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

Section 7:	**Biological Product Information**		**Standard #: 07.210**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
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	Adacel®	**Boostrix®**
Manufacturer	Sanofi Pasteur Limited	GlaxoSmithKline Inc.
Biological Classification	Inactivated	
Indications for Provincially Funded Vaccine	**Children 7 years up to and including 17 years of age:** • With an uncertain or no history of a primary series or those who have not completed **a primary** series for diphtheria, tetanus and pertussis. **Note:** ○ If polio vaccine is also indicated combined dTap-IPV vaccine should be used. See Diphtheria-Tetanus-Acellular Pertussis-Polio Conjugate Combined Vaccine Biological Page #07.213. • Who are due for a reinforcing dose of diphtheria, tetanus and pertussis vaccine in **grade 9** and have not received a dose of acellular pertussis vaccine as an adolescent (i.e., 12 years up to and including 17 years of age) as part of the routine school immunization program. • Who are candidates or recipients of SOT - immunize using the routine age appropriate schedule for tetanus-diphtheria-pertussis containing vaccine • For recipients of HSCT refer to Transplant Guidelines #08.304 to determine appropriate tetanus-diphtheria-pertussis containing vaccine. • Who sustain a tetanus prone wound need to have their tetanus immunization history assessed (Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard #08.400) and be offered age-appropriate tetanus containing vaccine as recommended. **Notes:** • Students in ungraded classes or those who do not continue in the school system to grade 9 can still be immunized on a case by case basis, generally at 14 years up to and including 18 years of age. ○ The guiding principle should be to offer protection to students prior to them leaving the school system. • Grade 9 students who have received a dose of tetanus, diphtheria, acellular pertussis containing vaccine prior to 12 years of age should receive a dose of dTap in grade 9 regardless of the interval in order to ensure best protection as an adolescent and adult. • Grade 9 students who have received a dose of Td (i.e., as part of wound management) should receive a dose of dTap vaccine regardless of the spacing. • Children needing tetanus prophylaxis for wound management should be referred to public health for age-appropriate tetanus containing vaccine. If this is not possible they should be provided with available tetanus containing vaccine for wound management and subsequently referred to public health for further assessment of immunization recommendations. See Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard # 08.400).	

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	Individuals 18 years of age and older:
	• Primary or reinforcing immunization of individuals 18 years of age and older.
	• For candidates or recipients of SOT immunize using the routine age appropriate schedule for tetanus-diphtheria-pertussis containing vaccine.
	• For recipients of HSCT refer to Transplant Guidelines #08.304 to determine appropriate tetanus-diphtheria-pertussis containing vaccine.
	• Who sustain a tetanus prone wound need to have their tetanus immunization history assessed (see Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard #08.400) and be offered tetanus-containing vaccine as recommended.
	Pregnant Females:
	• Pregnant women in every pregnancy from 27 weeks up to and including 32 weeks gestation.
	  ○ Ideally, one dose of dTap should be offered in every pregnancy from 27 weeks up to and including 32 weeks gestation, irrespective of immunization history.
	  ○ dTap may, however, be provided from 13 weeks gestation up to the time of delivery.
	  ○ If dTap is provided early in pregnancy (e.g., prior to recognition of pregnancy), it is not necessary to re-immunize for this pregnancy.
	Notes:
	• Close contacts (e.g. household, classroom) of a diphtheria case should receive a dose of a diphtheria toxoid-containing vaccine as appropriate for age unless the contact is known to have been fully immunized for age and the last dose of diphtheria toxoid-containing vaccine was given within 10 years. The diphtheria toxoid-containing vaccine series should be completed for previously unimmunized or incompletely immunized contacts.
	• For disease investigation, contact assessment and reporting requirements, refer to Public Health Disease Management Guidelines – Diphtheria https://open.alberta.ca/publications/diphtheria.
	• Carriers of diphtheria, if not previously immunized, and those of unknown immunization status should receive immunization promptly and ensure completion of vaccine series. If a carrier has been immunized previously but has not received a booster of diphtheria toxoid within 10 years, a booster dose of a diphtheria toxoid-containing vaccine should be given.
	• Infection with diphtheria does not necessarily confer immunity; therefore immunization should be given during convalescence from diphtheria disease.	

Serology	**Pre-Immunization and Post immunization** • There is no serological test available for pertussis. • Serological testing is not typically recommended to assess levels of immunity to diphtheria or tetanus. For additional information see the AH DAT/TAT Interpretation tables https://open.alberta.ca/publications/aefi-policy-for-alberta-immunization-providers	

Schedule	**Primary Series for Eligible Individuals:**
	• **7 years up to and including 17 years of age:**
	  ○ Dose 1 – day 0
	  ○ Dose 2 – 4 to 8 weeks after dose 1
	  ○ Dose 3 – 6 to 12 months after dose 2
	Reinforcing Dose:
	  ○ A reinforcing dose of dTap should be given to eligible children 12 years up to and including 17 years of age as outlined in the indications section (typically given in the grade 9 school immunization program).	

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	Primary Series for Eligible Individuals:
	• **18 years of age and older:**
	  ○ Dose 1 – day 0
	  ○ Dose 2 – 4 to 8 weeks after dose 1
	  ○ Dose 3 – 6 to 12 months after dose 2
	Reinforcing Dose:
	  ○ One dose every 10 years
	Pregnant Females:
	• One dose of dTap should be offered in every pregnancy from 27 weeks up to and including 32 weeks gestation irrespective of immunization history.
	• It may, however, be provided from 13 weeks up to the time of delivery.
	• If dTap was provided early in pregnancy (e.g., prior to recognition of pregnancy) it is not necessary to re-immunize for this pregnancy.
	Spacing Considerations:
	• In order to provide protection for pertussis eligible individuals may receive a dose of dTap vaccine regardless of the spacing since the last dose of Td.
	• For individuals being followed for wound management see Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard #08.400).
	• Individuals who have had tetanus, diphtheria or pertussis illness should still be immunized as these clinical infections do not always confer immunity.
	• In Alberta, dTap is not provided to individuals less than 7 years of age. Individuals less than 7 years of age should receive the age appropriate combined vaccines as per provincial eligibility criteria.	

Preferred Use	There will be no preference indicated for the use of Adacel® or Boostrix® 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	
Preparation/ Reconstitution	See vaccine product monograph	
Route	IM	
Contraindications/ Precautions	**Contraindications:** • Known severe hypersensitivity to any component of the vaccine. • Anaphylactic or other allergic reaction to a previous dose of vaccine containing tetanus, diphtheria or pertussis antibodies. • 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. • Boostrix® 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:** • 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	

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	develop GBS outside this interval or have an alternative cause identified may receive subsequent doses of tetanus-containing vaccine. • 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. **Note:** In order to provide protection for pertussis Alberta Health recommends providing dTap regardless of spacing since last dose of Td. There is no monovalent acellular pertussis vaccine available in Canada at this time.	
Possible Reactions	**Common:** • Pain, redness and swelling at the injection site • Fever, chills • Irritability, fatigue, malaise, dizziness, somnolence • Headache, myalgia, sore or swollen joints • Decreased appetite, nausea, vomiting, diarrhea • Rash • Axillary lymph node swelling **Uncommon:** • Conjunctivitis • Disturbances in attention • Increased sweating • Joint and musculoskeletal stiffness • Lymphadenopathy • Pruritus • Cough, pharyngitis **Rare:** • Anaphylaxis • Angioedema, urticaria • Asthenia • Convulsions (with or without fever), severe migraine with unilateral facial paralysis, nerve compression in neck and arm • 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	Immunization with dTap has been shown to be safe in pregnant women and allows high levels of antibody to be transferred in utero that are protective to newborns during the first two months of life when the morbidity and mortality from pertussis infection is highest.	
Lactation	Can be administered to eligible breastfeeding women.	

Composition	Each 0.5 mL dose contains:
	Active Ingredients:
	• tetanus toxoid – 5 Lf
	• diphtheria toxoid – 2 Lf
	• five purified acellular pertussis antigens:
	  ○ pertussis toxoid (PT) - 2.5 µg
	  ○ filamentous haemagglutinin (FHA) – 5 µg
	  ○ pertactin (PRN) –3 µg
		Each 0.5 mL dose contains:
		Active Ingredients:
		• tetanus toxoid – 5 Lf
		• diphtheria toxoid – 2 Lf
		• three purified acellular pertussis antigens:
		  ○ pertussis toxoid (PT) – 8 µg
		  ○ filamentous haemagglutinin (FHA) – 8 µg
		  ○ pertactin (PRN) – 2.5 µg

	Adacel®	Boostrix®
	○ fimbriae types 2 and 3 (FIM) – 5 µg **Non-medical Ingredients:** • aluminum phosphate (adjuvant) – 1.5 mg • 2-phenoxyethanol – 0.6% v/v • Trace amounts of: ○ formaldehyde ○ glutaraldehyde	**Non-medical Ingredients:** • aluminum (as aluminum salts) • sodium chloride • water for injection • Residues: ○ disodium phosphate ○ formaldehyde ○ glutaraldehyde ○ glycine ○ monopotassium phosphate ○ polysorbate 80 ○ potassium chloride
Blood/Blood Products	Does not contain human 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.
Bovine/Porcine Products	Bovine-derived materials are components in the production process. Bovine cells are removed during purification of the vaccine. Porcine products are used in the early manufacturing process.	Ingredients of animal origin including bovine, equine and porcine derived materials are used as raw materials in the manufacturing process.
Latex	Does not contain latex.	
Interchangeability	dTap vaccines may be used interchangeably provided the appropriate dose and schedule recommended by the manufacturer are used.	
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. • If dTap and TIG are given at the same time for wound management, use separate anatomic sites (different limbs) for each injection.	
Appearance	Shake vial well to produce a uniform, cloudy suspension.	Shake well in order to obtain a homogeneous 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 when possible to protect from light.	
Vaccine Code	dTap	
Antigen Code	Tetanus – T Diphtheria – D Acellular pertussis - P	
Licensed for	• Licensed for booster immunization for individuals 4 years of age and older. • In Alberta, dTap vaccine has been approved for off license use for a primary series for individuals 7 years up to and including 17 years of age.	

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Program Notes:

- 2004 September 1: dTap vaccine was implemented as the reinforcing dose for students in Grade 9.
- 2012 February 1: dTap vaccine was implemented for the following adult populations.
  - healthcare workers providing care to children under 12 months of age.
  - adults who have not received an adolescent or adult dose of dTap vaccine as they present for service.
- 2014 July: adult dose of dTap was implemented regardless of previous history of adolescent dTap vaccine.
- 2019 January 1: maternal dTap program implemented.
- 2021 January 1: dTap replaced Td in routine adult immunization.

Related Resources:

- Diphtheria, Tetanus, Acellular Pertussis Vaccine Information Sheet (104516).

References:

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