

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

## **Engerix B 20 mcg**

### **Suspension for injection**

Each dose (1 mL) contains: Purified hepatitis B antigen 20 mcg

## **Engerix B 10 mcg**

### **Suspension for injection**

Each dose (0.5 mL) contains: Purified hepatitis B antigen 10 mcg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Engerix B is an active vaccine used against liver infection (jaundice) caused by the hepatitis B virus.

#### **Engerix B 20 mcg**

The vaccine is intended for adults and adolescents from 16 years of age and above.

#### **Engerix B 10 mcg**

The vaccine is intended for neonates, children and adolescents up to 15 years of age (including age 15 years).

Hepatitis B is an infectious illness of the liver caused by a virus. Some people have the virus that causes hepatitis B 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 which enters 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, sharing of injection needles or treatment with medical equipment, which has not been properly sterilised.

The main symptoms 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 the illness.

**Therapeutic group:** Hepatitis B vaccine.

How does the vaccine work?

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 it to protect itself against these viruses in the future.
- Engerix B will not protect you if you have already caught the virus that causes hepatitis B.
- Engerix B can only help protect you from infection from the virus that causes hepatitis B.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- you are sensitive (allergic) to Engerix B or to any of the additional ingredients contained in this vaccine (listed in section 6).
- you have a high fever.

Engerix B should not be used if any of the above conditions apply to you. If you are not sure, talk to your physician or pharmacist before receiving Engerix B. Please tell your physician or pharmacist if you have had any

allergies in the past or if you have ever had any health problems after receiving a vaccine.

### **Special warnings regarding use of the medicine**

Talk to your physician 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 being treated with dialysis, with long-term liver problems, or who are carriers of hepatitis C or HIV, may still be given Engerix B by their physician. 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 conditions apply to you, talk to your physician before receiving Engerix B.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore, tell the physician or nurse if you or your child have 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 physician may decide to have you perform a blood test or give you an additional dose of Engerix B to make sure you are protected.

### **Drug interactions**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.**

Engerix B can be given at the same time as most other routine vaccines. Your physician 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 physician 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.

### **Important information about some of the ingredients in the medicine**

#### **Engerix B contains sodium**

Engerix B contains less than 1 mmol sodium (23 mg) per dose, i.e., is essentially 'sodium free'.

## **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

Engerix B 20 mcg 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

Engerix B 10 mcg will be given:

- as an injection into the muscle of the upper arm in children and adolescents
- 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

The dosage and treatment regimen will be determined by the physician only.

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.

Shake before use.

### **Kidney problems and dialysis**

Engerix B 20 mcg

- people aged 16 and above

If you have kidney problems or are on dialysis, your physician may decide to vaccinate you with extra doses of the vaccine.

Your physician may also decide to have a blood test performed to make sure that you are protected against hepatitis B.

Engerix B 10 mcg

- If your child has kidney problems or is on dialysis, your physician may decide have a blood test performed or give extra doses of the vaccine to make sure that your child is protected.

**Do not exceed the recommended dose.**

Adhere to the treatment regimen recommended by your physician.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the physician or pharmacist.**

## **4. SIDE EFFECTS**

As with any medicine, use of Engerix B may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

### **Allergic reactions**

If you have an allergic reaction, refer to the physician straight away. The symptoms may include:

- facial swelling
- low blood pressure
- breathing difficulties

- skin going blue
- loss of consciousness.

These symptoms usually start very soon after the injection has been given to you. Refer to a physician straight away if they happen after leaving the clinic. For Engerix B 20 mcg, the frequency of these reactions is up to 1 in 10,000 doses of the vaccine.

#### **Other side effects include:**

##### **Very common side effects**

These may occur with **more than 1 in 10** doses of the vaccine:

- headache (this effect has been reported for Engerix B 10 mcg and may occur in more than 1 in 10 doses of the vaccine)
- pain and redness at the injection site
- feeling tired
- irritability.

##### **Common side effects**

These may occur with **up to 1 in 10** doses of the vaccine:

- headache (this effect has been reported for Engerix B 20 mcg and may occur in up to 1 in 10 doses of the vaccine)
- drowsiness
- nausea or vomiting
- diarrhoea or abdominal pain
- loss of appetite
- high fever
- feeling generally unwell
- swelling at the injection site
- reactions at the injection site, such as a hard lump.

##### **Uncommon side effects**

These may occur with **up to 1 in 100** doses of the vaccine:

- dizziness
- muscle pain

- flu-like symptoms.

### **Rare side effects**

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 side effects**

These may occur with **up to 1 in 10,000** doses of the vaccine:

- A tendency to become bruised easily and non-stop bleeding in the event of a cut
- low blood pressure
- inflammation of the blood vessels
- sudden swelling of the face, around your mouth and throat area (angioneurotic oedema)
- being unable to move the muscles (paralysis)
- inflammation of the 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 the brain (encephalitis)
- degenerative disease of the brain (encephalopathy)
- infection around the brain (meningitis)
- fits (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.

In babies born prematurely (at or before 28 weeks of gestation), longer gaps than normal between breaths may occur for 2-3 days after the vaccination.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the physician.**

### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.it](http://www.health.gov.it)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.it/>

## **5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store refrigerated (between 2°C to 8°C). Do not freeze.
- Do not use if the vaccine has been frozen.
- Store in the original package in order to protect from light.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

## **6. ADDITIONAL INFORMATION**

- In addition to the active ingredient, the medicine also contains:  
Sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, aluminium (as aluminium hydroxide), water for injection
- What the medicine looks like and the contents of the package:  
Engerix B is a cloudy white injectable liquid in a vial or pre-filled syringe.



**Engerix B 20 mcg - package sizes:**

Vial: 1, 10, 25, 50, 100

Pre-filled syringe: 1, 10, 25, 50, 100

**Engerix B 10 mcg - package sizes:**

Vial: 1, 10, 25, 50, 100

Pre-filled syringe: 1, 10, 25, 50

Not all package sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Engerix B 10 mcg: 055-06-26267-00

Engerix B 20 mcg: 035-60-25829-00

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*Eng B PT V4C*

**The following information is intended for healthcare professionals only:**

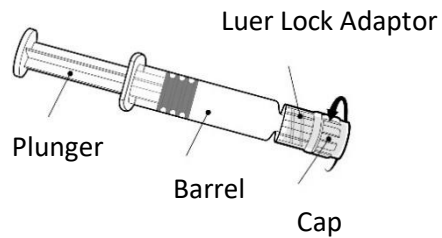
Shake before use.

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.

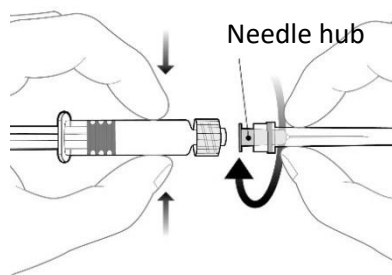
The entire contents of a mono-dose container must be withdrawn and should be used immediately.

## 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.