

HIBERIX

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I receiving HIBERIX?

HIBERIX is used to prevent Haemophilus influenzae type b (Hib) infection in children aged 2 months to 5 years. HIBERIX contains a non-infectious extract from Haemophilus influenzae type b bacteria bound to tetanus toxoid as the active ingredient. For more information, see Section [1. Why am I receiving HIBERIX?](#) in the full CMI.

2. What should I know before I receive HIBERIX?

Do not use if your child has ever had an allergic reaction to HIBERIX, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if your child has any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I receive HIBERIX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HIBERIX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is HIBERIX given?

Your doctor or nurse will give you HIBERIX as an injection (dose of 0.5 mL) generally given as a total of three doses at 2, 4 and 6 months of age. A booster dose is recommended at 12 months of age to ensure long term protection.

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

More instructions can be found in Section [4. How is HIBERIX given?](#) in the full CMI.

5. What should I know after receiving HIBERIX?

Things you should do	<ul style="list-style-type: none">Keep a record of your immunisation history.
Looking after your medicine	<ul style="list-style-type: none">HIBERIX will normally be stored at the doctor's surgery or in the pharmacy.If you need to store HIBERIX, keep it in the original box in the refrigerator between 2°C and 8°C. Do not freeze.

For more information, see Section [5. What should I know after receiving HIBERIX?](#) in the full CMI.

6. Are there any side effects?

Side effects which have been reported following administration of HIBERIX include pain, redness, 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, breathing difficulties, fainting due to injection, feeling sleepy, temporarily stopping breathing, hives, rash, large swelling of the injected limb and hard lump at the injection site.

Allergic reactions have also occurred following administration of HIBERIX. Allergy is rare and severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HIBERIX

Active ingredient(s): *inactivated* Haemophilus influenzae type b (Hib) bacteria bound to tetanus toxoid

Consumer Medicine Information (CMI)

This leaflet provides important information about using HIBERIX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using HIBERIX.**

Where to find information in this leaflet:

1. [Why am I receiving HIBERIX?](#)
2. [What should I know before I receive HIBERIX?](#)
3. [What if I am taking other medicines?](#)
4. [How is HIBERIX given?](#)
5. [What should I know after receiving HIBERIX?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I receiving HIBERIX?

HIBERIX is a non-infectious vaccine used to prevent Haemophilus influenzae type b (Hib) infection in children aged 2 months to 5 years.

HIBERIX contains *inactivated* Haemophilus influenzae type b (Hib) bacteria bound to tetanus toxoid as the active ingredient.

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. Hib can cause invasive diseases in young children and people who are immunocompromised. The case-fatality rate for Hib meningitis is between 3% and 6%. Up to 30% of individuals who survive Hib disease have permanent neurological conditions. 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.

2. What should I know before I receive HIBERIX?

Warnings

Do not receive HIBERIX 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.

- 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.
- your child has a severe infection with a high temperature. Your doctor may decide to delay vaccination with HIBERIX until the illness has passed. A minor infection such as a cold is not usually a reason to delay vaccination but talk to your doctor or nurse about this before being vaccinated.
- 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.

Check with your doctor if your child:

- 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.

You may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Fainting

Fainting can occur following, or even before, any needle injection. Tell the person giving you your injection if you or your child have ever fainted with a previous injection.

3. What if I am taking other medicines?

Tell your doctor or nurse if your child is taking any other medicines, including any medicines, vaccines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and vaccines may interfere with HIBERIX and affect how it works.

- steroids, ciclosporin – medicines used to suppress the immune system

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect HIBERIX.

4. How is HIBERIX given?

How much is given

- Your doctor or nurse will give you HIBERIX as an injection.
- The dose of HIBERIX is 0.5 mL.

How it is 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).

When is it given

Your doctor or nurse will give your child a HIBERIX as an injection (dose of 0.5mL) at 2, 4 and 6 months of age. Each dose is given on a separate visit.

- 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.

If you are given too much HIBERIX

If you think that you have been given too much HIBERIX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after receiving HIBERIX?

Things you should do

- keep a record of your vaccination history

Looking after your medicine

- HIBERIX will usually be stored at the doctor's clinic or at the pharmacy.
- If you need to store HIBERIX it is important to keep it in the refrigerator between 2°C and 8°C.
- Keep HIBERIX in the original pack until it is time for it to be given.
- **DO NOT FREEZE HIBERIX. FREEZING THIS MEDICINE WILL DESTROY THE VACCINE.**

Follow the instructions on the carton on how to take care of your medicine properly.

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

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

6. Are there any side effects?

All medicines and vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

HIBERIX helps protect most children from Hib infection, but it may have unwanted side effects in a few children.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Most side effects with HIBERIX are mild and usually clear up within a few days. These effects, as with other vaccines, usually occur around the injection site.

Less serious side effects

Less serious side effects	What to do
<p>Skin-related</p> <ul style="list-style-type: none"> • pain, redness or swelling around the injection site • skin rash or bruising • large swelling of the injected limb • hard lump at the injection site <p>Respiratory</p> <ul style="list-style-type: none"> • Fever • Cough, runny nose or symptoms of a cold <p>Gastrointestinal</p> <ul style="list-style-type: none"> • loss of appetite, vomiting or diarrhoea <p>General</p> <ul style="list-style-type: none"> • restlessness, unusual crying, sleeplessness or tiredness • irritability • fainting due to injection • feeling sleepy 	<p>Speak to your doctor if your child has any of these less serious side effects that are troublesome or ongoing and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Respiratory</p> <ul style="list-style-type: none"> • temporarily stopping breathing • 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). <p>Skin-related</p> <ul style="list-style-type: none"> • hives, rash <p>Allergic Reactions</p> <ul style="list-style-type: none"> • 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 muscle floppiness), periods of unconsciousness or lack of awareness, and paleness or bluish skin discolouration <p>Allergy to HIBERIX is rare. Severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What HIBERIX contains

Active ingredient (main ingredient)	10 mcg of Haemophilus influenzae type b polysaccharide conjugated to approximately 25 mcg tetanus toxoid as a carrier protein.
Other ingredients (inactive ingredients)	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 (Variant Creutzfeldt-Jakob disease- considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

Do not take this medicine if you are allergic to any of these ingredients.

What HIBERIX looks like

HIBERIX comes as single or 10 dose packs containing: a white powder in a glass vial, with a sterile saline diluent presented in a prefilled syringe (AUST R 60881).

Who distributes HIBERIX

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

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