Diphtheria-Tetanus-Acellular Pertussis Combined Vaccine (dTap)

Revision Date: November 16, 2018

Rationale for update: **Updated to include recommendation to offer dTap in every pregnancy. (Implementation January 1, 2019)**

	ADACEL®	BOOSTRIX®
Please consult the Product Monographs[1,2] for further information about the vaccine.		
Manufacturer	Sanofi Pasteur Limited	GlaxoSmithKline Inc.
Licensed use	Booster immunization for individuals four years of age and older.[1,2]	
Off-license use	Primary immunization for individuals 7 – 17 years of age.[3]	
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.[3] **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. • 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 who have not received an adult dose of dTap vaccine.[3] • Individuals presenting for a reinforcing dose of tetanus/diphtheria who have not received an adult dose of dTap vaccine.[3] • Candidates or recipients of solid organ transplantation (SOT). See Immunization for Adult Solid Organ Transplant Recipients. **Pregnant females** • Pregnant women in every pregnancy from 27 weeks up to and including 32 weeks gestation.[3,4] ➢ One dose of dTap should be offered in every pregnancy ideally 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.[4] ➢ If dTap was provided early in pregnancy (e.g. prior to recognition of pregnancy), it is not necessary to re-immunize for this pregnancy.[4] **Notes**: • Hematopoietic stem cell transplant recipients (HSCT). See Immunization for Child Hematopoietic Stem Cell Transplant Recipients and Immunization for Adult Hematopoietic Stem Cell Transplant Recipients. • 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).[3]	

	• 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.[3] For disease investigation, contact assessment and reporting requirements, refer to *Public Health Notifiable Disease Guidelines – Diphtheria.*[5] • Carriers of diphtheria if not previously immunized and those of unknown immunization status, should receive immunization promptly and ensure completion of vaccine series.[6] 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.[3] • Infection with diphtheria does not necessarily confer immunity; therefore, immunization should be given during convalescence from diphtheria disease.[6]
Dose	0.5 mL
Route	Intramuscular injection
Schedule	**<u>Children 7 years up to and including 17 years of age</u>** **Primary Series:** • Dose 1: day 0 • Dose 2: 4 – 8 weeks after dose 1 • Dose 3: 6 – 12 months after dose 2 **Reinforcing dose:** • **Grade 9 students or other children** (12-17 years of age) when a reinforcing dose is indicated.[3] **<u>Adults 18 years of age and older</u>** • One dose as an adult **<u>Pregnant women</u>** • One dose of dTap should be offered in every pregnancy from 27 weeks up to and including 32 weeks gestation irrespective of immunization history.[4] • dTap may, however, be provided from 13 weeks gestation up to the time of delivery.[4] • If dTap was provided early in pregnancy (e.g. prior to recognition of pregnancy), it is not necessary to re-immunize after 13 weeks of gestation.[4] **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.[7] • Students, who have received a dose of dTap at 12 years of age or older, do not require the routine booster in Grade 9.[7,8] • Eligible Grade 9 students, who missed the booster (dTap) in Grade 9, should receive the vaccine if they present to public health.

	• 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.Candidates/recipients of solid organ transplantation seven years of age an older. • 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.[3] • 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.[3]
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, occurring within 7 days following previous vaccination with pertussis containing vaccine.[1,2]
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.[3] 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.[3] Those who develop GBS outside this interval may receive subsequent doses of tetanus-containing vaccine.[3] 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.[3]
Possible reactions	**Common:** • Pain, redness, swelling and induration at the injection site.[1,2] • Irritability, somnolence, anorexia, dizziness, fever, headache, malaise, fatigue, nausea, vomiting, diarrhea, rash.[1,2] **Uncommon:** • Upper respiratory tract infection, pharyngitis, increased hyperhidrosis, arthralgia, myalgia, joint and musculoskeletal stiffness, pruritus, conjunctivitis and lymphadenopathy were reported.[1,2] **Rare:** • Severe local reactions occur rarely and may be associated with high levels of circulating tetanus antitoxin.[3] • Extensive swelling of the vaccinated limb, asthenia, angioedema, convulsions (with or without fever), urticaria.[1,2] • Anaphylaxis.[1,2] **Post-Marketing Surveillance:** • The following 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.[1,2]

	Notes: • 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.*[9]
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.[3]
Lactation	Breastfeeding woman who are due for the vaccine may be safely immunized.[3]

References

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

[2] GlaxoSmithKline Inc. (2018, March 5). BOOSTRIX®: Combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine for booster vaccination. *Product Monograph.*

[3] National Advisory Committee on Immunization. (2018) *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html

[4] National Advisory Committee on Immunization. (2018 February). Update on immunization in pregnancy with tetanus toxoid, reduced diphtheria toxoid and reduced acellular pertussis (Tdap) vaccine. https://www.canada.ca/en/public-health/services/publications/healthy-living/update-immunization-pregnancy-tdap-vaccine.html.

[5] Alberta Health . Diphtheria. In *Public Health Notifiable Disease Management Guidelines*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html.

[6] American Academy of Pediatrics. (2018). *Red book: 2018-2021 Report of the Committee on Infectious Diseases (31th ed.).* Elk Grove Village, IL.

[7] 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).*

[8] Centers for Disease Control and Prevention. (2018). Recommended immunization schedule for persons 0 through 18 years - United States. Retrieved 2018, May 10 from, https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

[9] 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.

