

ENGERIX-B

Recombinant DNA hepatitis B vaccine

Consumer Medicine Information Leaflet

What Is In This Leaflet?

This leaflet answers some of the common questions about ENGERIX-B 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 you or your child having ENGERIX-B against the expected benefits.

If you have any concerns about ENGERIX-B talk to your doctor, nurse or pharmacist.

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

What Is ENGERIX-B Used For

ENGERIX-B is a vaccine used to prevent Hepatitis B infection. The vaccine works by aiding the body to produce its own protection (antibodies) against this disease.

Hepatitis B is an infectious disease, which can affect the liver. This disease is caused by the Hepatitis B virus.

The Hepatitis B virus is found in body fluids such as blood, semen, vaginal secretions or saliva of infected people. You can catch the virus if it enters your bloodstream. Ways this can happen are through:

- injection (eg needlestick injury, or sharing needles for IV drug use)
- sexual intercourse
- sores, cuts or tiny wounds coming into contact with infected fluids (eg from a human bite, sharing razors or toothbrushes, or working with human blood or body fluids)
- an infected mother passing the virus onto her baby during or shortly after birth.

Some people infected with hepatitis B may not look or feel sick yet others will get symptoms. Symptoms may not appear for 6 weeks to 6 months after infection. Sometimes people will only have mild flu-like symptoms, but other people can become very ill. They may be extremely tired, and have dark urine, pale faeces, yellowish skin and/or eyes (jaundice), and may need to be admitted to hospital. There is a risk of serious liver disease, such as cirrhosis (liver scarring) and liver cancer for all chronic hepatitis B carriers.

Some groups of people are at a higher risk of exposure to hepatitis B. Vaccination is recommended for these people:

- some healthcare workers
- abusers of injectable drugs
- people with many sexual partners
- homosexual men
- haemodialysis patients or people who receive certain blood products
- people with chronic liver disease or hepatitis C
- people in contact with a hepatitis B carrier or an infected person
- staff and residents of institutions or homes
- inmates and prison staff at some correctional institutions
- some travellers to areas where the incidence of hepatitis B is high

Vaccination is the best way to protect against infection in the longer term. It may also help reduce disease complications such as chronic active hepatitis and liver cirrhosis as well as incidence of a type of liver cancer known as primary hepatocellular carcinoma.

Immunoglobulin protects you from Hepatitis B straight away but is only effective for a short time (8-12 weeks).

ENGERIX-B will not protect against hepatitis caused by other agents or viruses (such as Hepatitis A, Hepatitis C or Hepatitis E). As with all vaccines, not everyone who is vaccinated will be protected from getting the infection. If a person is already infected with the Hepatitis B virus at the time of vaccination, ENGERIX-B may not prevent the disease in these people.

Before Receiving ENGERIX-B

When you must not have ENGERIX-B

- you have/your child has had an allergic reaction to ENGERIX-B, 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.
- you have/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 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 ENGERIX-B should be given, talk to your doctor or nurse.

Tell your doctor if:

- you are or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of having ENGERIX-B during pregnancy.
- you are breast feeding. It is not known if ENGERIX-B passes into breast milk, however the vaccine is not expected to cause problems in breast-fed babies.
- If you have/your child has had ENGERIX-B before and became unwell, tell your doctor or nurse before the first dose is given.
- you have/your child has any medical conditions, such as:
 - a bleeding disorder. Sometimes ENGERIX-B may need to be given differently in people with bleeding problems.
 - an immune deficiency condition (eg. are HIV positive)
 - kidney problems
 - you have/your child has liver disease
- you have/your child has allergies to any other medicines or substances, such as dyes, foods or preservatives.
- you have/your child has received another vaccine. ENGERIX-B can be given at the same time as other vaccines including: hepatitis A, Haemophilus influenza b, typhoid, diphtheria, measles-mumps-rubella vaccine, pertussis (whooping cough), tetanus and polio. It can also be given at the same time as human immunoglobulin. ENGERIX-B will always be given separately from other injections.
- you are /your child is taking any prescription or OTC (over-the-counter) medicines or any medicine you have bought from a supermarket or health food shop.
- 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).

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 ENGERIX-B is to be given with another vaccine or medicine.

USE IN CHILDREN

ENGERIX-B is recommended for use in neonates (new-borns), infants and children. The vaccine can be given at any age from birth onwards.

Giving ENGERIX-B

How ENGERIX-B Is Given

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

How Much Is Given

For adults and adolescents aged 16 years and over: the dose is 20mcg in 1 mL

For adolescents from the age of 10 years up to and including 15 years, a 10mcg dose is recommended.

In newborns, infants and younger children up to 10 years of age, a dose of 10mcg of the antigen protein in 0.5mL is given although if this is not available, the 20mcg dose may be used.

HOW IS IT GIVEN

ENGERIX-B will be injected into the upper arm muscle in adults and older children, and into the thigh muscle in infants. For some people 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 IT WILL BE GIVEN

ENGERIX-B is generally given as a single dose on an elected date.

If travelling overseas, allow at least 3 weeks before departure for the final ENGERIX B dose to be given. This is so the body has time to respond to the vaccine. If there is a risk of Hepatitis B infection occurring before immunity develops, human immunoglobulin may need to be given at the same time as ENGERIX-B.

Depending on the dosing schedule that you received, a boosting dose of ENGERIX-B, given 12 months to 5 years after the third dose, gives longer term protection. It is not known how long booster dose protection lasts. Your doctor will advise on the need for booster dosing.

If A Dose Is Missed

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

While You Are Getting ENGERIX-B

Things you must do

Keep your visits with the doctor or clinic. It is important ENGERIX-B doses are given at the correct times. This will ensure the best effect of the vaccine in protecting you (or your child) against Hepatitis B.

Things to be careful of

Be careful driving or operating machinery until you know how ENGERIX-B affects you. ENGERIX-B should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or light-headedness. Make sure you know how you react to ENGERIX-B before you drive a car or operate machinery, or do anything that could be dangerous if you are dizzy or light-headed.

Side Effects

Tell your doctor, nurse or pharmacist as soon as possible if you (or your child) do not feel well during or after having had a dose of ENGERIX-B.

ENGERIX-B helps protect most people from Hepatitis B, but it may have unwanted side effects in a few people. 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.

Most unwanted effects with ENGERIX-B are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site such as tenderness, soreness and redness.

Mild effects

Tell your doctor if you notice any of the following that are troublesome or ongoing after vaccination:

- redness, swelling, a hard lump, soreness, bruising or itching around the injection site
- feeling generally unwell, fever, or headache
- loss of appetite, or feeling sick (nausea), vomiting, diarrhoea
- irritability

Serious effects

Tell your doctor immediately if you notice any of the following:

- difficulty in walking, numbness, weakness and/or fatigue in limbs, tingling in fingers or toes, pain, blurred vision or other visual changes
- drooping eyelid or sagging muscles on one side of the face, also called Bell's palsy
- aches or pains in joints, mild skin rash
- swelling with fluid in tissues
- difficulty in passing urine
- fever
- reddening of the skin, red swellings over the skin or in the mouth and on the lips, or other skin problems

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

- 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, muscular aches and pains
- fever, headache, dizziness

Allergy to ENGERIX-B 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 ENGERIX-B. **Check with your doctor or nurse if you notice any other effects.**

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

Storage

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

- Keep ENGERIX-B in the refrigerator stored between +2°C and +8°C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- Keep the vaccine out of the reach of children.
- Keep ENGERIX-B in the original pack until it is time for it to be given.

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

Product Description

WHAT IT LOOKS LIKE

ENGERIX-B is a solution, which comes in a neutral, colourless glass vial, closed by a grey rubber stopper. The vaccine is also available in a pre-filled syringe.

INGREDIENTS

The active ingredient of ENGERIX-B is the surface protein of the Hepatitis B virus. Two different vaccine strengths are available:

- ENGERIX-B 20mcg dose vaccine in 1mL suspension, containing 20mcg of HBsAg
- ENGERIX-B 10mcg dose vaccine in 0.5mL suspension, containing 10mcg of HBsAg

The vaccine may also contain traces of thiomersal. Inactive ingredients in the vaccine include aluminium hydroxide.

The vaccine is not infectious, and will not give you Hepatitis B.

ENGERIX-B does not contain human blood or blood products, or any other substances of human origin.

Further Information

ENGERIX-B is only available if prescribed by a doctor.

The vaccine comes in the following:

ENGERIX-B monodose vials in packs of 1, 10mcg/0.5mL dose and 20mcg/mL dose

ENGERIX-B monodose vials in packs of 3, 20mcg/mL dose

ENGERIX –B prefilled syringes in packs of 1, 10mcg/0.5mL dose and 20mcg/mL dose

Distributor

Distributed In New Zealand by:

GlaxoSmithKline NZ Ltd

Private Bag 106600

Downtown Auckland

Ph: (09) 367 2900

Fax (09) 367 2910

This leaflet is copyrighted to GlaxoSmithKline and may be reproduced but not altered in any way.

Date of Preparation: 28 July 2008, Version 1.0