

Diphtheria-Tetanus-Acellular Pertussis-Polio-Haemophilus Influenzae Type b Adsorbed (DTaP-IPV-Hib)

PEDIACEL®

Supplier: Sanofi Pasteur Limited

PENTACEL®

Supplier: Sanofi Pasteur Limited

INFANRIX®-IPV/Hib

Supplier: GlaxoSmithKline Inc.

INDICATIONS:

- Booster dose at 18 months of age. ^A
- Primary series for infants who have received hepatitis B vaccine by separate injection, i.e., beginning at birth and 1 month of age.
- Completion of primary series for children under 7 years of age who do not require hepatitis B vaccine, including those complete for Hib. ^B
- Select special populations as indicated in [Part 2 - Immunization of Special Populations](#).

These vaccines are not routinely indicated for individuals 7 years of age and older. ^C

DOSES AND SCHEDULE: ^{D, E}

Booster dose: 1 dose given as 0.5 mL **IM**.

Primary series for infants who have received hepatitis B vaccine at birth and 1 month of age:

- INFANRIX®-IPV/Hib: 2 doses given as 0.5 mL **IM** at 2 and 4 months. The 6 month dose should be given as INFANRIX hexa®.
- PEDIACEL® or PENTACEL®: 3 doses given as 0.5 mL **IM** at 2, 4 and 6 months of age.

Completion of a primary series for children under 7 years of age: 1 or 2 doses given as 0.5 mL **IM**, separated by 8 weeks.

ADMINISTRATION:

INFANRIX®-IPV/Hib: Vaccine must be reconstituted. Add the liquid INFANRIX®-IPV (pre-filled syringe) to the vial containing HIBERIX® (a lyophilized powder). The product should be used immediately after reconstitution. Stability of the vaccine has been demonstrated for 8 hours at 21°C following reconstitution.

PEDIACEL®: No reconstitution required.

^A This booster dose can be provided as DTaP-IPV-Hib to children up to 5 years of age who require Hib, as well as children less than 4 years of age who are complete for Hib. For children 4 years of age and older who do not require Hib, this booster dose is given as [Tdap-IPV](#).

^B Extra doses of Hib vaccine can be safely administered to children under 7 years of age who require protection against diphtheria, tetanus, pertussis and polio.

^C Although INFANRIX®-IPV/Hib is only approved for use up to 5 years of age the product may be used up to the 7th birthday (based on expert opinion).

^D 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.

^E Any DTaP-IPV-Hib vaccine can be used as a booster dose for those under 7 years of age who require protection against tetanus, diphtheria, pertussis, polio, and Hib, regardless of which product was used for the primary series.

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ADMINISTRATION (continued):

PENTACEL®: Vaccine must be reconstituted. Gently shake the vial of QUADRACEL®, withdraw the entire contents of the liquid vaccine and inject slowly into the vial of lyophilized Act-HIB®. Swirl the vial containing the reconstituted PENTACEL® gently until a uniform, cloudy, white to off-white suspension results. The product should be used immediately after reconstitution.

BOOSTER DOSES:

There are no routine additional doses of these vaccines required outside of the above indications.^A

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of diphtheria or tetanus toxoids or to pertussis, polio or *Haemophilus influenzae* type b vaccines or to any component of the specific vaccine being given.
2. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a tetanus-containing vaccine without any other cause being identified.

PRODUCT COMPONENTS:

INFANRIX®-IPV/Hib:

Potential allergens: polysorbate 80, neomycin sulphate, polymyxin B sulphate.

Other components: lactose, potassium chloride, disodium phosphate, monopotassium phosphate, aluminum salts, Medium 199, glycine, formaldehyde.

PEDIACEL®:

Potential allergens: neomycin, polymyxin B, streptomycin, polysorbate 80, bovine serum albumin.

Other components: aluminum phosphate, 2-phenoxyethanol, formaldehyde, glutaraldehyde.

PENTACEL®:

Potential allergens: neomycin, polymyxin B sulphate, streptomycin sulphate, polysorbate 80, bovine serum albumin.

Other components: aluminum phosphate, 2-phenoxyethanol, sucrose, formaldehyde, glutaraldehyde, tris(hydroxymethyl)aminomethane.

PRECAUTIONS:

Not applicable.

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

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SPECIAL CONSIDERATIONS:

- A hypotonic-hyporesponsive 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.
- 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 (iPV) 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](#).

ADVERSE EVENTS:

Local: pain, redness, swelling.

Systemic: irritability, crying, fever, drowsiness, decreased activity and appetite, vomiting and diarrhea.

The vaccines are associated with an increase in rates of local reactions following the booster dose than when used for the primary infant series. Rates of fever are also increased when INFANRIX®-IPV/Hib is used for the booster dose.