

Patient Information Leaflet for Engerix B® 20 micrograms/1 ml vaccine Suspension for injection

Hepatitis B recombinant vaccine, adsorbed

This leaflet tells you about hepatitis B vaccine. Please read it carefully. If there is anything you do not understand, or if you want to know more about this vaccine, ask your doctor, nurse or pharmacist (chemist). Please keep this leaflet. You may want to read it again.

What is in Engerix B vaccine?

The name of your vaccine is 'Engerix B 20 micrograms/1 ml' but will be referred to as 'Engerix B' throughout the remainder of the leaflet. This vaccine contains the outer coat of the hepatitis B virus. Each 1 ml contains 20 micrograms of protein, made up of at least 95% of this outer coat.

This vaccine also contains inactive ingredients. These are aluminium oxide hydrated, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate and water for injections.

The vaccine is available in vials or pre-filled syringes.

The 20 micrograms/1 ml vaccine is available as single dose vials (in packs of one and ten) and single dose syringes (in packs of one and ten). The 10 micrograms/0.5 ml vaccine is available in packs containing one single dose vial or syringe.

Who makes Engerix B?

The Product Licence holder is SmithKline Beecham plc, trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

The vaccine is manufactured by GlaxoSmithKline Biologicals s.a., 89 rue de L'Institut, 1330 Rixensart, Belgium.

What is Engerix B and how does it work?

Engerix B vaccine is a suspension for injection which contains a part (the outer coat) of the hepatitis B virus. When you are given the vaccine your body will make antibodies (your body's natural defence system) against the hepatitis B virus. This will protect you against hepatitis B infection. This vaccine will not, however, protect you from hepatitis B if you are already incubating the infection, nor will it protect you against other types of liver infection. This vaccine can also protect against hepatitis D, as hepatitis D does not occur in the absence of hepatitis B infection.

Before having this vaccine

Engerix B must not be given if the person who is to have the vaccine answers YES to any of the following questions:

- Do you think that you may be allergic to Engerix B or any of the ingredients listed?
 - Thiomersal is present (in trace amounts) in this vaccine, and it is possible that you may experience an allergic reaction. Please tell your doctor if you have any known allergies or if you have experienced any health problems after previous administration of a vaccine.
- Are you suffering from a fever or infection?
 - Administration of the vaccine should be postponed if you are suffering from a fever or infection.

Please tell your doctor or nurse if the answer to any of the following questions is YES for the person who is to have the vaccine (as the vaccine may have to be delayed, or the vaccination schedule varied):

- Are you on dialysis for kidney disease or do you have an illness which may affect your immune system? Even if you have a chronic liver disease,

are HIV positive or are a carrier of hepatitis C, vaccination with Engerix B may be recommended since hepatitis B infections can be severe in patients with these conditions.

- Are you pregnant or do you think you may be?
- Have you experienced any health problems after previous administration of a vaccine?
- Were you diagnosed as being a carrier of Hepatitis B when you gave birth to your baby?
- Are you being vaccinated because of a possible recent exposure to hepatitis B infection?

No vaccine is totally effective in all individuals who are vaccinated. A number of factors, for example older age, gender, being overweight, smoking and some chronic diseases, have been observed to reduce the immune response to hepatitis B vaccines. If they apply to the person who is to have the vaccine, the doctor or nurse may decide to do blood tests or give that person an additional dose of vaccine to ensure protection.

Effects on ability to drive and use machinery. May cause partial or complete loss of vision, dizziness, drowsiness, or fainting. If affected do not drive or operate machinery.

Your doctor or nurse will shake the vaccine well before it is used and it should not be used if it appears discoloured or clumped.

Having the vaccine

Engerix B is injected into the muscle of the upper arm in adults and children. In babies and young children, it is normally injected into the thigh muscle. However, this vaccine may be injected under the skin for patients with blood disorders.

This vaccine must NOT be injected into the buttocks, into the skin or into a vein.

Adults and children 16 years of age and over are given the 20 µg/1 ml vaccine and new-born babies and children 15 years of age and under are usually given the 10 µg/0.5 ml vaccine.

However, the 20 µg/1 ml vaccine may be given to children aged 11-15 years of age if it is thought unlikely that the child will receive the third injection in the vaccination schedule. This will provide a higher level of protection than two doses of the 10 µg/0.5 ml vaccine.

Your doctor will tell you when to receive the vaccine. The person who is to have the vaccine may receive it at the same time as another vaccine, but the vaccines should always be given at different injection sites.

You will need to receive a series of injections of Engerix B. Once you have completed the course of injections you will have long term protection against hepatitis B. Your doctor or nurse will choose the most appropriate schedule for your circumstances. There are several options as shown in the following table:

	1st injection	2nd injection	3rd injection
Schedule 1	now	in one month	6 months after first injection
Schedule 2*	now	in one month	2 months after first injection
Schedule 3* (18 years and over only)	now	in one week	3 weeks after first injection
Schedule 4**	now	in six months	See footnote

*If either of these schedules is used, it is recommended that you receive a fourth injection (booster injection) 12 months after the first injection.

**** For children 11-15 years of age only.**

the 20 µg/1 ml vaccine may be given using this two-dose schedule. However, in this case, protection may not be obtained until after the second dose. Therefore, this two-dose schedule should only be 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. If this schedule is used, it is very important that you return for the second dose at 6 months, otherwise there is a risk of catching hepatitis B.

Schedules 1 and 2

In infants, schedule 2 will allow this vaccine to be given at the same time as other childhood vaccines. Schedule 2 should also be used if you, or your child, are being vaccinated due to recent exposure to hepatitis B as it will confer protection more quickly. In such cases the first dose of Engerix B can be administered at the same time as hepatitis B immunoglobulin. However, it must be given at a different injection site. If you are a carrier of hepatitis B and recently gave birth, schedule 1 or schedule 2 can be used to vaccinate your baby. When available, hepatitis B immune globulins should be given at the same time, but at a separate injection site.

Schedule 3 (for 18 years and over only)

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

If your child is aged 15 or less and suffers from kidney disease or is a haemodialysis patient.

the 10 µg/0.5 ml dose vaccine can be used with schedules 1 or 2. Your doctor may decide to do a blood test or give extra doses of vaccine to make sure that your child is protected.

If you are 16 or over and your kidneys are not functioning properly or if you are a haemodialysis patient.

your doctor or nurse may decide to vaccinate you with four double doses (2 x 20 µg/1 ml) of vaccine at 0, 1 month, 2 months and 6 months from the date of your first vaccination.

Please 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.

After having the vaccine – possible side effects

Like all vaccines, Engerix B can have unwanted effects.

Very rarely, some people can have a serious allergic reaction to the vaccine. Tell the doctor or nurse if you get a rash, have tightness in the throat or shortness of breath or any other unwanted effects.

The following side effects have been reported following Engerix B vaccination:

Common (less than 1 in 10 but more than 1 in 100 doses of vaccine):

Pain, redness or hardness at the site of injection.

Rare (less than 1 in 1,000 but more than 1 in 10,000 doses of vaccine):

Dizziness, headache, numbness, pins and needles

Nausea, vomiting, diarrhoea, stomach pains

Abnormal liver function

Rash, itching and hives

Painful joints, muscle pain

Fever, tiredness, general body discomfort, flu-like symptoms

Very Rare (less than 1 in 10,000 doses of vaccine):

A blood disorder which may cause bruising or bleeding

Hypersensitivity reactions, swollen glands

Fainting, paralysis, inflammation of the nerves, disturbance of nerve function – e.g. Guillian Barre Syndrome, multiple sclerosis, and optic neuritis (which may cause partial or complete loss of vision)

inflammation of the brain, degenerative disease of the brain, meningitis, seizures

Low blood pressure, inflammation of the blood vessels

Difficulty in breathing or wheezing

Sudden swelling of the face, erythema multiforme (allergic rash)

Arthritis

Storage of this vaccine

This vaccine should be stored in a refrigerator at 2°- 8°C until it is given to you. The doctor or nurse should check that the expiry date on the label has not passed. The vaccine must not be frozen.

Discard any unused portion. Unused vaccine or partly used syringes should be disposed of safely, preferably by heat inactivation or incineration.

If your doctor has given you a prescription for Enderix B to collect from your pharmacy (chemist) instead of giving it to you straight away, you should store the vaccine carefully. Keep it in your fridge (between 2° and 8°C).

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Disease information on hepatitis B

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.



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