Diphtheria-Tetanus-Acellular Pertussis-Polio Combined Vaccine Biological Page (dTap-IPV)

Section 7:	**Biological Product Information**		**Standard #: 07.213**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
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	ADACEL®-POLIO	**BOOSTRIX®-POLIO**
Manufacturer	Sanofi Pasteur Ltd.	GlaxoSmithKline Inc
Biological Classification	Inactivated	
Indications for Provincially Funded Vaccine	**Children 4 years up to and including 6 years of age who have received 4 previous doses of DTaP-IPV±Hib vaccine:** • Reinforcing dose of diphtheria, tetanus, pertussis and polio vaccine routinely given as the preschool booster. **Note:** For children who are delayed in their immunization schedule refer to Diphtheria-Tetanus-Acellular Pertussis-Polio-Haemophilus Influenzae type B Conjugate Combined Vaccine Biological Page #07.211. **Children 7 years up to and including 17 years of age:** • Initiating or completing a primary immunization series for tetanus, diphtheria, pertussis and polio. **Individuals 18 years of age and older:** • When immunization with tetanus, diphtheria, pertussis and polio antigens are indicated (primary or reinforcing dose). Refer to Polio and Tetanus-Diphtheria-Pertussis vaccine biological pages. **Notes:** • Recipients of hematopoietic stem cell transplant (HSCT) and candidates/recipients of solid organ transplant (SOT), see *Standard for Immunization of Transplant Candidates and Recipients* for recommended vaccine and schedule information. • Individuals who sustain a tetanus prone wound need to have their tetanus immunization history assessed (Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard #08.400). • Individuals who have had pertussis infection should continue to receive pertussis-containing vaccines. • 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.	

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Serology	**Pre-Immunization and Post-Immunization** • There are no serological tests available for pertussis or polio. • 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 4 years up to and including 6 years of age:** • Reinforcing preschool booster given a minimum of 6 months from previous dose of tetanus, diphtheria, pertussis and polio containing vaccine. **Individuals 7 years up to and including 17 years of age initiating or completing a primary immunization series:** • Dose 1 – day 0 • Dose 2 – 4 to 8 weeks after dose 1 • Dose 3 – 6 to 12 months after dose 2 **Note:** For children with delayed immunization see # 03.110 Standard for Recommended Immunization Schedules, Section 2 and 3 to determine number of doses and correct spacing. **Individuals 18 years of age and older:** • One dose as part of a primary immunization series or a reinforcing dose where all 4 antigens are indicated. When additional doses of tetanus, diphtheria and polio vaccine are required see the corresponding vaccine biological pages for more information.	
Preferred Use	There will be no preference indicated for the use of Adacel®-Polio or Boostrix®-Polio in specific age or risk groups. • Both vaccines are safe and immunogenic in individuals four years of age and older. • Persons with medical contraindications to one product should be offered the alternate product if supply is available.	
Dose	0.5 mL	
Route	IM	
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, or polio. • 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. • Should not be administered to individuals who have experienced transient thrombocytopenia following a previous dose of diphtheria/tetanus containing vaccine. Consult with MOH on a case-by-case basis to determine immunization recommendations. **Precautions:** • Frequent booster doses of tetanus and diphtheria toxoids may lead to severe local and systemic reactions and may be associated with high levels of circulating antitoxin. • If Guillain-Barré Syndrome (GBS) occurred within 6 weeks of immunization with a previous dose of vaccine containing tetanus toxoid, it is prudent to	

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	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:**
	• All ages:
	  ○ Pain, redness, bruising and swelling at the injection site
	  ○ Fever, chills
	  ○ Headache, fatigue, irritability
	  ○ Sore, swollen joints
	  ○ Vomiting, diarrhea
	• Children 4 to 9 years of age:
	  ○ Pruritus and dermatitis at the injection site
	  ○ Decreased appetite
	  ○ Rash (children 3-5 years)
	• Individuals 10 years of age and older:
	  ○ Nausea
	  ○ Myalgia
	
	Uncommon:
	• Children 4 to 9 years of age:
	  ○ Abdominal pain
	  ○ Apathy
	  ○ Dry throat
	  ○ Nausea
	  ○ Sleep disorder
	• Individuals 10 years of age and older:
	  ○ Asthma
	  ○ Decreased appetite
	  ○ Dizziness
	  ○ Lymphadenopathy
	  ○ Oral herpes
	  ○ Paraesthesia
	  ○ Pruritus
	
	Rare:
	• Anaphylaxis
	• Angioedema, generalized urticaria
	• Asthenia
	• Convulsions (with or without fever)
	• Extensive swelling of the vaccinated limb
	• Persistent nodule at the site of injection
	• As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	

Pregnancy	May be administered to pregnant women 26 weeks of gestation or greater when there is significant risk of exposure to both pertussis and polio. Consultation with the Medical Officer of Health is required. Immunization during pregnancy requires careful consideration. The effect upon embryonic and fetal development has not been assessed. However, inactivated vaccines and toxoids are generally considered safe in pregnancy.	
Lactation	Can be administered to eligible breastfeeding women.	

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Composition	**Active Ingredients:**
	• Tetanus toxoid – 5 Lf
	• Diphtheria toxoid – 2 Lf
	• Acellular pertussis:
	  ○ Pertussis Toxoid (PT) – 2.5 mcg
	  ○ Filamentous Haemagglutinin (FHA) – 5 mcg
	  ○ Pertactin (PRN) – 3 mcg
	  ○ Fimbriae Types 2 and 3 (FIM) – 5 mcg
	• Inactivated Poliomyelitis Vaccine:
	  ○ Type 1 (Mahoney) – 40 D-antigen units*
	  ○ Type 2 (MEF-1) – 8 D-antigen units*
	  ○ Type 3 (Saukett) – 32 D-antigen units*
	* or the equivalent antigen quantity, determined by suitable immunochemical method
	
	Non-medicinal Ingredients:
	• Aluminum phosphate (adjuvant)
	• 2-phenoxyethanol 0.6% v/v
	• Polysorbate 80
	• Water for injection
	• Trace amounts of:
	  ○ Bovine serum albumin
	  ○ Formaldehyde
	  ○ Glutaraldehyde
	  ○ Streptomycin
	  ○ Neomycin
	  ○ Polymyxin B
		Active Ingredients:
		• Diphtheria toxoid – 2.5 Lf
		• Tetanus toxoid – 5 Lf
		• Acellular pertussis:
		  ○ Pertussis toxoid (PT) – 8 mcg
		  ○ Filamentous haemagglutinin (FHA) – 8 mcg
		  ○ Pertactin (PRN) – 2.5 mcg
		• Inactivated poliomyelitis vaccine:
		  ○ Type 1 (Mahoney) – 40 DU
		  ○ Type 2 (MEF1) – 8 DU
		  ○ Type 3 (Saukett) – 32 DU
		
		Non-medical Ingredients:
		• Sodium chloride
		• Aluminum salts
		• Medium 199
		• Water for injection
		• Trace amounts of:
		  ○ Formaldehyde
		  ○ Neomycin
		  ○ Polymixin

Blood/Blood Products	Does not contain human blood or blood products.	
Bovine/Porcine Products	Bovine serum albumin in trace amounts.	Ingredients of animal origin, including bovine and porcine derived materials, are used as raw materials in the manufacturing process.
Latex	Does not contain latex.	
Interchangeability	Individuals who begin their immunization with a different combined product may complete immunization using dTap-IPV.	
Administration with Other Products	• May be given at the same time as other inactivated and live vaccines 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	Uniform, cloudy white suspension.	

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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	
Antigen Code	Tetanus – T Diphtheria – D Acellular pertussis – P Inactivated polio vaccine – POL	
Licensed for	• Licensed for booster immunization of individuals 4 years of age and older. • Currently **off label** use is recommended, per Alberta Health Immunization Policy, for primary immunization of individuals 7 years of age and older who need all of the antigens contained in the vaccine.	

Program Notes:

- 2012 September: Introduced to replace DTaP-IPV as the preschool booster in the routine immunization program in Alberta and for primary immunization for individuals 7 years up to and including 17 years of age who require tetanus, diphtheria, pertussis and polio vaccine.

Related Resources:

- Diphtheria, Tetanus, Acellular Pertussis and Polio Vaccine Information Sheet (104503).

References:

1. Alberta Health. (2019,April 1). Alberta Immunization Policy. *Adverse Event Following Immunization (AEFI) Policy for Alberta Health Services Public Health*. Alberta Health.
2. Alberta Health. (2019, July 19). Alberta Immunization Policy. *Diphtheria-Tetanus-Acellular Pertussis-Polio Combined Vaccine:*.
3. 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.
4. GlaxoSmithKline. (2018, March 5). Product Monograph. *BOOSTRIX®-POLIO: Combined diphtheria, tetanus, acellular pertussis (adsorbed) and inactivated poliomyelitis vaccine*.
5. National Advisory Committee on Immunization. (2019). Canadian Immunization Guide (Evergreen Edition). Ottawa, ON: Public Health Agency of Canada. https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html
6. Sanofi Pasteur Limited. (2013, July 2). Adacel®Polio: Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed combined with inactivated poliomyelitis vaccine. *Product Monograph.*
7. GlaxoSmithKline. Personal communication with GSK representative. Presence of materials of animal origin. 5 Dec 2019.
8. GlaxoSmithKline. Personal communication with GSK representative. Presence of Equine Derived Materials in Tdap-IPV. 12 Dec 2019.