

Diphtheria-Tetanus-Acellular Pertussis-Polio-Haemophilus influenzae type b Conjugate Combined Vaccine (DTaP-IPV-Hib)

Revision Date: March 16, 2017

Rationale for Policy Update: DTaP-IPV (INFANRIX®-IPV or QUADRACEL®) combination vaccines will not be available in Canada starting June/July 2017.

Please consult the Product Monograph ¹ for further information about the vaccine.		
	INFANRIX®-IPV/Hib	PEDIACEL®
Manufacturer	GlaxoSmithKline Inc.	
Licensed use	Children six weeks up to and including four years of age.	Children two months up to and including six years of age.
Off-license use	Children five years up to and including six years of age. Child hematopoietic stem cell transplant (HSCT) recipients five years of age and older. Adult hematopoietic stem cell transplant (HSCT) recipients.	Children starting at six weeks of age. Child hematopoietic stem cell transplant (HSCT) recipients five years of age and older. Adult hematopoietic stem cell transplant (HSCT) recipients.
Indications for use of provincially funded vaccine	<ul style="list-style-type: none"> Primary immunization for children two months up to and including 59 months of age when diphtheria, tetanus, acellular pertussis, polio and Hib vaccines are indicated. Children five years up to and including six years of age who are presenting with no immunization or an incomplete primary series when diphtheria, tetanus, acellular pertussis and polio vaccines are indicated and require the first, second, third or fourth dose in that series. Note: These children need higher concentrations of diphtheria (designated as "D") and pertussis (designated as "P")² for the first, second, third or fourth dose of diphtheria, tetanus, acellular pertussis and polio. Children younger than seven years of age who sustain a wound injury that have not received the recommended number of tetanus toxoid doses for their age and need higher concentrations of diphtheria and pertussis. See Tetanus Post-exposure Prophylaxis in Injury/Wound Management. Child hematopoietic stem cell transplant (HSCT) recipients five years of age and older. See Immunization for Child Hematopoietic Stem Cell Recipients. Adult hematopoietic stem cell transplant (HSCT) recipients. See Immunization for Adult Hematopoietic Stem Cell Recipients. 	
Dose	0.5 mL	
Route	Intramuscular injection	
Schedule	Primary series: <ul style="list-style-type: none"> Dose 1: 2 months of age Dose 2: 4 months of age Dose 3: 6 months of age Dose 4: 18 months of age 	See Infants: Routine Immunization Schedule . <i>Routine Immunization Schedule for Infants Beginning Immunization at Younger than 12 Months of Age.</i>

	<p>Notes:</p> <ul style="list-style-type: none"> • Children may need fewer doses of the Hib component if they have received a dose of Hib vaccine at 15 months of age or older, however, it is acceptable to give additional doses of the Hib component using this combination vaccine. • When the fourth primary immunizing dose is administered after the fourth birthday, the fifth dose (preschool booster) is not necessary.² • Children receiving their fifth dose between four and six years of age should receive dTap-IPV. See dTap-IPV (Adacel®-Polio and Boostrix®-Polio) for indications. Note: Children receiving their fifth dose may receive a lower concentration of diphtheria (designated as “d”) and pertussis (designated as “p”).² • Child recipients of HSCT should have their immunization schedules restarted post-transplant. See Immunization for Child Hematopoietic Stem Cell Transplant Recipients. • Children expecting solid organ transplantation. See Immunization for Children Expecting Solid Organ Transplant before 18 months of age (Accelerated) and Immunization for Children Expecting Solid Organ Transplant after 18 months of Age (Catch-up Schedule). • Children who have had pertussis infection should continue to receive pertussis-containing vaccines.² • Children in whom invasive Hib disease develops before 24 months of age should receive Hib vaccine as recommended because natural disease may not induce protection.²
<p>Contraindications</p>	<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 diphtheria, tetanus, pertussis, polio or Hib antigens. • Encephalopathy (e. g., coma, decreased level of consciousness, prolonged seizures) within seven days of a previous dose of a pertussis-containing vaccine not attributable to another identifiable cause.^{1,4} <p><u>For INFANRIX®-IPV/Hib 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 and the vial stoppers do not contain latex.³
<p>Precautions</p>	<ul style="list-style-type: none"> • Capsular polysaccharide antigen (Hib antigen) can be detected in the urine of vaccine recipients for up to two weeks following immunization with conjugate vaccines. This phenomenon could be confused with antigenuria associated with invasive Hib infections.² • Hib vaccines should never be given to a child younger than six weeks of age.⁵ Data suggest that Hib conjugate vaccines given before six weeks of age may induce immunologic tolerance (reduced response to subsequent doses).⁵ • Children with neurologic conditions should be assessed carefully. See Immunization of Specific Populations (Immunosuppressed and Chronic Health Conditions) Neurologic Disorders. • 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

<p>Possible Reactions</p>	<p>Local reactions</p> <ul style="list-style-type: none"> • Pain, redness, swelling and induration at the injection site.¹ • Persistent nodules at the site of injection may occur. • Large injection site reactions (greater than 50 mm), including extensive limb swelling from the injection site beyond one or both joints have been reported. These reactions start within 24 to 72 hours after immunization, may be associated with erythema, warmth, tenderness or pain at the injection site and resolve spontaneously within 3 – 5 days.¹ The greatest risk is following the fourth dose.¹ <p>Systemic reactions:</p> <ul style="list-style-type: none"> • The most frequent systemic reactions are appetite loss, irritability, fussiness, crying, restlessness, somnolence, fever, diarrhea, and vomiting. Lymphadenopathy, cough, bronchitis, rhinorrhea, rash, urticaria, fever greater than 39.5°C, fatigue, pruritus, and dermatitis were also reported.¹ <p>Refer to: <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.</i></p>
<p>Pregnancy</p>	<p>Not intended for use in adults.¹</p>
<p>Lactation</p>	<p>Not intended for use in adults.¹</p>

References

¹ GlaxoSmithKline Inc. (2015, July). INFANRIX™-IPV/Hib: Combined diphtheria, tetanus, acellular pertussis vaccine, inactivated poliomyelitis and *Haemophilus influenzae* type b vaccine. *Product Monograph*.
 Sanofi Pasteur Limited. (2012, February 28). PEDIACEL®: Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed combined with inactivated poliomyelitis vaccine and *Haemophilus b* conjugate vaccine (tetanus Protein – conjugate). *Product Monograph*.

² National Advisory Committee on Immunization. (2016). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html

³ Personal communication from GSK regarding latex in vaccine vials and pre-filled syringes. (2012, April 26).

⁴ 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). Retrieved February 23, 2017 from, www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.

⁵ Centers for Disease Control and Prevention. (2015). *Haemophilus influenzae* type b. In *Epidemiology and Prevention of Vaccine-Preventable Diseases 13th ed.* (chap. 8). Retrieved February 23, 2017 from, www.cdc.gov/vaccines/pubs/pinkbook/hib.html.

⁶ 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>.