

DATA SHEET

Name of Medicinal Product

Hiberix®
Haemophilus influenzae type b (Hib) vaccine.

Presentation

Hiberix is a lyophilised vaccine of purified polyribosyl-ribitol-phosphate capsular polysaccharide (PRP) of Hib, covalently bound to tetanus toxoid.

Each single dose of vaccine is formulated to contain 10 mcg of purified capsular polysaccharide covalently bound to approximately 30 mcg tetanus toxoid.

Pharmaceutical form

Powder and solvent for solution for injection.

Uses

Indications

Hiberix is indicated for active immunisation of all infants from the age of 6 weeks against disease caused by Hib.

Hiberix does not protect against diseases due to other types of *H. influenzae*, nor against meningitis caused by other organisms.

Actions

Not applicable.

Dosage and administration

Posology

The primary vaccination schedule consists of three doses in the first 6 months of life and can start from the age of six weeks. To ensure a long-term protection, a booster dose is recommended in the second year of life.

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.

Method of administration

The reconstituted vaccine is for intramuscular injection. However, it is good clinical practice that in patients with thrombocytopenia or bleeding disorders the vaccine should be administered subcutaneously.

Contra-indications

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 previous administration of Hib vaccines.

Special warnings and special precautions for use

As with other vaccines, the administration of Hiberix should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, however, is not a contra-indication for vaccination.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Human Immunodeficiency Virus (HIV) infection is not considered as a contra-indication for Hiberix.

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 receipt of Hib vaccines, and therefore antigen detection may not have a diagnostic value in suspected Hib disease within 1-2 weeks of vaccination.

Hiberix should under no circumstances be administered intravenously.

The potential risk of apnoea and the need for respiratory monitoring for 48 to 72 hours 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.

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.

Interaction with other medicaments and other forms of interaction

Hiberix can be administered either simultaneously or at any time before or after a different inactivated or live vaccine.

Hiberix can be mixed in the same syringe with GlaxoSmithKline vaccine Infanrix[®] (DTPa vaccine). Other injectable vaccines should always be administered at different injection sites.

As with other vaccines it may be expected that in patients receiving immunosuppressive therapy or patients with immunodeficiency, an adequate response may not be achieved.

Pregnancy and lactation

Pregnancy

Adequate human data on use during pregnancy and adequate animal reproduction studies are not available.

Lactation

Adequate human data on use during lactation and adequate animal reproduction studies are not available.

Effects on ability to drive and use machines

Not applicable.

Adverse effects

In controlled clinical studies, signs and symptoms were actively monitored and recorded on diary cards following the administration of the vaccine.

Of the local solicited symptoms the most frequently reported within the first 48 hours was mild redness at the injection site which resolved spontaneously. Other local solicited symptoms reported were mild swelling and pain at the injection site.

The general symptoms which have been solicited and reported within the first 48 hours were mild and resolved spontaneously. These include fever, loss of appetite, restlessness, vomiting, diarrhoea and unusual crying. As for all Hib vaccines, these general symptoms have been also reported when administered concomitantly with other vaccines.

Post Marketing Data

Undesirable effects reported are listed according to the following frequency:
Very rare <1/10000

Immune system disorders

Very rare: allergic reactions (including anaphylactic and anaphylactoid reactions), angioedema

Nervous system disorders

Very rare: hypotonic-hyporesponsive episode, convulsion (with or without fever), syncope or vasovagal responses to injection, somnolence

Respiratory, thoracic and mediastinal disorders

Very rare: apnoea [see "Special warnings and Special Precautions for use"]

Skin and subcutaneous tissue disorders

Very rare: urticaria, rash

General disorders and administration site conditions

Very rare: extensive swelling of vaccinated limb, injection site induration

Overdose

Not applicable.

Pharmacological properties

Pharmacodynamic properties

A titre of ≥ 0.15 mcg/ml was obtained in 95-100% of infants one month after the completion of the 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 ≥ 1.0 mcg/ml).

Pharmacokinetics

Evaluation of pharmacokinetic properties is not required for vaccines.

Pharmaceutical precautions

Not applicable.

List of excipients

Vaccine : lactose

Diluent : sterile saline solution

Incompatibilities

Hiberix can be mixed in the same syringe with GlaxoSmithKline vaccine Infanrix[®] (DTPa vaccine)). Other injectable vaccines should always be administered at different injection sites.

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

Shelf-life

The expiry date of the vaccine is indicated on the label and packaging.

When stored under prescribed conditions, the shelf-life is 36 months.

Special precautions for storage

The lyophilised vaccine has to be stored at +2°C to +8°C. The lyophilised vaccine is not affected by freezing.

The diluent can be stored in the refrigerator (at +2°C to +8°C) or at ambient temperatures (up to 25°C) and should not be frozen.

Nature and contents of container

The lyophilised vaccine is presented as a white pellet in a glass vial.

The sterile diluent (saline) is clear and colourless and presented in a glass vial or prefilled syringe.

The vials and syringes are made of neutral glass type I, which conforms to European Pharmacopoeia Requirements.

Instructions for use/handling

The diluent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied container of diluent to the vial containing the pellet. After the addition of the diluent to

the pellet, the mixture should be well shaken until the pellet is completely dissolved in the diluent.

After reconstitution, the vaccine should be injected promptly.

Hiberix™ may be mixed with Infanrix® vaccine. In this case, the diluent supplied in the Hiberix package is replaced by the liquid vaccine.

Other Information

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 lyophilised in the presence of lactose as stabiliser.

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

Medicine Classification

Prescription Medicine

Package Quantities

Pack of one vial of lyophilised vaccine and one vial of diluent

Pack of one vial of lyophilised vaccine and one pre-filled syringe of diluent

Pack of 10 vials of lyophilised vaccine and 10 pre-filled syringes of diluent

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