

PRODUCT MONOGRAPH

HIBERIX

Haemophilus influenzae type b (Hib) conjugate vaccine
(Tetanus Protein – Conjugate)

Lyophilized vaccine for reconstitution

Active immunizing agent against infection by *Haemophilus influenzae* type b

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4

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HIBERIX

Haemophilus influenzae type b (Hib) conjugate vaccine

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Intramuscular Injection	Powder and diluent for injection/10 mcg of purified polyribosyl-ribitol-phosphate capsular polysaccharide of <i>Haemophilus influenzae</i> type b covalently bound to approximately 25 mcg tetanus toxoid per 0.5 mL dose.	Lactose, sodium chloride, and water for injection.

DESCRIPTION

HIBERIX (*Haemophilus influenzae* type b conjugate vaccine) is a lyophilized vaccine of purified polyribosyl-ribitol-phosphate capsular polysaccharide (PRP) of Hib, covalently bound to tetanus toxoid.

INDICATIONS AND CLINICAL USE

Pediatrics:

HIBERIX is indicated for active immunization of all infants from the age of 2 months against disease caused by Hib.

The primary vaccination schedule consists of three doses in the first 6 months of life. To ensure long-term protection, a booster is recommended in the second year of life.

Previously unvaccinated infants between the ages of 6 and 12 months should receive 2 injections one month apart, followed by a booster in the second year of life. Previously unvaccinated children aged 1-5 years should be given one dose of vaccine.

HIBERIX does not prevent against disease due to other types of *H. influenzae* nor against meningitis caused by other organisms.

CONTRAINDICATIONS

HIBERIX should not be administered to subjects with known hypersensitivity to any component of the vaccine, or to subjects having shown signs of hypersensitivity after a previous dose of this vaccine or any injection containing *Haemophilus influenzae* type b.

WARNINGS AND PRECAUTIONS

General

HIBERIX should under no circumstances be administered intravascularly.

As with any other vaccine, a protective immune response may not be elicited in all vaccinees.

Other injectable vaccines should always be administered at different injection sites with separate syringes.

As with any parenteral vaccine, appropriate medication (i.e. epinephrine 1:1000) and supervision should be readily available for immediate use in case of anaphylaxis or anaphylactoid reactions following administration of the vaccine.

As with other vaccines, the administration of HIBERIX should be postponed in subjects suffering from moderate or severe illness with or without fever. The presence of minor illnesses with or without a low grade fever are not a contraindication.

It is good clinical practice that immunization should be preceded by a review of the medical history (especially with regard to previous immunization and possible occurrence of undesirable events) and a clinical examination.

Although limited immune response to the tetanus toxoid component may occur, vaccination with HIBERIX alone does not substitute for routine tetanus vaccination.

Excretion of capsular polysaccharide antigen in the urine has been described following administration of Hib vaccines, and therefore antigen detection may not have a diagnostic value in suspected Hib disease within 1-2 weeks of vaccination.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Hematologic

As for other vaccines administered intramuscularly, HIBERIX should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.

Immune

Human Immunodeficiency Virus (HIV) infection is not considered as a contraindication for HIBERIX.

In patients receiving immunosuppressive therapy or patients with immunodeficiency, an adequate immunologic response may not be achieved.

Respiratory

Although a moderate or severe febrile illness with or without fever is a reason to defer vaccination, minor illness such as mild upper respiratory infections with or without low-grade fever are not a contraindication.

Special Populations

Pregnant Women: HIBERIX is not intended for use in adults.

Nursing Women: HIBERIX is not intended for use in adults.

Pediatrics: The potential risk of apnea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunization series to very premature infants (born \leq 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

HIBERIX is generally well tolerated.

Clinical Trial Adverse Drug Reactions

Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

The following frequencies were based on the analysis of approximately 3,000 infants enrolled in study Hib-097 and of approximately 1,200 infants enrolled in study DTPa-HBV-IPV-011.

Adverse reactions reported are listed according to the following frequency:

Very common	$\geq 1/10$
Common	$\geq 1/100$ to $< 1/10$
Uncommon	$\geq 1/1,000$ to $< 1/100$
Rare	$\geq 1/10,000$ to $< 1/1,000$
Very rare	$< 1/10,000$

Metabolism and nutrition disorders

Very common: loss of appetite

Psychiatric disorders

Very common: crying, irritability, restlessness

Nervous system disorders

Very common: somnolence

Rare: convulsions (including febrile convulsions)

Gastrointestinal disorders

Very common: diarrhea

Common: vomiting

General disorders and administration site conditions

Very common: fever, swelling, pain and redness at the injection site

Post-Market Adverse Drug Reactions

Undesirable effects reported are listed below (frequency is very rare, i.e., $< 1/10,000$).

Immune system disorders: Allergic reactions (including anaphylactic and anaphylactoid reactions), angioedema.

Nervous system disorders: Hypotonic-hyporesponsive episode, syncope or vasovagal responses to injection.

Respiratory, thoracic and mediastinal disorders: Apnea (see WARNINGS AND PRECAUTIONS for apnea in very premature infants (≤ 28 weeks of gestation)).

Skin and subcutaneous tissue disorders: Urticaria, rash.

General disorders and administration site conditions: Extensive swelling of vaccinated limb, injection site induration.

DRUG INTERACTIONS

Drug-Drug Interactions

HIBERIX can be administered either simultaneously or at any time before or after diphtheria-tetanus-acellular pertussis vaccine (DTaP), diphtheria-tetanus-whole cell pertussis vaccine (DTPw), inactivated polio vaccine (IPV), or measles, mumps, rubella, hepatitis B, pneumococcal or meningococcal vaccines or ROTARIX at different injection sites with separate syringes.

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Interactions with herbal products have not been established.

Drug-Laboratory Interactions

Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Recommended Dose

As recommended by the Canadian Immunization Guide, primary immunization consists of three intramuscular injections of 0.5 mL of vaccine. The first three doses, starting at 2 months of age, are given at 2 month intervals between doses. To ensure long term protection, a booster dose is recommended at 15 to 18 months of age.

Infants between the ages of 6 and 12 months previously unvaccinated should receive 2 injections, given with an interval of one month, followed by a booster in the second year of life. Previously unvaccinated children aged 1-5 years should be given one dose of vaccine.

Children in whom invasive Hib disease develops before 24 months of age should still receive vaccine as recommended, since such children may not have adequate antibody levels after natural disease.

HIBERIX can be mixed in the same syringe with INFANRIX-IPV (diphtheria, tetanus, pertussis and inactivated poliomyelitis vaccine).

HIBERIX should not be mixed with other vaccines in the same syringe except for authorised combinations.

Missed Dose

Interruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved with HIBERIX. There is no need to start the series over again regardless of the time elapsed between doses.

Administration

The diluent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to reconstitution or administration. In the event of either being observed, do not use the diluent or the reconstituted vaccine.

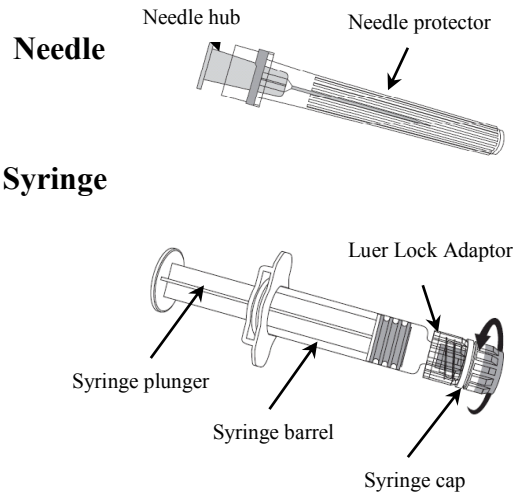
The vastus lateralis (mid-thigh laterally) is the preferred site of injection in infants. The deltoid muscle should be used as the injection site in children when the muscle has developed sufficiently to accommodate the vaccine. The site of injection should be prepared with a suitable antiseptic. **Do not inject intravascularly or subcutaneously.** However, it is good clinical practice that in patients with thrombocytopenia or bleeding disorders the vaccine should be administered subcutaneously.

Instructions for reconstitution of the vaccine

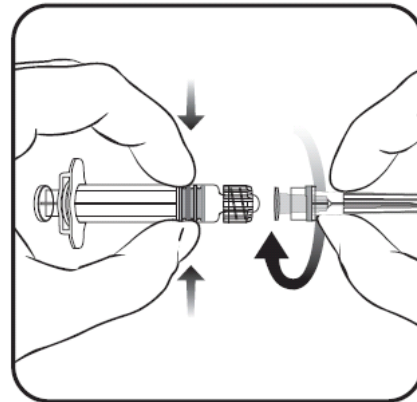
HIBERIX must be reconstituted by adding the entire contents of the pre-filled syringe of diluent to the vial containing the powder.

To attach the needle to the syringe, carefully read the instructions given with pictures 1 and 2.

Note: However, the syringe provided with HIBERIX might be slightly different (without screw thread) than the syringe illustrated. In that case, the needle should be attached without screwing.



Picture 1



Picture 2

Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock Adaptor (LLA), and maintain the needle in the axis of the syringe (as illustrated in picture 2). Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1).
2. Attach the needle to the syringe by gently connecting the needle hub into the LLA and rotate a quarter turn clockwise until you feel it lock (as illustrated in picture 2).
3. Remove the needle protector, which may be stiff.
4. Add the diluent to the powder. The mixture should be well shaken until the powder is completely dissolved in the diluent.

The reconstituted vaccine is a clear to opalescent and colourless solution.

After reconstitution, the vaccine should be used promptly.

5. Withdraw the entire contents of the vial.
6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the injection needle by repeating step 2.

As stated in section “**Recommended Dose**” above, HIBERIX can be mixed in the same syringe with INFANRIX-IPV (diphtheria, tetanus, pertussis and inactivated poliomyelitis vaccine). In this case, the diluent supplied in the HIBERIX package is replaced by the

liquid vaccine.

Make sure the container of the vaccine intended for mixing with HIBERIX is a monodose container. From the HIBERIX package, discard the pre-filled syringe containing the diluent.

The combined vaccine must be reconstituted by adding the entire contents of the other vaccine container to the vial containing the Hib white powder.

This extemporaneously combined vaccine should be handled in the same way as the monocomponent reconstituted HIBERIX vaccine.

Any unused product or waste material should be disposed of in accordance with local requirements.

OVERDOSAGE

In general, the adverse event profile reported following overdose was similar to that observed after administration of the recommended dose of HIBERIX.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

In the 1980s, prior to the widespread use of Hib vaccines, *Haemophilus influenzae* type b was a leading cause of invasive bacterial infection world-wide among infants and children less than 5 years. This included, in particular meningitis, pneumonia and epiglottitis. Without treatment, the mortality from *H. influenzae* disease is extremely high. Vaccines consisting of polyribosyl-ribitol-phosphate (PRP), the major surface polysaccharide of the type b bacteria conjugated to tetanus toxoid as a carrier protein, have been developed and have been shown to prevent invasive disease. Their widespread use has been associated with a decrease in the incidence of invasive Hib disease.

STORAGE AND STABILITY

The lyophilized Hib vaccine must be stored at 2°C to 8°C. The lyophilized vaccine is not affected by freezing. Do not use beyond the expiry date printed on the label.

The sterile diluent can be stored in the refrigerator (2°C to 8°C) or at ambient temperatures (up to 25°C). **DO NOT FREEZE DILUENT.**

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms

HIBERIX is supplied as a lyophilized white powder in a glass vial. The 0.5 mL sterile diluent (saline) is clear and colourless and is presented in a prefilled syringe.

Glass vials and prefilled syringes are made of neutral glass type 1, which conforms to European Pharmacopoeia Requirements.

Composition

HIBERIX (single 0.5 mL dose) contains 10 mcg of purified polyribosyl-ribitol-phosphate capsular polysaccharide of Hib, covalently bound to approximately 25 mcg tetanus toxoid. It also contains lactose, sodium chloride and water for injection.

Packaging

HIBERIX is available as a Monopack (1 vaccine dose per pack: 1 vial of lyophilized vaccine/1 prefilled syringe with diluent).

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: *Haemophilus influenzae* type b (Hib) conjugate vaccine

Product Characteristics

HIBERIX (*H. influenzae* type b conjugate vaccine) is a lyophilized vaccine of purified polyribosyl-ribitol-phosphate capsular polysaccharide (PRP) of Hib, covalently bound to tetanus toxoid.

The Hib polysaccharide is prepared from Hib, strain 20,752 and after activation with cyanogen bromide and derivatisation with an adipic hydrazide spacer is coupled to tetanus toxoid via carbodiimide condensation. After purification the conjugate is lyophilized in the presence of lactose as stabilizer.

HIBERIX meets WHO requirements for manufacture of biological substances and of Hib conjugated vaccines.

CLINICAL TRIALS

Study results

A titre of 0.15 mcg/mL was obtained in 95-100% of infants one month after the completion of the primary vaccination course. A titre of 0.15 mcg/mL was obtained in 100% of infants one month after the booster dose (94.7% with a titre of 10 mcg/mL).

DETAILED PHARMACOLOGY

Not applicable

MICROBIOLOGY

Not applicable

TOXICOLOGY

Not applicable

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PART III: CONSUMER INFORMATION**HIBERIX**

Haemophilus influenzae type b (Hib) conjugate vaccine

This leaflet is Part III of a three-part "Product Monograph" published when HIBERIX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HIBERIX. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE**What the vaccine is used for:**

HIBERIX is a vaccine used to protect your child against disease caused by *Haemophilus influenzae* type b (Hib).

Vaccination is the best way to protect against these diseases.

Haemophilus influenzae type b can cause swelling (inflammation). This can lead to serious problems such as: mental slowness (retardation), cerebral palsy, deafness, epilepsy or partial blindness. It can also cause swelling of the throat. This can cause death by suffocation. Less commonly, the bacteria can also infect the blood, heart, lungs, bones, joints and tissues of the eyes and mouth.

HIBERIX is for infants and children from 8 weeks of age.

What it does:

HIBERIX works by helping the body make its own protection (antibodies) which protect your child against these diseases.

As with all vaccines, HIBERIX may not fully protect all children who are vaccinated.

HIBERIX will only protect against infections caused by the *Haemophilus influenzae* type b for which the vaccine has been developed.

Children with a weakened immune system (such as due to HIV infection) may not get the full benefit from HIBERIX.

When it should not be used:

HIBERIX should not be used:

- in children with known allergy to any component of the vaccine (see "What the nonmedicinal ingredients are" section) or children having shown signs of an allergic reaction after a previous dose of this vaccine or any injection containing *Haemophilus influenzae* type b. Signs of an allergic reaction may include shortness of breath and swelling of the face or tongue.

- if your child has an infection or a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.

What the medicinal ingredient is:

HIBERIX contains conjugated *Haemophilus influenzae* type b.

None of the components in the vaccine are infectious. You cannot get the diseases from the HIBERIX vaccine.

What the nonmedicinal ingredients are:

Lactose, sodium chloride and water for injection.

What dosage forms it comes in:

HIBERIX is supplied as a powder in a vial and a diluent (liquid) in a pre-filled syringe. The powder is white and the diluent is clear and colourless.

The 2 components are mixed together before they are given to your child.

WARNINGS AND PRECAUTIONS

BEFORE you use HIBERIX talk to your doctor or pharmacist if:

- your child has a bleeding problem or bruises easily. HIBERIX should be given with caution since bleeding may occur following vaccination.
- your child has an infection, or a temperature over 38°C, or both.
- your child has any known allergies.
- your child is taking or has recently taken any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.
- your child is taking any medicines or has an infection that affect the immune system (the body's natural defence system) since your child may not get the full benefit from HIBERIX.
- your child has any serious health problem.
- your child has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).

Fainting can occur following, or even before, any needle injection; therefore, tell the doctor or nurse if your child fainted with a previous injection.

INTERACTIONS WITH THIS VACCINE

HIBERIX can be given at the same time as other childhood vaccines. A different place for the injection will be used for each vaccine.

PROPER USE OF THIS VACCINE

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Usual dose:

Your child will receive a total of 4 injections. Each injection will be given intramuscularly (into a muscle) at 2, 4 and 6 months of age. A booster should be given at 15 to 18 months.

Missed Dose:

If your child misses a scheduled injection, talk to your doctor and arrange another visit.

Make sure your child finishes the complete vaccination course. If not, your child may not be fully protected against infection.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all vaccines, HIBERIX can cause side effects, although not everybody gets them.

Side effects that occurred during clinical trials with HIBERIX were as follows:

Allergic reactions

As with all injectable vaccines, your child may experience an allergic reaction. Allergic reactions are **very rare** (these may occur with up to 1 in 10,000 doses of the vaccine). The signs of an allergic reaction may include: skin rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness.

These signs usually start very soon after the injection has been given. Take your child to see a doctor straight away if they happen after leaving the clinic.

Children who receive HIBERIX may occasionally have:

Very common (these may occur with more than 1 in 10 doses of the vaccine): irritability, feeling sleepy, fever, swelling, pain and redness at the injection site, loss of appetite, crying, restlessness, diarrhea.

Common (these may occur with up to 1 in 10 doses of the vaccine): vomiting.

Rare (these may occur with up to 1 in 1000 doses of the vaccine): fits (including fits due to fever).

Additionally, side effects not observed in clinical trials but reported after commercialisation of HIBERIX include:

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine): fainting due to injection, collapse (sudden onset of muscle floppiness), periods of unconsciousness or lack of awareness, and paleness or bluish skin discoloration, temporarily stopping breathing, hives, rash, large swelling of the injected limb, hard lump at the injection site.

Tell your doctor as soon as possible if:

- Any of the common and very common conditions above persists or worsens.
- Your child develops any rare and/or very rare symptoms within days following the vaccination.
- If you noticed any side effects not mentioned in this leaflet.

Do not be alarmed by this list of possible side effects. It is possible that your child will have no side effects from vaccination.

This is not a complete list of side effects. For any unexpected effects while taking HIBERIX, contact your doctor or pharmacist.

HOW TO STORE IT

Store HIBERIX at 2° to 8°C. **Do not freeze.** Discard if the vaccine has been frozen. Store in the original package in order to protect from light.

After reconstitution immediate use is recommended.

Do not use after expiration date shown on the label. The date for last use corresponds to the last day of the month mentioned.

Store all vaccines out of the reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: 1-866-844-0018

By toll-free fax: 1-866-844-5931

By email: caefi@phac-aspc.gc.ca

At the following website:

<http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

By regular mail:

The Public Health Agency of Canada

Vaccine Safety Section

130 Colonnade Road

Ottawa, Ontario

K1A 0K9 Address Locator 6502A

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

This document plus the full HIBERIX product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca> or by contacting the sponsor, GlaxoSmithKline Inc.

7333 Mississauga Road

Mississauga, Ontario

L5N 6L4

1-800-387-7374

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