lymphadenopathy • Rash, urticaria • Upper respiratory tract infection, cough, bronchitis, rhinorrhea • Diffuse swelling of the injected limb, sometimes involving the adjacent joint **Rare:** • Anaphylaxis • 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 is not 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 individuals who are pregnant. • 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 is not administered to individuals over 7 years of age, with the exception of HSCT recipients. • If indicated this vaccine can be administered to people who are lactating and feeding their milk to infants or children.		
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 B 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) – 29 D-antigen units ○ Type 2 (MEF1) – 7 D-antigen units ○ Type 3 (Saukett) – 26 D-antigen units • 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	**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 poliovirus • Type 1 (Mahoney) – 29 D-antigen units • Type 2 (MEF1) – 7 D-antigen units • Type 3 (Saukett) – 26 D-antigen units • Purified polyribosylribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b covalently bound to 18-30 mcg of tetanus protein – 10 mcg **Non-medical Ingredients:** • **Excipients:** ○ Aluminum phosphate (adjuvant) – 1.5 mg • 2-phenoxyethanol – 0.6% v/v • Polysorbate 80 – <8.1% w/v • Sucrose – 42.5 mg • Tris (hydoxymethyl) aminomethane – 0.6 mg • Water for injection • **Manufacturing residuals:** Trace amounts of: • Bovine serum albumin • Formaldehyde • Glutaraldehyde • Neomycin • Polymyxin B sulphate • Streptomycin sulphate

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Blood/Blood Products	Does not contain human blood or blood products.	Various materials of human origin are used during manufacturing. Presence of residual traces in the final product cannot be excluded.	The polio virus component is grown in MRC-5 human diploid cell culture.
Bovine/Porcine Products	**Bovine Products:** • Bovine milk-derived materials other than lactose are not used in the formulation; however, they are used as raw materials during the routine manufacturing process. **Porcine Products:** • Porcine derived materials are not used in the formulation; however, they are used as raw materials during the manufacturing process.	**Bovine Products:** • Bovine serum albumin is a manufacturing process residual. **Porcine Products:** • Various materials of porcine origin are used during manufacturing. Presence of residual traces in the final product cannot be excluded. Various materials of animal origin are used during manufacturing. Presence of residual traces in the final product cannot be excluded.	**Bovine Products:** • Bovine serum albumin is a manufacturing process residual. **Porcine Products:** • Various materials of porcine origin are used during manufacturing. Presence of residual traces in the final product cannot be excluded. 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 three doses of the series, with the same combination product. • If the original vaccine is not known or not available, use an alternate combination product to complete the primary series. ○ Either Pentacel 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 the entire liquid contents, INFANRIX® -IPV (diphtheria toxoid, tetanus, acellular pertussis and inactivated poliomyelitis vaccine), of the syringe or vial, to the vial containing the HIBERIX® (*Haemophilus influenzae* type b), a lyophilized powder. Do not remove the white back-stop from the syringe.	• Shake the vial well	• Gently shake the vial of QUADRACEL and then withdraw the entire contents • Inject the liquid into the lyophilized ActHIB vaccine vial • Swirl vial gently • After reconstitution, immediately withdraw the total volume of PENTACEL for administration
Appearance	• The Hib component will appear as a lyophilized white powder.	• Uniform, cloudy white to off-white suspension.	• Uniform, cloudy white to off-white suspension.

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	• The DTaP-IPV component is supplied as a turbid 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 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 for children 5 years up to and including 6 years of age. • Off-license use for child HSCT recipients 5 years of age. • Off-license use for adult HCST recipients.	• Children 2 months up to and including 6 years of age. • Off-license use for children starting at 6 weeks of age. • Off license use for child HSCT recipients 7 years of age and older. • Off license use for adult HSCT recipients.	• Children 2 months of age up to and including 6 years of age. • Off-license use for children starting at 6 weeks of age. • Off-license use for child HSCT recipients 7 years of age and older. • Off-license use for adult HSCT recipients.
Notes	• 1997 July 1: Pentacel, containing the acellular pertussis component, became available in the routine Alberta Immunization Program. • 2007 November 30: Pediacel was introduced into the routine Alberta Program. • 2012 November 20: Infanrix-IPV/Hib became available in the routine Alberta Immunization Program • 2016 September 21: 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 June 30: Removal of reference to Td as product no longer available in Alberta. • 2024 June 28: Updated to include Pentacel product, references to dTap changed to Tdap to align with national standards.		
Related Resources	Diphtheria, Tetanus, Acellular Pertussis, Polio and *Haemophilus influenzae* type b Conjugate Vaccine Information Sheet (104512).		

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