

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

BIOLOGICAL PAGE

Section 7	Biological Product Information	Standard # 07.210
Created and approved by	Provincial Immunization Program Standards and Quality	
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	ADACEL	BOOSTRIX
Manufacturer	Sanofi Pasteur Limited	GlaxoSmithKline Inc.
Classification	Non-live: Td (toxoid), ap (subunit)	
Indications for Provincially Funded Vaccine	<p>Children 7 years up to and including 17 years of age:</p> <ul style="list-style-type: none"> With an unknown/uncertain or no history of a primary series or those who have not completed a primary series for tetanus, diphtheria and pertussis. <ul style="list-style-type: none"> If polio vaccine is also indicated, use combined Tdap-IPV vaccine. See Tetanus-Diphtheria-Acellular Pertussis-Polio Conjugate Combined Vaccine Biological Page. Who are due for a reinforcing dose of tetanus, diphtheria and pertussis vaccine in grade 9 as part of the routine school immunization program and have not received a dose of acellular pertussis vaccine as an adolescent (12 years up to and including 17 years of age). Who sustain a tetanus prone wound and have not received the age-appropriate number of tetanus containing vaccine doses. See Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard Who are candidates or recipients of SOT –immunize using the routine age-appropriate schedule for tetanus, diphtheria and pertussis containing vaccine. Recipients of HSCT –refer to Immunization for Child HSCT Recipients to determine appropriate tetanus, diphtheria and pertussis containing vaccine. <p>Note:</p> <ul style="list-style-type: none"> Students (generally 14 –18 years of age) in ungraded classes or those who do not continue in the school system to grade 9 can be immunized on a case-by-case basis. <ul style="list-style-type: none"> Offer protection to students prior to leaving the school system. Offer grade 9 students who have received a dose of tetanus, diphtheria, acellular pertussis containing vaccine prior to 12 years of age a dose of Tdap in grade 9 regardless of the interval to ensure best protection as an adolescent and adult. Offer grade 9 students who have received a dose of Td (for example as part of wound management) a dose of Tdap vaccine regardless of the spacing. Refer children needing tetanus prophylaxis for wound management to public health for age-appropriate tetanus containing vaccine. <ul style="list-style-type: none"> If this is not possible, provide them with available tetanus containing vaccine for wound management and then refer them to public health for further assessment of immunization recommendations. See Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard. In Alberta, Tdap is not provided to individuals less than 7 years of age. Individuals less than 7 years of age should receive the age-appropriate tetanus, diphtheria and pertussis containing vaccines as per provincial eligibility criteria. 	

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	<p>Individuals 18 years of age and older:</p> <ul style="list-style-type: none"> Who are initiating (unknown/uncertain or no history of a primary series) or completing a primary vaccine series of tetanus and/or diphtheria. Who are presenting for a reinforcing dose of tetanus and/or diphtheria vaccine. Who are presenting for a first dose of pertussis containing vaccine. Who sustain a wound injury and need to have their tetanus immunization history assessed. See Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard. Who are healthcare workers/healthcare students with no documented history of a dose of acellular pertussis vaccine as an adult. <p>Note:</p> <ul style="list-style-type: none"> If polio vaccine is also indicated, use combined Tdap-IPV vaccine. See Tetanus-Diphtheria-Acellular Pertussis-Polio Conjugate Combined Vaccine Biological Page. For candidates or recipients of SOT immunize using the routine age-appropriate schedule for tetanus, diphtheria and pertussis containing vaccine. See Immunization for Adult Solid Organ Transplant (SOT) Candidates and Recipients. For recipients of HSCT refer to Immunization for Adult HSCT Recipients to determine appropriate tetanus, diphtheria and pertussis containing vaccine. Adults who are in contact or anticipating contact with infants (such as parents/guardians, grandparents, childcare providers) should be prioritized to receive 1 dose in adulthood (18 years of age and older). <p>Pregnant individuals:</p> <ul style="list-style-type: none"> Pregnant individuals in every pregnancy, regardless of the pregnant individual's age. <p>Note:</p> <ul style="list-style-type: none"> For diphtheria disease investigation, contact assessment and reporting requirements, refer to Public Health Disease Management Guidelines-Diphtheria. <ul style="list-style-type: none"> Offer close contacts (for example household, classroom) of a diphtheria case 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. Complete the diphtheria toxoid-containing vaccine series for previously unimmunized or incompletely immunized contacts. Offer carriers of diphtheria, if not previously immunized, and those of unknown immunization status prompt immunization 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, give a booster dose of a diphtheria toxoid-containing vaccine. Infection with diphtheria does not necessarily confer immunity; therefore, give immunization during convalescence from diphtheria disease. Immunize individuals who have had tetanus, diphtheria or pertussis illness, as these clinical infections do not always confer immunity. 	
Serology	<p>Pre-immunization and post-immunization</p> <ul style="list-style-type: none"> 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 Alberta Health DAT/TAT Interpretation tables in the Adverse Events Following Immunization (AEFI) Policy for Alberta immunization providers. 	
Schedule	<p>Primary series for eligible individuals:</p> <ul style="list-style-type: none"> 7 years up to and including 17 years of age: <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 4 to 8 weeks after dose 1 Dose 3: 6 to 12 months after dose 2 	

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	<p>Reinforcing dose:</p> <ul style="list-style-type: none"> Grade 9 students or other children (12 to 17 years of age) when a reinforcing dose is indicated. <p>Primary series for eligible individuals:</p> <ul style="list-style-type: none"> 18 years of age and older: <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 4 to 8 weeks after dose 1 Dose 3: 6 to 12 months after dose 2 <p>Reinforcing dose:</p> <ul style="list-style-type: none"> Every 10 years <p>In addition:</p> <ul style="list-style-type: none"> 1 dose of Tdap as an adult for individuals who have not previously received a pertussis-containing vaccine. <p>Note:</p> <ul style="list-style-type: none"> As a high priority group, offer a dose of Tdap to all health care workers/health care students with no documented history of an acellular pertussis-containing vaccine as an adult. Administer this dose as soon as feasible, regardless of the interval from the last dose of Td and/or Tdap vaccine. <ul style="list-style-type: none"> Pregnant individuals: <ul style="list-style-type: none"> Offer 1 dose of Tdap in every pregnancy, ideally from 27 weeks up to and including 32 weeks gestation, irrespective of immunization history. <ul style="list-style-type: none"> Tdap may be provided from 13 weeks up to the time of delivery. If Tdap was provided early in pregnancy (for example prior to recognition of pregnancy) it is not necessary to re-immunize after 13 weeks gestation. If Tdap was provided during pregnancy prior to 27 weeks gestation for post exposure prophylaxis, it is not necessary to re-immunize. <p>Spacing considerations:</p> <ul style="list-style-type: none"> Give students who have received a dose of Td prior to the grade 9 booster a dose of Tdap regardless of the interval since the previous Td dose. Students who have received a dose of Tdap at 12 years of age or older do not require the routine booster in grade 9. Give eligible grade 9 students who missed the booster (Tdap) in grade 9 the vaccine if they present to public health. Individuals who received a Tdap booster at age 12 or older do not immediately require an adult dose of Tdap at 18 years of age. <ul style="list-style-type: none"> Another Tdap dose can be offered at the regular 10-year interval, unless a dose is recommended sooner (see Adult indications above). Adults presenting for a first dose of pertussis containing vaccine do not need to wait 10 years from their last dose of tetanus containing vaccine to receive their Tdap dose. 	
Preferred Use	<p>None.</p> <ul style="list-style-type: none"> Both vaccines are safe and immunogenic in individuals 4 years of age and older. 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	<p>Contraindications:</p> <ul style="list-style-type: none"> Known severe hypersensitivity to any component of the vaccine. 	

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	<ul style="list-style-type: none"> Anaphylactic or other allergic reaction to a previous dose of vaccine containing tetanus, diphtheria or pertussis antigens. Encephalopathy of unknown etiology occurring within 7 days of a previous dose of a pertussis containing vaccine. Do not administer BOOSTRIX to individuals who have experienced transient thrombocytopenia or neurological complications following a previous dose of tetanus and/or diphtheria containing vaccine. Consult with MOH on a case-by-case basis to determine immunization recommendations. <p>Precautions:</p> <ul style="list-style-type: none"> Withhold subsequent doses of tetanus containing vaccine if Guillain-Barré Syndrome (GBS) occurred within 6 weeks of immunization with a previous dose of tetanus-containing vaccine. <ul style="list-style-type: none"> Those who 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. <p>Note:</p> <ul style="list-style-type: none"> In order to provide protection for pertussis, Tdap is recommended regardless of spacing since last dose of Td. There is no monovalent acellular pertussis vaccine available in Canada at this time. 	
Possible Reactions	<p>Common:</p> <ul style="list-style-type: none"> Pain, redness and swelling at the injection site Injection site reactions such as injection site mass and injection site sterile abscess Fever, chills Irritability, fatigue, malaise, dizziness, somnolence Headache, myalgia, sore or swollen joints Decreased appetite, nausea, vomiting, diarrhea Rash Lymphadenopathy. <p>Uncommon:</p> <ul style="list-style-type: none"> Conjunctivitis Disturbances in attention Increased sweating Joint and musculoskeletal stiffness Pruritus Syncope Induration Cough, pharyngitis, upper respiratory tract infection. <p>Rare:</p> <ul style="list-style-type: none"> Anaphylaxis Angioedema, urticaria Asthenia Convulsions (with or without fever) Extensive swelling of the vaccinated limb. <p>Unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</p>	
Pregnancy	<p>May use during pregnancy.</p> <ul style="list-style-type: none"> Tdap is safe in pregnant individuals. 	

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	<ul style="list-style-type: none"> Immunization with Tdap 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	May use for people who are lactating and feeding their milk to infants or children.	
Composition	<p>Each 0.5 mL dose contains:</p> <p>Active Ingredients:</p> <ul style="list-style-type: none"> tetanus toxoid –5 Lf diphtheria toxoid –2 Lf 5 purified acellular pertussis antigens: <ul style="list-style-type: none"> acellular pertussis toxoid (PT) -2.5 mcg filamentous haemagglutinin (FHA) –5 mcg pertactin (PRN) –3 mcg fimbriae types 2 and 3 (FIM) –5 mcg. <p>Non-medicinal Ingredients:</p> <ul style="list-style-type: none"> aluminum phosphate (adjuvant) –1.5 mg 2-phenoxyethanol –0.6% v/v Trace amounts of: <ul style="list-style-type: none"> formaldehyde glutaraldehyde. 	<p>Each 0.5 mL dose contains:</p> <p>Active Ingredients:</p> <ul style="list-style-type: none"> tetanus toxoid –5 Lf diphtheria toxoid –2.5 Lf 3 purified acellular pertussis antigens: <ul style="list-style-type: none"> pertussis toxoid (PT) –8 mcg filamentous haemagglutinin (FHA) –8 mcg pertactin (PRN) –2.5 µg. <p>Non-medicinal Ingredients:</p> <ul style="list-style-type: none"> aluminum (as aluminum salts) –0.5 mg sodium chloride water for injection.
Blood/Blood Products	Does not contain human blood/blood products.	Does not contain human blood/blood products.
Bovine/Porcine Products	<p>Bovine Products:</p> <ul style="list-style-type: none"> Bovine-derived materials are components in the production process. Bovine cells are removed during purification of the vaccine. <p>Porcine Products:</p> <ul style="list-style-type: none"> Porcine products are used in the early manufacturing process. 	<p>Bovine Products:</p> <ul style="list-style-type: none"> Casamino acids and casein peptone, pancreatine and meat extract are used as raw materials during the routine manufacturing process. <p>Porcine Products:</p> <ul style="list-style-type: none"> None.
Latex	Does not contain latex.	
Interchangeability	<p>Tdap vaccines may be used interchangeably.</p> <ul style="list-style-type: none"> Use the manufacturer recommended dose and schedule. 	
Administration with Other Products	<p>May be given at the same time as other inactivated and live vaccines.</p> <ul style="list-style-type: none"> Use a separate needle and syringe for each vaccine. The same limb may be used if necessary, but use different sites on the limb. If Tdap and TIG are given at the same time for wound management, use separate anatomic sites (different limbs) for each injection. 	
Preparation	Shake vial well prior to administration.	Shake vial well prior to administration.
Appearance	Uniform, cloudy suspension.	Homogeneous turbid white suspension.
Storage	<ul style="list-style-type: none"> Store at +2°C to +8°C Do not freeze Do not use beyond the labeled expiry date Store in original packaging to protect from light. 	
Vaccine Code	Tdap	

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Antigen Code	Tetanus – T Diphtheria – D Acellular pertussis - P	
Licensed for	<ul style="list-style-type: none">Booster immunization for individuals 4 years of age and older.	
Off-License Use	<ul style="list-style-type: none">Primary series for individuals 7 years up to and including 17 years of age.	
Program Notes	<ul style="list-style-type: none">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:<ul style="list-style-type: none">Healthcare workers providing care to children under 12 months of age.Adults who have not received an adolescent or adult dose of Tdap 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.2022 April 20: Note added for adults when polio vaccine is also indicated; diphtheria, tetanus, acellular pertussis and polio combined vaccine (dTap-IPV) should be used.2022 August 3: Updated to reflect the replacement of Td product (no longer available in Alberta as of June 30, 2022) with dTap.2023 April 1: Individuals who received a dTap booster at age 12 or older do not immediately require an adult dose of dTap at 18 years of age.2024 July 1: References to dTap changed to Tdap to align with national standards.2024 August 1: Updated to clarify that all pregnant individuals are eligible.2025 January 31: Updated to clarify that health care workers and health care students with no documented history of an acellular pertussis-containing vaccine as an adult should receive a dose of Tdap.	
Related Resources	<ul style="list-style-type: none">Tetanus, Diphtheria, Acellular Pertussis (Tdap) Vaccine Information Sheet (104516).	
References		
<p>Alberta Health. (2025, January 31). Tetanus-Diphtheria-Acellular Pertussis combined vaccine (Tdap). <i>In Alberta Immunization Policy: Biological Products</i>. Government of Alberta.</p> <p>Alberta Health. (2024, April). Adverse Event Following Immunization (AEFI) Policy for Alberta Immunization Providers. <i>In Alberta Immunization Policy: Adverse events – immunization</i>. Government of Alberta.</p> <p>Alberta Health. (2021, September). Diphtheria. <i>In Alberta Public Health Disease Management Guidelines</i>. Government of Alberta.</p> <p>Committee on Infectious Diseases, American Academy of Pediatrics. (2021, May). <i>Red Book: 2021-2024 Report of the Committee on Infectious Disease (32nd ed.)</i>. American Academy of Pediatrics.</p> <p>U.S. Centers for Disease Control and Prevention (2009, April 17). FDA approval of expanded age indication for a tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine. Recommendations of the Advisory Committee on Immunization practices. <i>In Morbidity and Mortality Weekly Report</i>.</p> <p>U.S. Centers of Disease Control and Prevention. (2024, August 14). Child and Adolescent Immunization Schedule by Age. <i>In Vaccines and Immunization</i>. Centers for Disease Control and Prevention.</p> <p>GlaxoSmithKline Inc. (2023, Nov 9). Boostrix: Combined diphtheria, tetanus, acellular pertussis (adsorbed) vaccine for booster vaccination. Health Canada database. https://pdf.hres.ca/dpd_pm/00073316.PDF</p> <p>Grabenstein, J. D. (2013). <i>ImmunoFacts: Vaccines and Immunologic Drugs (38th Revision ed.)</i>. St. Louis, MO: Wolters Kluwer Health.</p> <p>Public Health Agency of Canada. (2014, October). Tetanus toxoid. <i>In Canadian Immunization Guide: Part 4: Immunizing agents</i>. Government of Canada.</p> <p>Public Health Agency of Canada. (2016, November). Diphtheria toxoid. <i>In Canadian Immunization Guide: Part 4: Immunizing agents</i>. Government of Canada</p>		

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National Advisory Committee on Immunization. (2018 February). *Update on immunization in pregnancy with tetanus toxoid, reduced diphtheria toxoid and reduced acellular pertussis (Tdap) vaccine: An advisory committee statement*. Public Health Agency of Canada.

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