

HIBERIX®

Haemophilus influenzae type b (Hib) vaccine

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some of the common questions about HIBERIX vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of your child having HIBERIX against the expected benefits.

If you have any concerns about your child receiving HIBERIX talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again.

What is HIBERIX used for?

HIBERIX is a non-infectious vaccine used to prevent *Haemophilus influenzae type b* (Hib) infection in children aged 2 months to 5 years. The vaccine works by causing the body to produce its own protection (antibodies) against the disease.

Haemophilus influenzae type b is a bacteria that can cause serious life-threatening illness. Hib infection most frequently causes brain inflammation (swelling), which is generally seen in infants under 18 months of age. The death rate is 5-10% of infants in this age group. In 15-30% of surviving infants there will be some type of serious complication such as: mental retardation, cerebral palsy, deafness, epilepsy or partial blindness. Hib infection also causes inflammation of the throat, which is mostly seen in children over 18 months of age. It occasionally causes death by suffocation. Less commonly, the bacteria can also infect the blood, heart, lungs, bones, joints, and tissues of the eyes and mouth.

Vaccination is the best way to protect against Hib infection. HIBERIX vaccine is not infectious, and cannot give your child Hib infection. The vaccine will not protect against diseases caused by other types of bacteria or organisms.

Before vaccination

HIBERIX SHOULD NOT BE GIVEN IF:

- your child has had an allergic reaction to HIBERIX, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- If your child had HIBERIX before and became unwell, tell your doctor or nurse before the vaccine is given.
- your child has had an allergic reaction to any other *Haemophilus influenzae type b* vaccine. (ie. HibTITER and PedvaxHIB)
- your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before vaccination
- the expiry date printed on the pack has passed

- the packaging is torn or shows signs of tampering.

If you are not sure whether your child should have HIBERIX, talk to your doctor or nurse. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for your child.

BEFORE HIBERIX IS GIVEN TELL YOUR DOCTOR OR NURSE IF:

- your child has any medical conditions, such as an immune deficiency condition or a bleeding problem. HIBERIX may need to be given differently in children with bleeding problems.
- your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- your child has received another vaccine, or is having any prescription or OTC (over-the-counter) medicines. In particular, mention if your child is being given medicines which suppress the immune system, such as high-dose steroids or cyclosporin.

Some vaccines may be affected by other vaccines or medicines. Your doctor, nurse or pharmacist will be able to tell you what to do if HIBERIX is to be given with another vaccine or medicine.

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

How HIBERIX is given

The doctor or nurse will give HIBERIX as an injection. If you have any concerns about how this vaccine is to be given, talk to your doctor or pharmacist.

HOW MUCH IS GIVEN

The dose of HIBERIX is 0.5mL.

HOW IS IT GIVEN

HIBERIX will be injected into the upper leg muscle in infants under 12 months of age. In children over 12 months of age the injection will be given in the upper arm muscle. For some children with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should never be given intravenously (into a vein).

HOW OFTEN IS IT GIVEN

HIBERIX is generally given as a total of three doses over 6 months. Each dose is given on a separate visit. The first dose will be given when the child is 2 months of age. The remaining two doses will be given at 4 months, and 6 months of age.

- First dose: 2 months of age
- Second dose: 4 months of age
- Third dose: 6 months of age.

It is important to return at the recommended times for follow up doses.

To ensure long term protection a booster dose is generally given in the second year of life.

IF A DOSE IS MISSED

If your child misses a scheduled dose, talk to your doctor or nurse and arrange another visit as soon as possible.

While you are taking HIBERIX

THINGS YOU MUST DO:

Keep your child's follow up visits with the doctor, nurse or clinic. It is important the 2 follow-up doses of HIBERIX are given at the correct times. This will ensure the best effect of the vaccine in protecting your child against Hib infection.

What are the side effects?

Tell your doctor or nurse as soon as possible if your child does not feel or look well during or after having had a dose of HIBERIX.

HIBERIX helps protect most children from Hib infection, but it may have unwanted side effects in a few children. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Like other vaccines, most unwanted effects with HIBERIX are mild and usually clear up within a few days.

MILD EFFECTS

Tell your doctor if your child has any of the following that are troublesome or ongoing:

- pain, redness or swelling around the injection site
- restlessness, unusual crying, sleeplessness or tiredness
- loss of appetite, vomiting or diarrhoea
- fever, cough, runny nose or symptoms of a cold
- irritability
- skin rash or bruising.
- if 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).

Other events that have been reported with HIBERIX include:

- fainting due to injection
- feeling sleepy
- temporarily stopping breathing
- hives, rash
- large swelling of the injected limb
- hard lump at the injection site

MORE SERIOUS EFFECTS

As with all vaccines given by injection there is a very small risk of serious allergic reaction. Contact your doctor immediately or take your child to the casualty department of your nearest hospital if any of the following happens:

- fits (including fits due to fever)
- swelling of limbs, face, eyes, inside of nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties
- hives, itching (especially of the hands or feet), reddening of skin (especially around the ears) or severe skin reactions

- unusual tiredness or weakness that is sudden and severe
- Collapse (sudden onset of muscled floppiness), periods of unconsciousness or lack of awareness, and paleness or bluish skin discolouration
- Allergy to HIBERIX is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other side effects not listed above, can also occur during or soon after a dose of HIBERIX.

Check with your doctor if your child has any other effects.

Do not be alarmed by this list of possible side effects. Your child may not experience any of them.

How do I store HIBERIX?

HIBERIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store HIBERIX always:

- Keep HIBERIX in the refrigerator stored between 2°C and 8°C. DO NOT FREEZE.
- Keep the vaccine out of the reach of children.
- Keep HIBERIX in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over HIBERIX that has expired or has not been used.

Product description

WHAT IT LOOKS LIKE

HIBERIX comes as a white powder in a glass vial, with a sterile saline diluent presented in a prefilled syringe.

INGREDIENTS:

The active ingredient of HIBERIX is a non-infectious extract from Haemophilus influenzae type b bacteria bound to tetanus toxoid. Each 0.5 mL dose contains:

- 10 mcg of Haemophilus influenzae type b polysaccharide conjugated to approximately 25 mcg tetanus toxoid as a carrier protein.

The inactive ingredients in the vaccine are: lactose, sodium chloride (salt), and water.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

HIBERIX is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street,
Abbotsford, Victoria, 3067

Where to go for further information

HIBERIX is only available if prescribed by a doctor.

This leaflet was prepared on 28 April 2016

The information provided applies only to: HIBERIX®.

HIBERIX is a registered trade mark of the GSK group of companies.

HIBERIX comes as single or 10 dose packs containing:

a white powder in a glass vial and the diluent in a prefilled syringe (AUST R 60881).

Version 5.0

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