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

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

Engerix B contains sodium
This vaccine contains less than 1 mmol sodium (23 mg) per dose, this is to say 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 micrograms/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 the 20 micrograms/1 ml vaccine is used. This will provide a higher level of protection than 2 doses of the 10 micrograms/0.5ml 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 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 (hypoaesthesia), 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 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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Engerix B

- Keep this vaccine out of the sight and reach of children
- Do not use Engerix B 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 between 2°C and 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.

Engerix B (20 micrograms/ml) is available in:

- 1-dose pre-filled syringe with or without separate needles, pack sizes of 1, 10 and 25.
- 1-dose vial, pack sizes of 1, 3, 10, 25 and 100.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
SmithKline Beecham Ltd, 79 New Oxford Street, London, WC1A 1DG, United Kingdom

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

This leaflet was last revised in November 2024

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	**Engerix B**
Reference number	10592/0165
	10592/0166

This is a service provided by the Royal National Institute of Blind People.

Detailed information on this medicine is available on the website of: the Medicines and Healthcare products Regulatory Agency (MHRA)

***GlaxoSmithKline* (logo)**

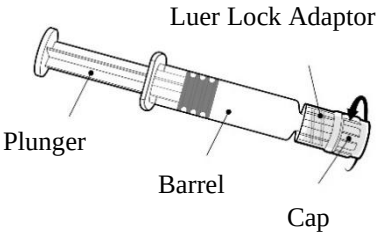
The following information is intended for healthcare professionals only

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 abnormal physical appearance prior to administration. In the event of either being observed, do not administer the vaccine.

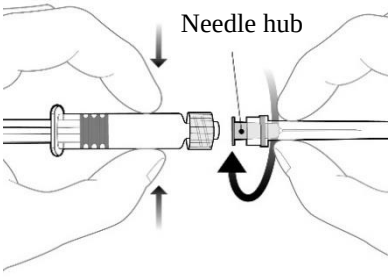
The entire contents of a mono-dose container must be withdrawn and should be used immediately.

Instructions for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



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

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

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

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