

## Package Leaflet: Information for the User

### Engerix B<sup>®</sup> 20 micrograms/1 ml suspension for injection

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

#### Read all of this leaflet carefully before you receive this vaccine.

- 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. Do not pass it on to others.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

- 1 What Engerix B is and what it is used for
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## 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 children. In this leaflet, any reference to 'you' can also mean 'your child'.

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 Before receiving Engerix B

#### Engerix B should not be given if:

- you are allergic (hypersensitive) to Engerix B or any of the ingredients (listed in Section 6)

- 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.

### **Take special care with Engerix B**

Talk to your doctor before the vaccine is given 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 or 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.

### **Using other medicines and vaccines**

Please tell your doctor or pharmacist if you are taking, about to take or have recently taken 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**

- Women who are pregnant may sometimes be vaccinated.
- Talk to your doctor if you think you are pregnant or might become pregnant.
- Talk to your doctor if you are breast-feeding.

Ask your doctor or your pharmacist for advice before taking any medicines.

### **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.

### **Important information about some of the ingredients of Engerix B**

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 in adults and children
- as an injection into the thigh muscle for babies and young children
- 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 will have long term protection against hepatitis B.

- Adults and children above 16 years of age will be given the 20 microgram / 1 ml vaccine.

- New born babies and children 15 years of age and under are usually given the 10 microgram / 0.5 ml vaccine.

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

#### **Schedule 1 – for adults or children**

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

#### **Schedule 2 – for adults or children**

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

- In infants, schedule 2 will allow Enderix B to be given at the same time as other routine childhood vaccines.
- 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 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 microgram/ 1 ml vaccine is used. This will provide a higher level of protection than 2 doses of the 10 microgram/ 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.

#### **Vaccination and child birth**

If you have hepatitis B and just gave birth, schedule 1 or 2 can be used to vaccinate your baby. Your doctor may also decide to give your baby hepatitis B immunoglobulins (human antibodies) at the time as the first injection. This will help protect your baby from hepatitis B. It will be given at a separate injection site.

#### **Kidney problems and dialysis**

- Children aged 15 or less  
If your child has a kidney problem or is on dialysis, your doctor may decide to do a blood test or give extra doses of vaccine to make sure that your child is protected.
- 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 microgram/1 ml) of vaccine at 0, 1, 2 and 6 months from the date of your first vaccination. 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, Engerix B can cause side effects although not everybody gets them. The following side effects may happen with this vaccine:

**Allergic reactions** (may occur with up to 1 in 10,000 doses of 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 1 in 10 doses or more 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

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5 How to store Engerix B

- Keep out of the reach and sight of children.
- Store between 2°C and 8°C in a refrigerator.
- Do not freeze.
- Do not use Engerix B after the expiry date which is stated on the label and carton.
- Store in the original package with this leaflet.
- Discard any unused vaccine after opening.
- Medicines should not be disposed of via wastewater or household waste. Your doctor will dispose of vaccine no longer required.

## 6 Further information

### What Engerix B contains

- The active ingredient is the 'outer coating' of the hepatitis B virus. Each dose contains either 20 micrograms/ 1 ml or 10 micrograms/ 0.5 ml of protein, made up of this outer coat.
- The other ingredients are aluminium hydroxide hydrated, 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 available in vials or pre-filled syringes.

- Engerix B is a cloudy white injectable liquid.
- The 20 micrograms/1 ml vaccine is available as single dose vials in packs of 1, 3, 10, 25 or 100, or as single dose syringes in packs of 1, 10 or 25, however not all pack sizes may be marketed.
- The 10 micrograms/0.5 ml vaccine is available as single dose vials in packs of 1, 10, 25, 50 or 100, or as a single dose pre-filled syringes in packs of 1, 10, 25 or 50, however not all pack sizes may be marketed.

### Marketing Authorisation Holder

Marketing Authorisation holder:

SmithKline Beecham plc, trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT

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

**Other formats:**

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:

<b>Product name</b>	<b>Engerix B</b>
Reference number	10592/0165
	10592/0166

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

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