

Package leaflet: Information for the user

ENGERIX B 20 micrograms/1 ml, suspension for injection

Hepatitis B (rDNA) vaccine (adsorbed) (HBV)

Read all of this leaflet carefully before you start receiving this vaccine because 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 you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Engerix B is and what it is used for
- 2 What you need to know before you receive Engerix B
- 3 How Engerix B is given
- 4 Possible side effects
- 5 How to store Engerix B
- 6 Contents of the pack and other information

1 What Engerix B is and what it is used for

Engerix B is a vaccine used to prevent hepatitis B infection. It can also help to prevent hepatitis D infection.

This vaccine can be given to both adults and adolescents 16 years of age and over. In exceptional circumstances it can also be given to children and adolescents 11 to 15 years of age (see section 3).

Hepatitis B is an infectious illness of the liver caused by a virus. Some people have the hepatitis B virus in their body but cannot get rid of it. They can still infect other people and are known as carriers. The disease is spread by the virus entering the body following contact with body fluids, most often blood, from an infected person.

If the mother is a carrier of the virus she can pass the virus to her baby at birth. It is also possible to catch the virus from a carrier through, for example, unprotected sex, shared injection needles or treatment with medical equipment which has not been properly sterilised.

The main signs of the illness include headache, fever, sickness and jaundice (yellowing of the skin and eyes) but in about three out of 10 patients there are no signs of illness. In those infected with hepatitis B one out of 10 adults and up to nine out of 10 babies will become carriers of the virus and are likely to go on to develop serious liver damage and in some cases cancer of the liver.

How Engerix B works

Engerix B contains a small amount of the 'outer coating' of the hepatitis B virus. This 'outer coating' is not infectious and cannot make you ill.

- When you are given the vaccine it will trigger the body's immune system to prepare itself to protect against these viruses in the future
- Engerix B will not protect you if you have already caught the hepatitis B virus
- Engerix B can only help to protect you against infection with hepatitis B virus

2 What you need to know before you receive Engerix B

Engerix B should not be given:

- If you are allergic (hypersensitive) to Engerix B or any of the other ingredients of this vaccine (listed in section 6)
- if you have a high temperature (fever)

Engerix B should not be given if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before receiving Engerix B. Please tell your doctor or pharmacist if you have any allergies or if you have ever had any health problems after being given a vaccine.

Warnings and precautions

Talk to your doctor or pharmacist before you receive Engerix B if you:

- Are on dialysis for a kidney problem or have an illness which may affect your immune system. People who have dialysis, long-term liver problems, carry hepatitis C or are HIV positive may still be given Engerix B by their doctor. This is because hepatitis B infections can be severe in these patients. More information about kidney problems and dialysis is in Section 3

If you are not sure if any of the above apply to you, talk to your doctor before having Engerix B.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you/your child fainted with a previous injection.

Like other vaccines, Engerix B may not be totally effective in protecting you against hepatitis B. A number of factors, such as older age, gender, being overweight, smoking and some long-term problems reduce your immune response to the vaccine. If any of these apply to you, your doctor may decide to give you a blood test or give you an additional dose of Engerix B to make sure you are protected.

Other medicines and Engerix B

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Engerix B can be given at the same time as most other routine vaccines. Your doctor will ensure that the vaccines are injected separately and into different parts of the body.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Engerix B may affect your ability to drive or use machines. Do not drive or use machines if you are feeling unwell.

Engerix B contains sodium

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

3 How Engerix B is given

How your vaccine is given

The doctor will give the recommended dose of Engerix B to you.

Engerix B will be given:

- as an injection into the muscle of the upper arm
- as an injection under the skin if you bruise easily or have a bleeding problem

How much is given

You will be given a series of injections of Engerix B. Once you have completed the course of injections you can expect long term protection against hepatitis B.

Adults and adolescents 16 years and over will be given the 20 microgram / 1 ml vaccine.

There are several ways in which you can be given Engerix B. Your doctor will choose the most appropriate course for you:

Schedule 1 – for adults or adolescents 16 years and over

First injection - now
Second injection - 1 month after first injection
Third injection - 6 months after first injection

Schedule 2 – for adults or adolescents 16 years and over

First injection - now
Second injection - 1 month after first injection
Third injection - 2 months after first injection
Fourth injection - 12 months after first injection

- This schedule can also be used if you are being vaccinated due to recent exposure to hepatitis B, as it will give protection more quickly.

Schedule 3 – for adults (18 years and over) only

This schedule will only be given to you in exceptional circumstances, for example if you have to travel to a high risk area within one month of being vaccinated.

First injection - now
Second injection - 1 week after first injection
Third injection - 3 weeks after first injection
Fourth injection - 12 months after first injection

Schedule 4 – for children and adolescents 11 to 15 years of age only

This schedule is only used if it is doubtful your child will receive the third injection. During this schedule Engerix B (20 micrograms/1 ml) is used. This will provide a higher level of protection than 2 doses of Engerix B (10 micrograms/0.5 ml) vaccine.

First injection - now
Second injection - 6 months after first injection

- When this schedule is used protection is not always achieved until after the second dose. This two-dose schedule is only used when there is a relatively low risk of hepatitis B infection during the vaccination course and when completion of this course can be assured.

It is very important for you to return for your injections at the recommended times. If you have any questions about the amount of vaccine you are being given, please speak to your doctor.

Kidney problems and dialysis

- People aged 16 years or over
If you have a kidney problem or are on dialysis, your doctor may decide to vaccinate you with four double doses (2 x 20 micrograms/1 ml) of vaccine at 0, 1, 2 and 6 months. Your doctor may also decide to do a blood test to make sure you are protected against hepatitis B.

4 Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them. The following side effects may happen with this vaccine:

Allergic reactions (these may occur with up to 1 in 10,000 doses of the vaccine)

If you have an allergic reaction, see your doctor straight away. The signs may include:

- your face swelling
- low blood pressure

- difficulty breathing
- your skin going blue
- loss of consciousness

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

Other side effects include:

Very Common (these may occur with more than 1 in 10 doses of the vaccine)

- pain and redness at the injection site
- feeling tired
- irritability

Common (these may occur with up to 1 in 10 doses of the vaccine)

- headache
- drowsiness
- nausea (feeling sick) or vomiting (being sick)
- diarrhoea or abdominal pain
- loss of appetite
- a high temperature (fever)
- feeling generally unwell
- swelling at the injection site
- reactions at the injection site such as a hard lump

Uncommon (these may occur with up to 1 in 100 doses of the vaccine)

- dizziness
- muscle pain
- flu like symptoms

Rare (these may occur with up to 1 in 1,000 doses of the vaccine)

- swollen glands
- hives, rash and itchiness
- joint pain
- pins and needles

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine)

- bruising easily and not being able to stop bleeding if you cut yourself
- low blood pressure
- inflammation of your blood vessels
- sudden swelling of your face around your mouth and throat area (angioneurotic oedema)
- being unable to move muscles (paralysis)
- inflammation of your nerves (neuritis) which may cause loss of feeling or numbness, including a temporary inflammation of the nerves, causing pain, weakness and paralysis in the extremities and often progressing to the chest and face (Guillain-Barré syndrome), a disease of the nerves of the eye (optic neuritis) and multiple sclerosis
- problems moving your arms or legs (neuropathy)
- inflammation of your brain (encephalitis)
- degenerative disease of the brain (encephalopathy)
- infection around the brain (meningitis)
- fit (convulsions)
- loss of skin sensitivity to pain or touch (hypoesthesia)
- purple or reddish-purple bumps on the skin (lichen planus)
- red or purple spots on your skin
- painful and stiff joints (arthritis)
- weakness of the muscles

Reporting of side effects

If you/your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Engerix B

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. 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 Engerix B contains

- The active substance is the 'outer coating' of the hepatitis B virus. Each dose contains 20 micrograms/1 ml of protein made up of this outer coat adsorbed on aluminium hydroxide hydrated
- The other ingredients are sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate and water for injections

What Engerix B looks like and contents of the pack

- Engerix B is a cloudy white injectable liquid
- Suspension for injection in pre-filled syringe (20 micrograms/ml). Pack size of 1, 3, 10 or 25 .
- Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24

Manufacturer

GlaxoSmithKline Biologicals s.a., Rue de l' Institut 89, B-1330 Rixensart, Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Denmark, Finland, Iceland, Netherlands, Norway, Spain, Sweden: Engerix-B
Belgium, Luxembourg, Portugal, United Kingdom: Engerix B
France, Ireland, Italy: Engerix B-20
Germany: Engerix-B Adult
Greece: Engerix

This leaflet was last revised in September 2015

Other sources of information

Detailed information on this medicine is available on the web site of the Health Products Regulatory Authority www.hpra.ie

Engerix B is a registered trade mark of the GSK group of companies.

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The following information is intended for healthcare professionals only

Upon storage, the content may present a fine white deposit with a clear colourless supernatant. Once shaken the vaccine is slightly opaque.

The vaccine should be inspected visually for any foreign particulate matter and/or coloration prior to administration. Discard if the content appears otherwise.

The entire contents of a mono-dose container must be withdrawn and should be used immediately.

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

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