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
do 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 influenza 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
disesases 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 unless the 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

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• 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).