

Diphtheria-Tetanus-Acellular Pertussis-Polio Combined Vaccine (DTaP-IPV)

Revision Date: November 19, 2012

Please consult the Product Monograph¹ for further information about the vaccine.

	INFANRIX®-IPV	QUADRACEL®
Manufacturer	GlaxoSmithKline Inc.	Sanofi Pasteur Limited
Licensed use	As a booster dose in children up to and including 6 years of age who have previously been immunized with three or four doses of diphtheria, tetanus and acellular pertussis-containing vaccines.	For the primary immunization of children 2 months of and up to and including 6 years of age.
Off-license use	Children, younger than seven years of age, initiating or completing, (less than three doses) an immunization series of diphtheria, tetanus, acellular pertussis and polio. Child/adult recipients of hematopoietic stem cell transplantation (HSCT).	Children (seven years of age and older) and adult recipients of hematopoietic cell transplantation (HSCT)
Indications for use of provincially funded vaccine	<p>Children 7 months up to and including 6 years of age:</p> <ul style="list-style-type: none"> Children seven months up to and including four years of age when immunization with <i>Haemophilus influenzae</i> type b vaccine (Hib) is not necessary. Children five years up to and including six years of age initiating a primary vaccine series (unknown/uncertain or no history of a primary series) or completing a vaccine series. Children six years of age and younger who sustain a wound injury and have not received the recommended number of tetanus toxoid doses for their age. Children younger than five years of age who are not adequately immunized for Hib should receive diphtheria, tetanus, acellular pertussis, polio and Hib combined vaccine. See Tetanus Post-exposure Prophylaxis in Injury/Wound Management. <p>Individuals 7 years of age and older:</p> <ul style="list-style-type: none"> Adult and child recipients of hematopoietic stem cell transplantation (HSCT). See Immunization for Child Hematopoietic Stem Cell Transplant Recipients and Immunization for Adult Hematopoietic Stem Cell Transplant Recipients. 	
Dose	0.5 mL	
Route	Intramuscular injection	
Schedule	<p>Children up to and including 6 years of age:</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: 4 – 8 weeks after dose 1 ❖ Dose 3: 4 – 8 weeks after dose 2 ❖ Dose 4: 6 – 12 months after dose 3 <p>Notes:</p> <ul style="list-style-type: none"> If children younger than five years of age are initiating or completing a vaccine series, diphtheria, tetanus, acellular pertussis, polio and Hib combined vaccine may be the vaccine of choice for some of the doses. See Infants: Routine Immunization Schedule. 	

	<ul style="list-style-type: none"> Children who have had pertussis infection should continue to receive pertussis-containing vaccines.² When the fourth primary immunizing dose is administered after the fourth birthday, the fifth dose (pre-school booster) is not necessary.² <p>Individuals 7 years of age and older (HSCT recipients)</p> <p>See Immunization for Child Hematopoietic Stem Cell Transplant Recipients and Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.</p>
Contraindications	<ul style="list-style-type: none"> Known severe hypersensitivity to any component of the vaccine. Anaphylactic or other allergic reaction to a previous dose of vaccine containing tetanus, diphtheria, pertussis or polio antigens. Encephalopathy within seven days of a previous dose of a pertussis-containing vaccine not attributable to another identifiable cause is a contraindication to immunization with any pertussis-containing vaccine.^{1,4} <p><u>For INFANRIX®-IPV only:</u></p> <ul style="list-style-type: none"> The tip cap on the pre-filled syringes may contain latex.³ The pre-filled syringe plunger stoppers do not contain latex.³
Precautions	<ul style="list-style-type: none"> 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 eight 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 or have an alternative cause identified may receive subsequent doses of tetanus-containing vaccine.²
Possible reactions	<p>Local reactions:</p> <ul style="list-style-type: none"> Tenderness, redness and swelling are the most common reactions and are generally mild and transient in duration¹ Persistent nodules at the site of injection may occur. Local swelling at the injection site (greater than 50mm).¹ Diffuse swelling of the injected limb sometimes involving the adjacent joint is more likely to occur with the booster dose.¹ <p>Systemic reactions:</p> <ul style="list-style-type: none"> Fever, appetite loss, restlessness, unusual crying, agitation, irritability, somnolence, headache, nausea, vomiting, diarrhea, asthenia, malaise, allergic dermatitis, lymphadenopathy, bronchitis, cough, urticaria and rash.¹ The rate of reactions to acellular pertussis vaccines is less than that reported with whole-cell preparations.¹ <p><u>For INFANRIX®-IPV only:</u></p> <ul style="list-style-type: none"> The following additional adverse events have been reported from post-marketing surveillance; anaphylactic and allergic reactions, convulsions, hypotonic-hyporesponsive episodes, apnea, pruritus, angioneurotic edema, swelling of the entire injected limb and injection site vesicles.¹

	<p>For QUADRACEL® only:</p> <ul style="list-style-type: none"> The following additional adverse events have been reported from post-marketing surveillance: anaphylactic and allergic reactions, screaming, somnolence, convulsion, febrile convulsion, hypotonic-hyporesponsive episodes, hypotonia, cyanosis, pallor and listlessness.¹ <p>Note: DAT/TAT level testing may be recommended for some reactions. See Interpretation of Diphtheria Antitoxin Levels (DAT) and Tetanus Antitoxin Levels (TAT).</p> <p>Refer to: <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers</i>.⁵</p>
Pregnancy	Should not be used for pregnant women. Adequate human data in use during pregnancy and adequate animal reproduction studies are not available. ¹
Lactation	Should not be used for breastfeeding women. Adequate human data in use during lactation and adequate animal reproduction studies are not available. ¹

References

- GlaxoSmithKline Inc. (2011, August 16). INFANRIX®-IPV: Diphtheria and tetanus, acellular pertussis and inactivated poliomyelitis vaccine. *Product Monograph*.
- Sanofi Pasteur Limited. (2011, August). QUADRACEL®: Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed combined with inactivated poliomyelitis vaccine. *Product Monograph*.
- National Advisory Committee on Immunization. (2006). *Canadian Immunization Guide* (7th ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html
- Personal communication from GSK regarding latex in vaccine vials and pre-filled syringes. (2012, May 26).
- 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).
- 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>.