

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

<b>Section 7:</b>	<b>Biological Product Information</b>	<b>Standard #: 07.213</b>
<b>Created by:</b>	Provincial Immunization Program Standards and Quality	
<b>Approved by:</b>	Provincial Immunization Program Standards and Quality	
<b>Approval Date:</b>	September 10, 2012	<b>Revised:</b> July 1, 2024

	ADACEL®-POLIO	BOOSTRIX®-POLIO
<b>Manufacturer</b>	Sanofi Pasteur Ltd.	GlaxoSmithKline Inc
<b>Biological Classification</b>	Inactivated	
<b>Indications for Provincially Funded Vaccine</b>	<p><b>Children 4 years up to and including 6 years of age who have received 4 previous doses of DTaP-IPV±Hib vaccine:</b></p> <ul style="list-style-type: none"> <li>Reinforcing dose of tetanus, diphtheria, acellular pertussis and polio vaccine routinely given as the preschool booster.</li> </ul> <p><b>Note:</b> For children who are delayed in their immunization schedule refer to <a href="#">Diphtheria, Tetanus, Acellular Pertussis, Polio, Haemophilus influenzae b Conjugate Vaccine Biological Page</a>.</p> <p><b>Children 7 years up to and including 17 years of age:</b></p> <ul style="list-style-type: none"> <li>Initiating or completing a primary immunization series for tetanus, diphtheria, pertussis and polio.</li> </ul> <p><b>Individuals 18 years of age and older:</b></p> <ul style="list-style-type: none"> <li>Initiating or completing a primary immunization series for tetanus, diphtheria, pertussis and polio. <ul style="list-style-type: none"> <li>Refer to <a href="#">Polio</a> and <a href="#">Tdap</a> vaccine biological pages.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>For those requiring polio only – see <a href="#">Polio</a> vaccine biological page.</li> <li>Recipients of hematopoietic stem cell transplant (HSCT) and candidates/recipients of solid organ transplant (SOT), see <a href="#">Adult SOT</a> or <a href="#">Adult HSCT</a> charts for recommended vaccine and schedule information.</li> <li>Individuals who sustain a tetanus prone wound need to have their tetanus immunization history assessed (see <a href="#">Tetanus Prevention, Prophylaxis and Wound/Injury Management Standard</a> for vaccine recommendations).</li> <li>Individuals who have had pertussis infection should continue to receive pertussis-containing vaccines.</li> <li>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.</li> </ul>	
<b>Serology</b>	<p><b>Pre-Immunization and Post-Immunization</b></p> <ul style="list-style-type: none"> <li>There are no serological tests available for pertussis or polio.</li> <li>Serological testing is not typically recommended to assess levels of</li> </ul>	

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	immunity to tetanus or diphtheria.	
<b>Schedule</b>	<p><b>Children 4 years up to and including 6 years of age:</b></p> <ul style="list-style-type: none"> <li>Reinforcing booster given a minimum of 6 months from previous dose of tetanus, diphtheria, acellular pertussis and polio containing vaccine.</li> </ul> <p><b>Individuals 7 years up to and including 17 years of age initiating or completing a primary immunization series:</b></p> <ul style="list-style-type: none"> <li>Dose 1 – day 0</li> <li>Dose 2 – 4 to 8 weeks after dose 1</li> <li>Dose 3 – 6 to 12 months after dose 2</li> </ul> <p><b>Note:</b> For children with delayed immunization see <a href="#">Standard for Recommended Immunization Schedules</a> Section 2 and 3 to determine number of doses and correct spacing.</p> <p><b>Individuals 18 years of age and older initiating or completing a primary immunization series:</b></p> <ul style="list-style-type: none"> <li>Dose 1 – day 0</li> <li>Dose 2 – 4 to 8 weeks after dose 1</li> <li>Dose 3 – 6 to 12 months after dose 2</li> </ul> <p><b>Individuals 18 years of age and older reinforcing dose:</b></p> <ul style="list-style-type: none"> <li>When indicated for individuals requiring all 4 antigens.</li> <li>Refer to <a href="#">Polio</a> and <a href="#">Tdap</a> vaccine biological pages.</li> </ul>	
<b>Preferred Use</b>	<p>There will be no preference indicated for the use of Adacel®-Polio or Boostrix®-Polio in specific age or risk groups.</p> <ul style="list-style-type: none"> <li>Both vaccines are safe and immunogenic in individuals four years of age and older.</li> <li>Persons with medical contraindications to one product should be offered the alternate product if supply is available.</li> </ul>	
<b>Dose</b>	0.5 mL	
<b>Route</b>	IM	
<b>Contraindications/Precautions</b>	<p><b>Contraindications:</b></p> <ul style="list-style-type: none"> <li>Known severe hypersensitivity to any component of the vaccine.</li> <li>Anaphylactic or other allergic reaction to a previous dose of a vaccine containing tetanus, diphtheria, pertussis, or polio.</li> <li>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.</li> <li>Should not be administered to individuals who have experienced transient thrombocytopenia following a previous dose of tetanus/diphtheria containing vaccine. Consult with MOH on a case-by-case basis to determine immunization recommendations.</li> </ul> <p><b>Precautions:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>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 develop GBS outside this interval or have an alternative cause identified may receive subsequent doses of tetanus-containing vaccine.</li> </ul>	

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<b>Possible Reactions</b>	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>• All ages: <ul style="list-style-type: none"> <li>○ Pain, redness, bruising and swelling at the injection site</li> <li>○ Fever, chills</li> <li>○ Headache, fatigue, irritability</li> <li>○ Arthralgia</li> <li>○ Vomiting, diarrhea</li> </ul> </li> <li>• Children 4 to 9 years of age: <ul style="list-style-type: none"> <li>○ Pruritus and dermatitis at the injection site</li> <li>○ Decreased appetite</li> <li>○ Rash</li> </ul> </li> <li>• Individuals 10 years of age and older: <ul style="list-style-type: none"> <li>○ Nausea</li> <li>○ Myalgia</li> </ul> </li> </ul> <p><b>Uncommon:</b></p> <ul style="list-style-type: none"> <li>• Children 4 to 9 years of age: <ul style="list-style-type: none"> <li>○ Abdominal pain</li> <li>○ Apathy</li> <li>○ Dry throat</li> <li>○ Nausea</li> <li>○ Sleep disorder</li> </ul> </li> <li>• Individuals 10 years of age and older: <ul style="list-style-type: none"> <li>○ Asthma</li> <li>○ Decreased appetite</li> <li>○ Dizziness</li> <li>○ Lymphadenopathy</li> <li>○ Oral herpes</li> <li>○ Paraesthesia</li> <li>○ Pruritus</li> </ul> </li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>• Anaphylaxis</li> <li>• Angioedema, generalized urticaria</li> <li>• Asthenia</li> <li>• Convulsions (with or without fever)</li> <li>• Extensive swelling of the vaccinated limb</li> <li>• Persistent nodule at the site of injection</li> <li>• As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</li> </ul>	
<b>Pregnancy</b>	<p>Data from post-marketing surveillance where pregnant women were administered Tdap-IPV in the third trimester do not suggest any vaccine related adverse effects on the pregnancy or on fetal/newborn health.</p> <p>If Tdap-IPV is administered to a pregnant woman, it should ideally be given during the third trimester of pregnancy.</p> <p>Human data from prospective clinical studies on the use of Tdap-IPV during the first and second trimester of pregnancy are not available. However, inactivated vaccines and toxoids are generally considered safe in pregnancy.</p>	
<b>Lactation</b>	<p>Can be administered to eligible breastfeeding women if indicated.</p>	

	ADACEL®-POLIO	BOOSTRIX®-POLIO
<b>Composition</b>	<p><b>Active Ingredients:</b></p> <ul style="list-style-type: none"> <li>• Tetanus toxoid – 5 Lf</li> <li>• Diphtheria toxoid – 2 Lf</li> <li>• Acellular pertussis: <ul style="list-style-type: none"> <li>○ Pertussis Toxoid (PT) – 2.5 mcg</li> <li>○ Filamentous Haemagglutinin (FHA) – 5 mcg</li> <li>○ Pertactin (PRN) – 3 mcg</li> <li>○ Fimbriae Types 2 and 3 (FIM) – 5 mcg</li> </ul> </li> <li>• Inactivated Poliomyelitis Vaccine: <ul style="list-style-type: none"> <li>○ Type 1 (Mahoney) – 40 D-antigen units*</li> <li>○ Type 2 (MEF-1) – 8 D-antigen units*</li> <li>○ Type 3 (Saukett) – 32 D-antigen units*</li> </ul> </li> </ul> <p>* or the equivalent antigen quantity, determined by suitable immunochemical method</p> <p><b>Non-medicinal Ingredients:</b></p> <ul style="list-style-type: none"> <li>• Aluminum phosphate (adjuvant)</li> <li>• 2-phenoxyethanol 0.6% v/v</li> <li>• Polysorbate 80</li> <li>• Water for injection</li> <li>• Trace amounts of: <ul style="list-style-type: none"> <li>○ Bovine serum albumin</li> <li>○ Formaldehyde</li> <li>○ Glutaraldehyde</li> <li>○ Streptomycin</li> <li>○ Neomycin</li> <li>○ Polymyxin B</li> </ul> </li> </ul>	<p><b>Active Ingredients:</b></p> <ul style="list-style-type: none"> <li>• Tetanus toxoid – 5 Lf</li> <li>• Diphtheria toxoid – 2.5 Lf</li> <li>• Acellular pertussis: <ul style="list-style-type: none"> <li>○ Pertussis toxoid (PT) – 8 mcg</li> <li>○ Filamentous haemagglutinin (FHA) – 8 mcg</li> <li>○ Pertactin (PRN) – 2.5 mcg</li> </ul> </li> <li>• Inactivated poliomyelitis vaccine: <ul style="list-style-type: none"> <li>○ Type 1 (Mahoney) – 40 DU</li> <li>○ Type 2 (MEF1) – 8 DU</li> <li>○ Type 3 (Saukett) – 32 DU</li> </ul> </li> </ul> <p><b>Non-medical Ingredients:</b></p> <ul style="list-style-type: none"> <li>• Sodium chloride</li> <li>• Aluminum salts</li> <li>• Medium 199</li> <li>• Water for injection</li> <li>• Trace amounts of: <ul style="list-style-type: none"> <li>○ Formaldehyde</li> <li>○ Neomycin</li> <li>○ Polymixin</li> </ul> </li> </ul>
<b>Blood/Blood Products</b>	Does not contain human blood or blood products.	
<b>Bovine/Porcine Products</b>	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.
<b>Latex</b>	Does not contain latex.	
<b>Interchangeability</b>	Individuals who begin their immunization with a different combined product may complete immunization using Tdap-IPV.	
<b>Administration with Other Products</b>	<ul style="list-style-type: none"> <li>• May be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine, and a different anatomical site.</li> <li>• With the exception of TIG, the same limb may be used, if necessary, but different sites on the limb must be chosen.</li> </ul>	
<b>Appearance</b>	Uniform, cloudy white suspension.	

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<b>Storage</b>	<ul style="list-style-type: none"> <li>• Store at +2°C to +8°C.</li> <li>• Do not freeze.</li> <li>• Do not use beyond the labeled expiry date.</li> <li>• Store in original packaging when possible to protect from light.</li> </ul>	
<b>Vaccine Code</b>	Tdap-IPV	
<b>Antigen Code</b>	Tetanus – T Diphtheria – D Acellular pertussis – P Inactivated polio vaccine – POL	
<b>Licensed Use</b>	<ul style="list-style-type: none"> <li>• Booster immunization for individuals 4 years of age and older.</li> </ul>	
<b>Off-License Use</b>	<ul style="list-style-type: none"> <li>• Primary immunization for individuals 7 years of age and older who need tetanus, diphtheria, acellular pertussis and polio vaccines.</li> </ul>	
<b>Program Notes:</b>		
<ul style="list-style-type: none"> <li>• 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.</li> <li>• 2022 April 20: Due to the limited supply of IPV vaccine, dTap-IPV is the vaccine of choice for adults who require polio immunization only.</li> <li>• 2024 January 29: Removed limited supply constraints related to IPV vaccine, adults in health care setting should receive a primary series and a single lifetime reinforcing dose of polio-containing vaccine, adults previously unimmunized with polio vaccine should receive a primary series.</li> <li>• 2024 July 1: References to dTap changed to Tdap to align with national standards.</li> </ul>		
<b>Related Resources:</b>		
<ul style="list-style-type: none"> <li>• Tdap-IPV Vaccine Information Sheet (104503).</li> </ul>		
<b>References:</b>		
<ol style="list-style-type: none"> <li>1. Advisory Committee on Immunization Practices (ACIP). (2023 August 1) General Best Practice Guidelines for Immunization. Accessed on November 21, 2023 <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</a>.</li> <li>2. Alberta Health. (2019, April 1). Alberta Immunization Policy. <i>Adverse Event Following Immunization (AEFI) Policy for Alberta Health Services Public Health</i>. Alberta Health.</li> <li>3. Alberta Health, Health System Accountability and Performance Division. Alberta Immunization Policy. (2024, May 6). <i>Tetanus-Diphtheria-Acellular Pertussis-Polio Combined Vaccine</i>.</li> <li>4. Centers for Disease Control and Prevention. (2011). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. <i>Morbidity and Mortality Weekly Report</i>, 60(2), 36-39.</li> <li>5. GlaxoSmithKline. (2023, November 9). Product Monograph. <i>BOOSTRIX®-POLIO: Combined diphtheria, tetanus, acellular pertussis (adsorbed) and inactivated poliomyelitis vaccine</i>.</li> <li>6. GlaxoSmithKline. Personal communication with GSK representative. Presence of materials of animal origin. 5 Dec 2019.</li> <li>7. GlaxoSmithKline. Personal communication with GSK representative. Presence of Equine Derived Materials in Tdap-IPV. 12 Dec 2019.</li> <li>8. National Advisory Committee on Immunization. (2018). <i>Canadian Immunization Guide (Evergreen Edition)</i>. Ottawa, ON: Public Health Agency of Canada. <a href="https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html">https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html</a></li> <li>9. Sanofi Pasteur Limited. (2023, August 8). Product Monograph. <i>Adacel®Polio: Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed combined with inactivated poliomyelitis vaccine</i>.</li> </ol>		