Diphtheria-Tetanus-Acellular Pertussis Combined Vaccine (dTap)

Revision Date: March 24, 2014

Please consult the Product Monograph[1] for further information about the vaccine.

	ADACEL®	BOOSTRIX®
Manufacturer	Sanofi Pasteur Limited	GlaxoSmithKline Inc.
Licensed use	Booster immunization for individuals four years of age and older.[1]	
Off-license use	Primary immunization for individuals 7 – 17 years of age.[2]	
Indications for use of provincially funded vaccine	**Children 7 years up to including 17 years of age including:** ➢ Children initiating (unknown/uncertain or no history of a primary series) or completing a primary vaccine series.[2] **Note:** If polio vaccine is also indicated, diphtheria, tetanus, acellular pertussis and polio combined vaccine (dTap-IPV) should be used. ➢ Grade 9 students reinforcing doses: routine immunization program. ➢ Other children (7 – 17 years of age) requiring a reinforcing dose. ➢ Children who sustain a wound injury and have not received the age-appropriate number of tetanus vaccine doses. See Tetanus Post-exposure Prophylaxis in Injury/Wound Management. **Adults 18 years of age and older including:** ➢ Individuals initiating (unknown/uncertain or no history of a primary series) or completing a primary vaccine series of tetanus/diphtheria.[3] ➢ Individuals presenting for a reinforcing dose of tetanus/diphtheria.[3] ➢ Health care workers providing care to children younger than 12 months of age. ➢ Candidates or recipients of solid organ transplantation (SOT). See Immunization for Adult Solid Organ Transplant Recipients. **Notes**: • Diphtheria, tetanus, and acellular pertussis combined vaccine (dTap) may be provided to acute care emergency departments or urgent care centres. • Hematopoietic stem cell transplant recipients (HSCT). See Immunization for Child Hematopoietic Stem Cell Transplant Recipients and Immunization for Adult Hematopoietic Stem Cell Transplant Recipients and INFANRIX™-IPV. • At the discretion of the Medical Officer of Health (MOH) and depending upon local or regional epidemiology, immunization with dTap may be offered during pertussis outbreaks to: ➢ Pregnant women who are 26 weeks of gestation or greater irrespective of their immunization history[2,3] (i.e., regardless of the interval from a previous tetanus/diphtheria vaccine or a pertussis- containing vaccine). ➢ Adults who are in contact or anticipating contact with infants (e.g., parents/guardians, grandparents, childcare providers) should be prioritized to receive one dose in adulthood (18 years of age and older).[2] ➢ Consideration should be given when pregnant women who are 26 weeks of gestation or greater, irrespective of their immunization history, travel to areas where pertussis is circulating.	

Dose	0.5 mL
Route	Intramuscular injection
Schedule	**Series:** **Children 7 years up to and including 17 years of age:** ❖ Dose 1: day 0 ❖ Dose 2: 4 – 8 weeks after dose 1 ❖ Dose 3: 6 – 12 months after dose 2 **Notes:** • Adults needing a primary series of tetanus/diphtheria vaccine (Td) should receive one dose of dTap replacing the first dose of Td in the series. • Candidates/recipients of solid organ transplantation seven years of age an older. See Immunization for Children Expecting Solid Organ Transplant After 18 Months of Age (Catch-up Schedule) and: Immunization for Adult Solid Organ Transplant Candidates and Recipients. **Reinforcing dose:** ❖ **Grade 9 students or other children** (7-17 years of age) when a reinforcing dose is indicated. **Notes:** • Students, who have received a dose of Td prior to the Grade 9 booster, should receive a dose of dTap regardless of the interval since the previous Td dose.[4] • Students, who have received a dose of dTap at 12 years of age or older, do not require the routine booster in Grade 9.[4,5] • Eligible Grade 9 students, who missed the booster (dTap) in Grade 9, should receive the vaccine if they present to public health. • **Health care workers providing care to children younger than 12 months of age** should receive a one-time dose of dTap in adulthood regardless of the interval from their last dose of Td. • **Adults presenting for a Td booster**, should receive a one-time reinforcing dose of dTap if they have not received a dose of dTap in adulthood.[2] • **Pregnant woman 26 weeks of gestation or greater**: During local or regional outbreaks with MOH approval – one dose of dTap irrespective of previous pertussis immunization.[3] **Note:** Candidates and recipients of solid organ transplantation seven years of age and older. See Immunization for Children Expecting Solid Organ Transplant after 18 Months of Age (Catch-up Schedule) and Immunization for Adult Solid Organ Candidates and Recipients.
Contraindications	• Known severe hypersensitivity to any component of the vaccine. • Pre-filled syringe units (BOOSTRIX®) may contain latex.[6] • Anaphylactic or other allergic reaction to a previous dose of vaccine containing tetanus, diphtheria or pertussis antibodies • Encephalopathy of unknown etiology, occurring within 7 days following previous vaccination with pertussis containing vaccine.[1,7]

	• Should not be administered to individuals who have experienced transient thrombocytopenia following a previous immunization with diphtheria-tetanus containing vaccines.[1] GlaxoSmithKline has no specific references for this statement on the product monograph but states that it is a theoretical risk.[8] The Medical Officer of Health should be consulted on a case-by-case basis to determine whether or not to proceed with immunization.
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.[2] See Interpretation of Diphtheria Antitoxin Levels (DAT) and Tetanus Antitoxin Levels (TAT). • If Guillain-Barré Syndrome (GBS) occurred within six weeks of immunization with a previous dose of vaccine containing tetanus toxoid, it is prudent to withhold subsequent doses of tetanus-containing vaccine.[2] Those who develop GBS outside this interval may receive subsequent doses of tetanus-containing vaccine.[2] If there is a history of both *Campylobacter* infection and receipt of a tetanus-containing vaccine within six weeks before the onset of GBS, consultation with an infectious disease specialist is advised.[2]
Possible reactions	**Local reactions:** • Pain, redness, swelling and induration at the injection site.[1] • Severe local reactions occur rarely and may be associated with high levels of circulating tetanus antitoxin.[2] **Systemic reactions:** • Irritability, somnolence, anorexia, dizziness, fever, headache, malaise, fatigue, vomiting and diarrhea.[1] • Rarely, increased hyperhidrosis, arthralgia, myalgia, joint and musculoskeletal stiffness, pruritus, conjunctivitis, rash and lymphadenopathy were reported.[1] • The following additional adverse events have been reported from post-marketing surveillance: angioedema, convulsions (with or without fever), urticaria, extensive swelling of the injected limb, asthenia, allergic reaction and anaphylactoid reactions.[1] **Notes:** • In clinical trials involving adolescents and adults, the adverse-event rates observed with dTap were comparable to those observed with a tetanus-diphtheria combined vaccine booster.[9] • DAT/TAT level testing may be recommended for some reactions. See Interpretation of Diphtheria Antitoxin Levels (DAT) and Tetanus Antitoxin Levels (TAT). Refer to: *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.*[10]
Pregnancy	May be offered to pregnant women 26 weeks of gestation or greater if indicated (as defined in the Indications for use section).[2,3] Immunization during pregnancy requires careful consideration of the risks from the disease versus the benefit of vaccine. Adequate human data on the use of BOOSTRIX® during pregnancy are not available.[1] However, inactivated vaccines and toxoids are usually considered safe for the fetus.[2]
Lactation	Breastfeeding woman who are due for the vaccine may be safely immunized.[2]

References

[1] Sanofi Pasteur Limited. (2012, June 11). ADACEL®: Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed. *Product Monograph*.

GlaxoSmithKline Inc. (2013, January 16). BOOSTRIX®: Combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine for booster vaccination. *Product Monograph.*

[2] National Advisory Committee on Immunization. (2014). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html

[3] National Advisory Committee on Immunization. (2014). Update on pertussis vaccination in pregnancy. *Public Health Agency of Canada*.

[4] Centers for Disease Control and Prevention. (2011, September). FDA approval of expanded age indication for a tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine. *Morbidity and Mortality Weekly Report 60(37).*

[5] Centers for Disease Control and Prevention. (2014). Recommended immunization schedule for persons 0 through 18 years - United States. Retrieved 2014, February 4 from, www.cdc.gov/vaccines/schedules/index.html

[6] Personal communication from GSK regarding latex in vaccine vials and pre-filled syringes. (2012, April 26).

[7] Centers for Disease Control and Prevention. (2011, January). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report, 60(2).*

[8] Personal communication from GlaxoSmithKline, Medical Services. (2011, September 11).

[9] Grabenstein, J.D. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs 2013.* St. Louis, MO, Wolters Kluwer Health.

[10] Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.* https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/7598f59a-3dfc-4c70-9065-c3bf5b4ee363/download/AIP-AEFI-Policy.pdf

