Diphtheria-Tetanus-Acellular Pertussis Hepatitis B-Polio-\textit{Haemophilus influenzae} type b Conjugate Combined Vaccine

Revision Date: March 20, 2018

Rationale for update: Expand indications to include hepatitis B vaccine as Universal Infant Hepatitis B program for infants born March 1, 2018 or after.

Please consult the Product Monograph\textsuperscript{1} for further information about the vaccine.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>GlaxoSmithKline Inc.</th>
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<tbody>
<tr>
<td>Licensed Use</td>
<td>Children six weeks up to two years of age\textsuperscript{1,2}</td>
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<tr>
<td>Off-license use</td>
<td>None</td>
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<tr>
<td>Indications for use of provincially funded vaccine</td>
<td></td>
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</tbody>
</table>
|• Primary immunization for children two months up to 23 months of age when diphtheria, tetanus, acellular pertussis, polio, Hib, and hepatitis B vaccines are indicated. Note: Hepatitis B vaccine indicated for: 
  ➢ Infants born March 1, 2018 or later. 
  ➢ Infants born to hepatitis B infected mothers or whose primary caregiver is hepatitis B infected (acute cases or carriers). 
  ➢ Infants who are household contacts of a hepatitis B case or carrier. 
  ➢ Infants whose families have immigrated to Canada from areas where there is a high prevalence (8% or higher) of hepatitis B. See \textit{Hepatitis B Virus Infection – High Endemic Geographic Areas}. 
|• Primary series for high risk infants who have received HBIG and/or hepatitis B vaccine at birth. Note: INFANRIX hexa\textregistered contains only a single dose (10 µg) of Engerix® Hepatitis B vaccine and \textbf{is not} indicated for infants and children requiring a double dose (20 µg of Engerix®) Hepatitis B vaccine. |

| Dose       | 0.5 mL |
| Route      | Intramuscular injection |

Schedule

\textbf{Primary series:}

• Dose 1: 2 months of age
• Dose 2: 4 months of age
• Dose 3: 6 months of age

Notes:

• Spacing recommendation for off-schedule children is 2 months between doses.
• The minimum interval between the first and second dose of vaccine is 4 weeks, the minimum interval between the second and third dose of vaccine is 8 weeks, and the minimum interval between the first and third dose is 16 weeks.
• The third dose in the series should not be administered to infants before 24 weeks (6 months) of age.
• Where a dose of hepatitis B vaccine is given at birth, INFANRIX hexa® can be used for the second dose from the age of six weeks.1,3

• The first three doses of an immunization series should be completed with the same combination product whenever possible. If this is not possible an alternative combination may be used.3

  ➢ Ideally series started with INFANRIX hexa® will be completed with INFANRIX hexa®.

  ➢ Series started with a combination of DaPT-IPV-Hib (PediaCel® or Infanrix®-IPV/Hib) and Hepatitis B vaccine will be completed with PediaCel® or Infanrix®-IPV/Hib and Hepatitis B vaccine.

  ➢ The exception as detailed above are infants given a dose of hepatitis B vaccine at birth.

• The routine 18th month booster will be completed with a diphtheria, tetanus, acellular pertussis, polio, and Hib containing vaccine (PediaCel® or Infanrix®-IPV/Hib).

• Children who have had a pertussis infection should continue to receive pertussis-containing vaccines.3

• 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.3

• Children seven months up to and including 23 months of age who are starting a primary series or who have an incomplete primary series of INFANRIX hexa® should continue to receive INFANRIX hexa® as indicated above. These children may need fewer doses of the Hib component; however, it is acceptable to give the additional doses of Hib vaccine in this combination vaccine for convenience of administration.

### Post-immunization Serology and Follow-up

<table>
<thead>
<tr>
<th>Infants born to infected mothers:</th>
<th>Household contacts of a hepatitis B case or carrier:</th>
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<tbody>
<tr>
<td>Serology is recommended 1 – 6 months following the primary series of INFANRIX hexa® and the infant should be at least 9 months of age.³</td>
<td>Serology should be done 1 – 6 months following the primary series of INFANRIX hexa® and at least 6 months after HBIG.</td>
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<tr>
<td>Both anti-HBs and HBsAg should be done.</td>
<td>If the individual is negative for antibody after the first series, a second hepatitis B vaccine series³ should be administered, with repeat serology testing one month later.</td>
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</table>

### Contraindications

| Known severe hypersensitivity to any component of INFANRIX hexa®. | Anaphylactic reaction to a previous dose of vaccine containing diphtheria, tetanus, pertussis, polio, Hib, or hepatitis B 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 |
### Precautions
- Child Hematopoietic Stem Cell Transplant (HSCT) Recipients and Children Pre and Post Solid Organ Transplant should not receive INFANRIX hexa® as INFANRIX hexa® contains single dose (10 µg) of Engerix® Hepatitis B vaccine.
- 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.\(^1,3\)
- 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.\(^1\)
- 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.\(^3\) Those who develop GBS outside this interval or have an alternative cause identified may receive subsequent doses of tetanus-containing vaccine.\(^3\)

### Possible reactions

#### Local reactions:
- Most common reactions include pain, redness, swelling and induration at the injection site. Common reactions include local swelling at the injection site (> 50 mm) Uncommon reactions include diffuse swelling of the injected limb, sometimes involving the adjacent joint.\(^1\)

#### Systemic reactions:
- The most common systemic reactions are appetite loss, irritability, unusual crying, restlessness, fever, and fatigue. Common reactions include diarrhea, vomiting, pruritus, nervousness. Other reactions include cough, bronchitis, rash, urticaria, bronchospasm and dermatitis. Fever greater than 39.5°C reported when INFANRIX hexa® administered at the same time as pneumococcal conjugate vaccine.\(^1\)
- The following additional adverse events have been reported from post-marketing surveillance: Lymphadenopathy, thrombocytopenia, allergic reactions (including anaphylactic and anaphylactoid reactions) apnea in very premature infants, collapse or shock-like state (increased risk for hypotonic hyporesponsive episode when given with pneumococcal conjugate vaccine), angioneurotic-edema, extensive swelling of the entire limb, and vesicles at the injection site.\(^1\)

### Note:
DAT/TAT level testing may be recommended for some reactions. See [Interpretation of Diphtheria Antitoxin (DAT) Levels and Tetanus Antitoxin (TAT) Levels](#).

Refer to: [Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers.\(^6\)](#)

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<tr>
<th>Pregnancy</th>
<th>Not intended for use in adults.(^1)</th>
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<tr>
<td>Lactation</td>
<td>Not intended for use in adults.(^1)</td>
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References


