***Haemophilus influenzae* Type b (Hib)**

**Tetanus Toxoid Conjugate Vaccine - HIBERIX®**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Vaccine Information Statements**

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide a non-English speaking patient with a copy of the VIS in their native language, if one is available and desired; these VISs can be found at <http://www.immunize.org/vis>.

**FDA Approved Indications and Usage (See Package Insert, current version dated 01/2016)**

* **HIBERIX**® is a vaccine indicated for active immunization for the prevention of invasive disease caused by *Haemophilus influenzae* type b.
* **HIBERIX**® is approved for use in children aged 6 weeks through 4 years of age (prior to fifth birthday).

**Recommended Schedule**

* **HIBERIX**® is recommended for children aged 2 months through 4 years of age (prior to fifth birthday). **HIBERIX**® is administered as a 4-dose series
  + Primary series (3 doses): One dose each at 2, 4, and 6 months of age.
  + Booster dose: One dose administered at 15 through 18 months of age.
* **HIBERIX**® and other Hib conjugate vaccines can be administered as early as 6 weeks of age, in accordance with Hib vaccination schedules for routine and catch-up immunization.
* Licensed monovalent Hib conjugate vaccines are considered interchangeable for the primary as well as the booster doses (dose 3 or 4, depending on vaccine type used for primary series), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm>.

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**Dosage and Route**

* Administer **HIBERIX**® vaccine 0.5 mL intramuscularly (IM) after reconstitution.
* Administer IM vaccines at a 90° angle.
* See Immunize.org reference below for a table about needle size and length, <http://www.immunize.org/catg.d/p3085.pdf>.
* **Always check the package insert prior to administration of any vaccine.**

**Anatomical Site**

* The preferred sites are the anterolateral aspects of the thigh or into the deltoid muscle.
* The vaccine should not be injected into the gluteal area or areas where there is a major nerve trunk.

**Do not administer intravenously, intradermally, or subcutaneously**.

**Preparation for Administration**

* **Reconstitution Instructions**
  + **HIBERIX**® vaccine is to be reconstituted only with the accompanying saline diluent. The reconstituted vaccine should be a clear and colorless solution.
  + See the package insert for reconstitution instructions for **HIBERIX**® vaccine.
  + **HIBERIX**® vaccine should be inspected visually for particulate matter and discoloration prior to administration.
  + After reconstitution, withdraw 0.5 mL of reconstituted vaccine into the syringe.
  + Administer by intramuscular injection.
  + If not administered promptly, **HIBERIX**® should be refrigerated between   
    36° and 46°F (2° and 8°C) and administered within 24 hours. If the vaccine is not administered promptly, shake the solution vigorously before injection.

**Warnings and Precautions**

* Prior to administering the vaccine, obtain a vaccination history to determine any possible vaccine hypersensitivity.
* Moderate to severe illness with or without fever (temporary precaution).
* As with other intramuscular injections, use with caution in patients on anticoagulant therapy.
* If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including **HIBERIX**®, should be based on careful consideration of the potential benefits and possible risks.
* If **HIBERIX**® is administered to immunosuppressed children, including children receiving immunosuppressive therapy, the expected immune response may not be obtained.
* Urine antigen detection may not have a diagnostic value in a suspected disease due to *H. influenzae* type b within 1 to 2 weeks after receipt of a *H. influenzae* type b-containing vaccine, including **HIBERIX**®.
* Immunization with **HIBERIX**® does not substitute for routine tetanus immunization.

**Contraindications**

* A severe allergic reaction (e.g., anaphylaxis) after a previous dose of any *H. influenzae* type b- or tetanus toxoid-containing vaccine or any component of the vaccine.
* Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including **HIBERIX**®, to infants born prematurely should be based on consideration of the individual infant’s medical status, and the potential benefits and possible risks of vaccination.

**Adverse Events**

* See the product’s package insert
* See Adverse Events following vaccinations page of this section

**Storage and Handling**

* Before reconstitution:
  + Store refrigerated between 36° and 46°F (2° and 8°C).
  + Protect vials from light.
  + DO NOT FREEZE; discard **HIBERIX**® vaccine that has been frozen.
* After reconstitution:
  + Store refrigerated between 36° and 46°F (2° and 8°C).
  + **HIBERIX**® should be administered within 24 hours of reconstitution.
  + Discard the reconstituted vaccine if not used within 24 hours.
  + DO NOT FREEZE; discard if the vaccine has been frozen.

**Comment**

**HIBERIX**® does not contain thimerosal or other preservatives.

**References**

Advisory Committee on Immunization Practices; Vaccines for Children Program; Vaccines to Prevent *Haemophilus influenza* type b (Hib) Resolution No. 2/13.-2 [http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/02-13-2-hib.pdf](http://www.merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi2.pdf)

Briere EC, Rubin L, Moro PL, Cohn, A, Clark T, Messonnier N. Prevention and Control of *Haemophilus influenzae* Type b Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014;63(No. RR-1):1-14, [http://www.cdc.gov/mmwr/pdf/rr/rr6301.pdf](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm).

Package Insert: **HIBERIX**® (Dated 1/2016) [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\_Information/Hiberix/pdf/HIBERIX.PDF](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5049a5.htm)

Immunize.org. Administering Vaccines: Dose, Route, Site, and Needle Size, Item #P3085 (11/15), [http://www.immunize.org/catg.d/p3085.pdf](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm)

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