

## Diphtheria-Tetanus-Acellular Pertussis-Hepatitis B-Polio-Haemophilus Influenzae Type b Adsorbed (DTaP-HB-IPV-Hib) INFANRIX hexa®

Supplier: GlaxoSmithKline Inc.

### INDICATIONS:

- Routine infant schedule.
- Infants at high risk of hepatitis B who have received a birth dose of HBIg and/or hepatitis B vaccine.
- Completion of primary series of INFANRIX hexa® before 7 years of age.
- Select special populations as indicated in [Part 2 – Immunization of Special Populations](#).

INFANRIX hexa® is not routinely indicated for those 7 years of age and older.

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### DOSES AND SCHEDULE: A, B

Routine infant schedule and high risk infants: 3 doses given as 0.5 mL **IM** at 2, 4, and 6 months of age.

Unimmunized or incompletely immunized infants and children less than 7 years of age: up to 3 doses given as 0.5 mL **IM**, separated by 8 weeks.

Select special populations: as indicated in [Part 2 – Immunization of Special Populations](#).

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### ADMINISTRATION:

Vaccine must be reconstituted. Add the entire contents of the pre-filled syringe to the vial containing the Hib pellet. The product should be used immediately after reconstitution. Stability of the vaccine has been demonstrated for 8 hours at 21°C following reconstitution.

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### BOOSTER DOSES:

None using this product.<sup>c</sup>

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### SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

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### CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, hepatitis B, inactivated polio or *Haemophilus influenzae* type b-containing vaccine or to any component of INFANRIX hexa®.

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<sup>A</sup> The primary series of 3 doses of DTaP-containing vaccine should be completed with the product from the same manufacturer whenever possible. However, if the product used for prior dose(s) is unknown or unavailable, the primary series may be completed with an alternative combination vaccine from a different manufacturer.

<sup>B</sup> INFANRIX hexa® can be used as a booster dose for those under 7 years of age who require protection against tetanus, diphtheria, pertussis, polio, Hib and hepatitis B, regardless of which product was used for the primary series.

<sup>C</sup> Refer to [Part 1 – Immunization Schedules](#) for information regarding booster doses using the age appropriate tetanus and diphtheria-containing vaccines.

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**CONTRAINDICATIONS (continued):**

2. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a tetanus-containing vaccine.

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**PRODUCT COMPONENTS:**

Potential allergens: neomycin sulphate, polymyxin B sulphate.

Other components: aluminum (as aluminum salts), lactose, Medium 199.

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**PRECAUTIONS:**

Not applicable.

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**SPECIAL CONSIDERATIONS:**

- INFANRIX hexa® contains only a single dose of HB vaccine (as ENGERIX®-B) and is not indicated for infants and children requiring a [Hepatitis B Vaccine Higher Dose Schedule](#).
- A hypotonic-hyposensitive episode (HHE) following a prior dose of DTaP-containing vaccine is not a contraindication to future immunization and continued immunization with all antigens is recommended.
- While the number of Hib doses varies with age of presentation, INFANRIX hexa® should be administered using the indicated schedules even if an 'extra' dose of Hib is administered for age.
- Any dose(s) of oral polio vaccine (OPV) received on or after April 1, 2016 will not be considered as a valid dose within the routine BC immunization schedule. For more information, see [Part 4 – Biological Products, Polio Vaccine, Special Considerations](#).
- A history of two fractional doses of inactivated polio vaccine (fIPV) can be considered equivalent to a single IPV dose provided the first dose was given at a minimum age of 6 weeks with a minimum interval of 4 weeks between doses. For more information, see [Part 4 – Biological Products, Polio Vaccine, Special Considerations](#).

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**ADVERSE EVENTS:**

**Local:** soreness, redness, swelling.

**Systemic:** fever, anorexia, restlessness, irritability, persistent or unusual crying, vomiting, diarrhea.