HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HIBERIX safely and effectively. See full prescribing information for HIBERIX.

HIBERIX [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)]
Solution for Intramuscular Injection
Initial U.S. Approval: 2009

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.1, 2.2)	12/2010
Warnings and Precautions, Syncope (5.3)	xx/xxxx

----------INDICATIONS AND USAGE----------

HIBERIX is a vaccine indicated for active immunization as a booster dose for the prevention of invasive disease caused by *Haemophilus influenzae* type b. HIBERIX is approved for use in children 15 months through 4 years of age (prior to fifth birthday). (1)

No clinical data are available from controlled studies comparing booster immunization with HIBERIX and a US-licensed Haemophilus b Conjugate Vaccine. (1)

---------- DOSAGE AND ADMINISTRATION ----------

A single intramuscular injection (approximately 0.5 mL) after reconstitution. (2.2)

---------- DOSAGE FORMS AND STRENGTHS ----------

Solution for injection supplied as vials of lyophilized vaccine to be reconstituted with the accompanying saline diluent in prefilled syringes. A single dose, after reconstitution, is approximately 0.5 mL. (3)

----------CONTRAINDICATIONS----------

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 HIBERIX. (4)

---------- WARNINGS AND PRECAUTIONS ----------

- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give HIBERIX should be based on potential benefits and risks. (5.1)
- The tip cap of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. (5.2, 16)
- Syncope (fainting) can occur in association with administration of injectable vaccines, including HIBERIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope. (5.3)

---------- ADVERSE REACTIONS ----------

Common solicited adverse events (≥20%) were pain and redness at the injection site, fever, fussiness, loss of appetite, and restlessness. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------

Do not mix HIBERIX with any other vaccine in the same syringe or vial. (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: xx/xxxx

FULL PRESCRIBING INFORMATION: CONTENTS*

***Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

HIBERIX® is indicated for active immunization as a booster dose for the prevention of invasive disease caused by *Haemophilus influenzae* type b. HIBERIX is approved for use in children 15 months through 4 years of age (prior to fifth birthday).

HIBERIX is to be used as a booster dose in children who have received a primary series with a Haemophilus b Conjugate Vaccine that is licensed for primary immunization. HIBERIX is not approved for primary immunization.

The evaluation of effectiveness of HIBERIX as a booster dose was based on immune responses in children using serological endpoints that predict protection from invasive disease due to *H. influenzae* type b *[see Clinical Pharmacology (12.1) and Clinical Studies (14.1)]*. These protective antibody levels have not been evaluated in clinical trials in which a booster dose of HIBERIX is compared to a booster dose of a US-licensed Haemophilus b Conjugate Vaccine in children who previously received a primary series with a US-licensed Haemophilus b Conjugate Vaccine *[see Clinical Studies (14.1)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Reconstitution Instructions

HIBERIX is to be reconstituted only with the accompanying saline diluent. The reconstituted vaccine should be a clear and colorless solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Figure 1. Cleanse vial stopper. Attach appropriate needle to accompanying prefilled syringe of saline diluent and insert into vial.

Figure 2. Transfer entire contents of prefilled syringe into vial. With needle still inserted, vigorously shake the vial.

Figure 3. After reconstitution, withdraw entire contents of vial (approximately 0.5 mL) and administer by intramuscular injection.

After reconstitution, HIBERIX should be administered promptly or stored refrigerated between 2° and 8°C and administered within 24 hours. If the vaccine is not administered promptly, shake the solution vigorously again before injection.

2.2 Dose and Administration

HIBERIX is administered as a single dose (approximately 0.5 mL) by intramuscular injection into the anterolateral aspect of the thigh or deltoid.

Do not administer this product intravenously, intradermally, or subcutaneously.

HIBERIX is to be used as a booster dose in children who have received a primary series with a Haemophilus b Conjugate Vaccine that is licensed for primary immunization *[see Indications and Usage (1)]*.

3 DOSAGE FORMS AND STRENGTHS

HIBERIX is a solution for injection supplied as single-dose vials of lyophilized vaccine to be reconstituted with the accompanying saline diluent in prefilled TIP-LOK® syringes. A single dose, after reconstitution, is approximately 0.5 mL.

4 CONTRAINDICATIONS

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 is a contraindication to administration of HIBERIX *[see Description (11)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

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.

5.2 Latex

The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals *[see How Supplied/Storage and Handling (16)]*.

5.3 Syncope

Syncope (fainting) can occur in association with administration of injectable vaccines, including HIBERIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

5.4 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the patient's immunization history for possible vaccine hypersensitivity. Epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

5.5 Altered Immunocompetence

Safety and effectiveness of HIBERIX in immunosuppressed children have not been evaluated. If HIBERIX is administered to immunosuppressed children, including children receiving immunosuppressive therapy, the expected immune response may not be obtained.

5.6 Interference With Laboratory Tests

Urine antigen detection may not have a diagnostic value in 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 *[see Drug Interactions (7.1)]*.

5.7 Tetanus Immunization

Immunization with HIBERIX does not substitute for routine tetanus immunization.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine, and may not reflect the rates observed in practice. There is the possibility that broad use of HIBERIX could reveal adverse reactions not observed in clinical trials.

In 7 clinical studies, 1,008 children received HIBERIX as a booster dose following primary vaccination with either HIBERIX (not approved for primary series in US, N = 530), Haemophilus b Conjugate Vaccine manufactured by Sanofi Pasteur SA (N = 235), Haemophilus b Conjugate Vaccine manufactured by Merck & Co., Inc. (N = 26), or Haemophilus b Conjugate Vaccine manufactured by Wyeth Pharmaceuticals Inc. (no longer licensed in the US, N = 217). None of the studies included a comparator group that received a booster dose with a US-licensed Haemophilus b Conjugate Vaccine. Studies were conducted in Europe, Canada, and Latin America. Across these studies, the mean age of subjects at the time of booster vaccination with HIBERIX ranged from 16 to 19 months. At the time of vaccination, 172 (17.1%) subjects were 11 to 14 months of age, 642 (63.7%) subjects were 15 to 18 months of age, and 194 (19.2%) subjects were 19 to 25 months of age. Approximately half of the subjects were male. Among subjects for whom information on race/ethnicity was available, nearly all subjects were white.

In these 7 studies, HIBERIX was administered concomitantly with non-US formulations (containing 2.5 mg 2-phenoxyethanol per dose as preservative) of one of the following US-licensed vaccines: INFANRIX® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) (DTaP), KINRIX® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine) (DTaP-IPV), or PEDIARIX® [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine] (DTaP-HBV-IPV). In the studies, DTaP-IPV and DTaP-HBV-IPV were administered in dosing regimens not approved in the US. Some subjects received DTaP-HBV (GlaxoSmithKline Biologicals, not licensed in US) concomitantly with HIBERIX.

Solicited Adverse Events: In an open-label, multicenter study conducted in Germany, 371 children received a booster dose of HIBERIX administered concomitantly with DTaP-HBV-IPV. The mean age at the time of vaccination was 16 months. Subjects in this study had previously received a primary series with either HIBERIX (not approved for primary series in US, N = 92), Haemophilus b Conjugate Vaccine manufactured by Sanofi Pasteur SA (N = 96), or Haemophilus b Conjugate Vaccine manufactured by Wyeth Pharmaceuticals Inc. (no longer licensed in the US) (N = 183). All subjects previously received 3 doses of DTaP-HBV-IPV. Information on adverse events was collected by parents/guardians using standardized forms for 4 consecutive days following vaccination with HIBERIX (i.e., day of vaccination and the next 3 days). The reported frequencies of solicited local and general adverse events are presented in Table 1.

Table 1. Percentage of Children With Solicited Local And General Adverse Events Within 4 Days of Vaccination[a] With HIBERIX[b] Coadministered With DTaP-HBV-IPV[c], Intent to Treat Cohort (N = 371)

	% Any	% Grade 3
Local[d]		
Redness	24.5	2.4[e]
Pain	20.5	1.1[f]
Swelling	14.8	2.2[e]
General		
Fever[g]	34.8	3.8
Fussiness	25.9	0.8[h]
Loss of appetite	22.9	0.8[i]
Restlessness	21.8	0.5[i]
Sleepiness	19.9	1.1[i]
Diarrhea	14.6	0.8[i]
Vomiting	4.9	0.5[i]

N = all subjects for whom safety data were available.

[a] Within 4 days of vaccination defined as day of vaccination and the next 3 days.

[b] In this study, 92 subjects previously received 3 doses of HIBERIX (not approved for primary immunization in the US), 96 subjects previously received 3 doses of a US-licensed Haemophilus b Conjugate Vaccine (manufactured by Sanofi Pasteur SA), and 183 subjects previously received 3 doses of a Haemophilus b Conjugate Vaccine that is no longer licensed in the US.

[c] In this study, DTaP-HBV-IPV was given to subjects who previously received 3 doses of DTaP-HBV-IPV. In the US, PEDIARIX is approved for use as a 3-dose primary series; use as a fourth consecutive dose is not approved in the US.

[d] Local reactions at the injection site for HIBERIX.

[e] Grade 3 redness or swelling defined as >20 mm.

[f] Grade 3 pain defined as causing crying when limb moved.

[g] Fever defined as ≥100.4°F (≥38.0°C) rectally or ≥99.5°F (≥37.5°C) axillary, oral or tympanic; Grade 3 fever defined as >103.1°F (>39.5°C) rectally or >102.2°F (>39.0°C) axillary, oral or tympanic.

[h] Grade 3 fussiness defined as persistent crying and could not be comforted.

[i] Grade 3 for these symptoms defined as preventing normal daily activity.

Serious Adverse Events: Two of 1,008 subjects reported a serious adverse event that occurred in the 31-day period following booster immunization with HIBERIX. One subject developed bilateral pneumonia 9 days post-vaccination and one subject experienced asthenia following accidental drug ingestion 18 days post-vaccination.

6.2 Postmarketing Experience

In addition to reports in clinical trials, worldwide voluntary reports of adverse events received for HIBERIX since market introduction (1996) of this vaccine are listed below. This list includes serious events and/or events which have a plausible causal connection to HIBERIX. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccination.

General Disorders and Administration Site Conditions: Extensive swelling of the vaccinated limb, injection site induration.

Immune System Disorders: Allergic reactions (including anaphylactic and anaphylactoid reactions), angioedema.

Nervous System Disorders: Convulsions (with or without fever), hypotonic-hyporesponsive episode, somnolence, syncope or vasovagal responses to injection.

Respiratory, Thoracic, and Mediastinal Disorders: Apnea.

Skin and Subcutaneous Tissue Disorders: Rash, urticaria.

7 DRUG INTERACTIONS

7.1 Interference With Laboratory Tests

Haemophilus b capsular polysaccharide derived from Haemophilus b Conjugate Vaccines has been detected in the urine of some vaccinees.[1] Urine antigen detection may not have a diagnostic value in 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 *[see Warnings and Precautions (5.6)]*.

7.2 Concomitant Vaccine Administration

In clinical studies, a booster dose of HIBERIX was administered concomitantly with 1 of the following vaccines: DTaP, DTaP-IPV, DTaP-HBV-IPV, or DTaP-HBV (GlaxoSmithKline Biologicals, not licensed in the US). The formulations of DTaP, DTaP-IPV, and DTaP-HBV-IPV were non-US formulations (containing 2.5 mg 2-phenoxyethanol per dose as preservative) of the following US-licensed vaccines: INFANRIX, KINRIX, and PEDIARIX, respectively. In these studies, DTaP-IPV and DTaP-HBV-IPV were administered in dosing regimens that are not approved in the US. *[See Adverse Reactions (6.1) and Clinical Studies (14.1).]*

Sufficient data are not available to confirm lack of interference in immune responses to other vaccines administered concomitantly with HIBERIX.

If HIBERIX is administered concomitantly with other injectable vaccines, they should be given with separate syringes and at different injection sites. HIBERIX should not be mixed with any other vaccine in the same syringe or vial.

7.3 Immunosuppressive Therapies

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune response to HIBERIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with HIBERIX. It is also not known whether HIBERIX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

8.4 Pediatric Use

Safety and effectiveness of HIBERIX were established in the age group 15 through 18 months on the basis of clinical studies *[see Adverse Reactions (6.1) and Clinical Studies (14.1)]*. Safety and effectiveness of HIBERIX in the age group 19 months through 4 years are supported by evidence in children 15 through 18 months of age. Safety and effectiveness of HIBERIX in children younger than 15 months of age and in children 5 to 16 years of age have not been established.

11 DESCRIPTION

HIBERIX [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)] is a sterile, lyophilized powder which is reconstituted at the time of use with the accompanying saline diluent for intramuscular injection. HIBERIX contains Haemophilus b capsular polysaccharide (polyribosyl-ribitol-phosphate [PRP]), a high molecular weight polymer prepared from the *Haemophilus influenzae* type b strain 20,752 grown in a synthetic medium that undergoes heat inactivation and purification. The tetanus toxin, prepared from *Clostridium tetani* grown in a semi-synthetic medium, is detoxified with formaldehyde and purified. The capsular polysaccharide is covalently bound to the tetanus toxoid. After purification, the conjugate is lyophilized in the presence of lactose as a stabilizer. The diluent for HIBERIX is a sterile saline solution (0.9% sodium chloride) supplied in prefilled TIP-LOK syringes.

When HIBERIX is reconstituted with the accompanying saline diluent, each dose is formulated to contain 10 mcg of purified capsular polysaccharide conjugated to approximately 25 mcg of tetanus toxoid, 12.6 mg of lactose, and ≤0.5 mcg of residual formaldehyde.

HIBERIX does not contain preservatives.

The tip caps of the prefilled syringes may contain natural rubber latex. The rubber plungers of the prefilled syringes and the vial stoppers do not contain latex. *[See How Supplied/Storage and Handling (16).]*

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Haemophilus influenzae is a gram-negative coccobacillus. Most strains of *H. influenzae* that cause invasive disease are type b. *H. influenzae* type b can cause invasive disease such as sepsis and meningitis.

Specific levels of antibodies to polyribosyl-ribitol-phosphate (anti-PRP) have been shown to correlate with protection against invasive disease due to *H. influenzae* type b. Based on data from passive antibody studies[2] and a clinical efficacy study with unconjugated *Haemophilus* b

polysaccharide vaccine[3], an anti-PRP concentration of 0.15 mcg/mL has been accepted as a minimal protective level. Data from an efficacy study with unconjugated *Haemophilus* b polysaccharide vaccine indicate that an anti-PRP concentration of ≥1.0 mcg/mL predicts protection through at least a 1-year period.[4,5] These antibody levels have been used to evaluate the effectiveness of Haemophilus b Conjugate Vaccines, including HIBERIX.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

HIBERIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

14 CLINICAL STUDIES

14.1 Immunological Evaluation

In 6 clinical studies, the immune response to HIBERIX administered as a booster dose was evaluated in a total of 415 children 12 to 23 months of age. At the time of vaccination, 30 children were 12 to 14 months of age, 316 children were 15 to 18 months of age, and 69 children were 19 to 23 months of age. Among subjects, 43% to 60% were male. Among subjects for whom information on race/ethnicity was available, nearly all subjects were white. None of the studies included a comparator group that received a booster dose with a US-licensed Haemophilus b Conjugate Vaccine. Characteristics of 3 of these studies are presented in Table 2.

Table 2. Characteristics of 3 Open-Label Booster Immunization Studies of HIBERIX

Study	Country	Per Protocol Immunogenicity Cohort N	Priming History	Booster Vaccination With HIBERIX	
				Age at Vaccination (months)	Concomitantly Administered Vaccine[a]
1	Canada	42	DTaP-HBV-IPV[b] + Haemophilus b Conjugate Vaccine[c] at 2, 4, and 6 months of age	16-18	DTaP-HBV-IPV[b]
2	Canada	64	DTaP-IPV[d] + HIBERIX[e] at 2, 4, and 6 months of age	16-19	DTaP-IPV[d]
3	Germany	108	DTaP-HBV[f] + HIBERIX[e] at 3, 4, and 5 months of age	16-23	DTaP-HBV[f]

[a] Administered at a separate site.

[b] Non-US formulation equivalent to PEDIARIX with the exception of containing 2.5 mg 2-phenoxyethanol per dose as preservative. In the US, PEDIARIX is approved for use as a 3-dose primary series; use as a fourth consecutive dose is not approved in the US.

[c] US-licensed Haemophilus b Conjugate Vaccine manufactured by Sanofi Pasteur SA.

[d] Non-US formulation equivalent to KINRIX with the exception of containing 2.5 mg 2-phenoxyethanol per dose as preservative. In the US, KINRIX is approved for use as the fifth dose of DTaP and the fourth dose of IPV in children 4 to 6 years of age previously primed with approved dosing regimens of INFANRIX and/or PEDIARIX. The DTaP-IPV dosing regimen is not approved in the US.

[e] In the US, HIBERIX is not approved for primary immunization.

[f] Manufactured by GlaxoSmithKline Biologicals (not licensed in the US).

Antibodies to PRP were measured in sera obtained immediately prior to and 1 month after booster vaccination with HIBERIX. Geometric mean concentrations and anti-PRP seroprotection rates are presented in Table 3.

Table 3. Anti-PRP GMCs and Seroprotection Rates Prior to and 1 Month Following a Booster Dose of HIBERIX, Per Protocol Immunogenicity Cohort

Study	N	Anti-PRP GMC (mcg/mL)		% Anti-PRP ≥0.15 mcg/mL		% Anti-PRP ≥1.0 mcg/mL	
		Pre-	Post-	Pre-	Post-	Pre-	Post-
1[a]	42	0.46	59.07	76.2	100	35.7	97.6
2[b]	63-64	0.25	47.78	71.4	100	12.7	100
3[c]	108	0.59	96.12	77.8	100	32.4	100

GMC = geometric mean antibody concentration.

N = number of children for whom serological results were available for the pre- and post-dose immunological evaluations.

Studies 1, 2, and 3 correspond to Studies 1, 2, and 3, respectively in Table 2.

[a] Canadian study in children 16 to 18 months of age who previously received 3 doses of DTaP-HBV-IPV and Haemophilus b Conjugate Vaccine (manufactured by Sanofi Pasteur SA). The booster dose of HIBERIX was coadministered with DTaP-HBV-IPV (a fourth consecutive dose of PEDIARIX is not approved in the US). In this study, pre-vaccination sera may have been obtained up to 1 week prior to booster vaccination with HIBERIX.

[b] Canadian study in children 16 to 19 months of age who previously received 3 doses of DTaP-IPV and HIBERIX (not approved for primary immunization in the US). The booster dose of HIBERIX was coadministered with DTaP-IPV. The DTaP-IPV dosing regimen is not approved in the US.

[c] German study in children 16 to 23 months of age who previously received 3 doses of DTaP-HBV (GlaxoSmithKline Biologicals, not licensed in the US) and HIBERIX (not approved for primary immunization in the US). The booster dose of HIBERIX was coadministered with DTaP-HBV.

15 REFERENCES

1. Rothstein EP, Madore DV, Girone JAC, et al. Comparison of antigenuria after immunization with three *Haemophilus influenzae* type b conjugate vaccines. *Pediatr Infect Dis J* 1991;10:311-314.
2. Robbins JB, Parke JC, Schneerson R, et al. Quantitative measurement of “natural” and immunization-induced *Haemophilus influenzae* type b capsular polysaccharide antibodies. *Pediatr Res* 1973;7:103-110.
3. Peltola H, Käythy H, Sivonen A, et al. *Haemophilus influenzae* type b capsular polysaccharide vaccine in children: A double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. *Pediatrics* 1977;60:730-737.
4. Käythy H, Peltola H, Karanko V, et al. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1983;147:1100.
5. Anderson P. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1984;149:1034.

16 HOW SUPPLIED/STORAGE AND HANDLING

HIBERIX is available in single-dose vials (contains no latex) of lyophilized vaccine, accompanied by disposable prefilled TIP-LOK syringes (may contain latex) (packaged without needles) containing 0.7 mL of saline diluent. The tip caps of the needleless prefilled syringes may contain natural rubber latex.

Supplied as:

NDC 58160-806-01 Vial of lyophilized vaccine in Package of 10: NDC 58160-806-05
NDC 58160-951-02 Syringe containing diluent in Package of 10: NDC 58160-951-11

16.1 Storage Before Reconstitution

Lyophilized vaccine vials: Store refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light.

Diluent: Store refrigerated between 2° and 8°C (36° and 46°F) or at a controlled room temperature between 20° and 25°C (68° and 77°F). Do not freeze. Discard if the diluent has been frozen.

16.2 Storage After Reconstitution

HIBERIX should be administered within 24 hours of reconstitution. After reconstitution, store refrigerated between 2° and 8°C (36° and 46°F). Discard the reconstituted vaccine if not used within 24 hours. Do not freeze. Discard if the vaccine has been frozen.

17 PATIENT COUNSELING INFORMATION

Parents or guardians should be:

- informed of the potential benefits and risks of immunization with HIBERIX.
- informed about the potential for adverse reactions that have been temporally associated with administration of HIBERIX or other vaccines containing similar components.
- instructed to report any adverse events to their healthcare provider.
- given the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

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