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Package leaflet: Information for the user

Hiberix Haemophilus Type b (Hib) vaccine
Powder and Solvent for Solution for Injection

Read all of this leaflet carefully before your child receives/you receive this vaccine as it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for your child/you only. Do not pass it on to others. It may harm them.
- If you get any side-effects talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hiberix is and what it is used for

Hiberix is a vaccine that can be given to children after the age of 2 months to prevent infectious diseases caused by *Haemophilus influenzae* type b (Hib) bacteria. The vaccine works by causing the body to produce its own protection (antibodies) against these bacteria. The vaccine cannot cause Hib.

***Haemophilus influenzae* type b (Hib):** Hib bacteria most frequently cause meningitis (inflammation of the coverings of the brain and spinal cord). Even after recovery from Hib meningitis there can be complications such as mental retardation, spastic paralysis, deafness or epilepsy. Hib infection can also cause a life-threatening inflammation of the throat with severe swelling that can cause suffocation. Less commonly, the bacteria can infect other parts of the body, particularly the lungs (causing pneumonia) and the bones and joints.

Vaccination is the best way to protect against diseases caused by Hib. Remember, however, that no vaccine can provide complete, life-long protection in all people vaccinated. Also, Hiberix can only protect against meningitis and other infections caused by *Haemophilus influenzae* type b (Hib). It cannot protect against meningitis caused by other bacteria or viruses, including other types and groups of Haemophilus bacteria.

The national introduction in 1992 of *Haemophilus Influenzae* type b vaccine for young children has started to reduce the number of cases of the illness. It is important for the child to be vaccinated to keep up the decrease in the number of cases reported.

2. What you need to know before your child receives/you receive Hiberix

Do not take Hiberix:

- if your child has/you have previously had any allergic reaction to Hiberix, to any Hib vaccine, to tetanus toxoid or to any other ingredient present in the vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- if your child has/you have a high temperature (38°C or above) or a severe infection. It is usual to wait until the child is/you are better before giving the vaccine. A minor infection such as a cold should not be a problem but talk to your doctor or nurse first.
- if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Remember that the first dose of Hiberix should not be given before your child is 2 months of age.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before receiving Hiberix
- if your child has/you have a bleeding problem or he/she bruises/you bruise easily.
- if your child takes/you take medicines or has any treatment which may affect the immune system. Also, if your child has/you have HIV infection or any other illness that can reduce his/her/your immunity to infections. Your child/you can still be given Hiberix if your doctor or nurse advises it but your child/you may not develop as good protection against Hib infections as other recipients of Hiberix.

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

In the first 1-2 weeks after a dose of Hiberix it is possible that urine tests to detect Hib infection could give the wrong (false positive) results.

Other medicines and Hiberix

Tell your doctor if your child is taking, has recently taken or might take/you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.

Hiberix can be given at the same time or at any time before or after different inactivated or live vaccines. Any other vaccines that are given at the same time as Hiberix will be injected separately at different parts of the body.

Although Hiberix contains tetanus toxoid (inactivated bacterial toxin), which is used to immunise people against tetanus (lockjaw), it is still necessary that your child should receive the recommended childhood vaccinations against tetanus.

Pregnancy, breast-feeding and fertility

Do not take this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. If pregnancy occurs during the course of vaccination your doctor should be consulted.

Driving and using machines

Hiberix is not likely to affect your ability to drive or use machines. However, do not drive or use any machines if you are feeling unwell.

Hiberix contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

3. How Hiberix is given

Each dose of Hiberix is a single injection of half a millilitre (0.5 ml). The nurse or doctor will give Hiberix as an injection into the muscle and will make sure that the vaccine is not given into a blood vessel. If your child has/you have a bleeding problem or he/she bruises/you bruise easily, the nurse or doctor may give Hiberix into the upper layer of the skin.

<u>If Hiberix is used in infants for the first vaccinations against Hib:</u>

Your child will receive three doses of Hiberix. The first dose should not be given before the age of 2 months and there should be a gap of two months between injections.

If your child is over the age of 13 month and has not previously received Hib vaccine, one dose of Hiberix is recommended.

<u>If Hiberix is used to boost protection against Hib:</u>

After the first course of vaccinations against Hib has been completed a booster dose of Hib should be given, if this is in accordance with official recommendations.

If your child receives/you receive more Hiberix than he/she/you should
It is very unlikely that your child/you will receive too much or too little vaccine because each dose is provided in a separate vial and the vaccine is given by a doctor or nurse. If you are concerned about the dose or doses that have been given, please talk to your doctor or nurse.

If you forget to take your child for vaccination with Hiberix
Your doctor or nurse will advise when your child should attend for these injections. If you miss an appointment, it is very important that you contact the surgery or clinic and make a new appointment for your child to have the missed dose or doses as soon as possible.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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, face, mouth
- difficulty in breathing or swallowing
- a sudden drop in blood pressure
- loss of consciousness.

These signs usually start very soon after the injection has been given. See a doctor straight away if they happen after leaving the clinic.

See your doctor straight away if your child has/you have any of the following serious side effects:
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
- diarrhoea

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)

Side effects not observed in clinical trials but reported after commercialisation of Hiberix include:
Very rare (may occur with up to 1 in 10,000 doses of 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, skin rash present on one or several areas, or all over the body
- large swelling of the injected limb
- hard lump at the injection site

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website:www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hiberix

Keep out of the sight and reach of children.

Do not use Hiberix after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hiberix contains

- The active substances are:

Haemophilus type b polysaccharide (polyribosyl-ribitol phosphate)	10 micrograms
conjugated to tetanus toxoid as carrier protein	approximately 25 micrograms

- The other ingredients are:

Powder: lactose
Solvent: sodium chloride, water for injections

What Hiberix looks like and contents of the pack
Hiberix is supplied as a white powder of Hib vaccine in a glass vial, together with half a millilitre (0.5 ml) of clear colourless solvent (0.9 % sodium chloride) in a pre-filled syringe for a 1 dose vaccine. This powder is dissolved in the solvent provided, just before injection.

Hiberix is available in packs of 1 dose vial of powder + pre-filled syringe with 2 separate needles or without needles.

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The following information is intended for medical or healthcare professionals only:

As with all vaccinations, appropriate medical treatment should be available for injection should an anaphylactic reaction occur. Recipients of the vaccine should remain under observation until they have been seen to be in good health and not to be experiencing an immediate adverse reaction. It is not possible to specify an exact length of time.

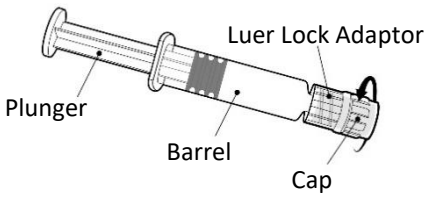
Hiberix should under no circumstances be administered intravascularly.

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

Different injectable vaccines should be administered at different injection sites.

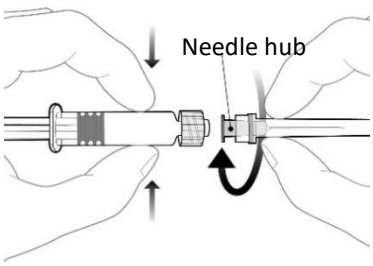
The solvent and reconstituted Hiberix vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance prior to reconstitution or administration. If either is observed, do not use the solvent or the reconstituted vaccine.

Instructions for reconstitution of the vaccine with solvent presented in pre-filled syringe
Hiberix must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder using a suitable needle (21G to 25G).
To attach the needle to the syringe, carefully read the instructions.



Hold the syringe by the barrel, not by the plunger or by the Luer Lock Adaptor (LLA).

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, gently connect the hub to the LLA and rotate a quarter turn clockwise until you feel it lock.

Maintain the needle in the axis of the syringe. 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.

Reconstitute the vaccine as described below.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

1. Add the solvent to the powder. Shake well until the powder is completely dissolved in the solvent.
   After reconstitution, use the vaccine promptly.
2. Withdraw the entire contents of the vial.
3. A new needle should be used to administer the vaccine.
   Unscrew the needle form the syringe and attach the injection needle by repeating steps above.

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

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