

# ENGERIX-B

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor/pharmacist.

### 1. Why am I being given ENGERIX-B?

ENGERIX-B is a vaccine used to protect you or your child against hepatitis B infection. The vaccine works by causing the body to produce its own protection (antibodies) against this disease.

For more information, see Section [1. Why am I being given ENGERIX-B?](#) in the full CMI.

### 2. What should I know before I am given ENGERIX-B?

Do not use if you have ever had an allergic reaction to ENGERIX-B or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given ENGERIX-B?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ENGERIX-B and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is ENGERIX-B given?

- ENGERIX-B will be injected into your upper arm muscle. For babies, the vaccine may be given in the upper thigh muscle. For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).
- ENGERIX-B is generally given as a total of three doses over 6 months.

More instructions can be found in Section [4. How is ENGERIX-B given?](#) in the full CMI.

### 5. What should I know when I'm given ENGERIX-B?

|                                    |   |
|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>• Check with your doctor if you have an allergy to yeast, you are or think you may be pregnant, or if you intend to become pregnant, you are breastfeeding, you have any medical conditions, such as a severe heart or lung disease, a bleeding disorder, a liver or kidney problem, an immune deficiency condition (e.g. are HIV positive), or a nervous system illness.</li></ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>• Do not have ENGERIX-B if you have an allergic reaction to ENGERIX-B, any ingredients in the vaccine, to H-B-Vax II, or another hepatitis B vaccine, or have a severe infection with a high temperature.</li></ul>   |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how ENGERIX-B affects you. ENGERIX-B should not normally interfere with your ability to drive a car or operate machinery. In some people vaccination can cause dizziness or light-headedness.</li></ul>  |
| <b>Looking after your medicine</b> | ENGERIX-B is usually stored at the doctor's clinic or surgery, or at the pharmacy. If you need to store ENGERIX-B always store in the refrigerator between +2°C and +8°C in the original pack until it is time for it to be given. The pack should never be frozen. Freezing destroys the vaccine.  |

For more information, see Section [5. What should I know when I am given ENGERIX-B?](#) in the full CMI.

### 6. Are there any side effects?

Side effects that have been most commonly reported include irritability, headache, pain and redness at injection site, and fatigue. There is a rare risk of serious allergic reactions. Contact your doctor immediately if or go to the casualty department of your nearest hospital if you notice any of the following, swelling of limbs, face, eyes, inside of nose, mouth or throat. Shortness of breath, breathing or swallowing difficulties, hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions, unusual tiredness or weakness that is sudden and severe. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ENGERIX-B

Active ingredient: *Hepatitis B surface protein (yeast)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ENGERIX-B. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ENGERIX-B.**

**Where to find information in this leaflet:**

- [1. Why am I being given ENGERIX-B?](#)
- [2. What should I know before I am given ENGERIX-B?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ENGERIX-B given?](#)
- [5. What should I know while being given ENGERIX-B?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given ENGERIX-B?

ENGERIX-B is a vaccine used to protect you or your child against hepatitis B infection. The vaccine works by causing your body to produce its own protection (antibodies) against this disease. ENGERIX-B can be given to adults, adolescents, children and infants.

Hepatitis B is an infectious disease, which causes the liver to become swollen (inflamed). It is caused by a virus (hepatitis B virus).

The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva of infected people. You can catch the virus if it can enter your bloodstream. Ways this can happen are through:

- injection (e.g. needlestick injury, or sharing needles for IV drug use)
- sexual intercourse
- sores, cuts or tiny wounds coming into contact with infected fluids (e.g. from a human bite, sharing razors or toothbrushes, or working with human blood or body fluids)
- an infected mother passing the virus onto her baby during or shortly after birth.

Some people infected with hepatitis B may not look or feel sick. But others will get symptoms, which may not be seen for 6 weeks to 6 months after infection. Sometimes people will only have mild flu-like symptoms, but other people can become very ill. They may be extremely tired, and have dark urine, pale faeces, yellowish skin and/or eyes (jaundice), and other symptoms possibly requiring hospitalisation.

Most adults fully recover from the disease. But some people, particularly children, who may not have had symptoms can remain infected. They are called hepatitis B virus carriers. Hepatitis B carriers can infect others throughout their lives.

Babies infected with hepatitis B at birth almost always become carriers. Often they do not show symptoms, and seem healthy for many years. However, after 30, 40 or 50 years they can become sick and develop symptoms.

For all chronic hepatitis B carriers there is a risk of serious liver disease, such as cirrhosis (liver scarring) and liver cancer.

There is no specific treatment for hepatitis B. Therefore vaccination is the best way to help protect against infection and possible serious long-term disease.

ENGERIX-B will not protect against hepatitis caused by other agents or viruses (such as hepatitis A, hepatitis C, hepatitis E). If a person is already infected with the hepatitis B virus at the time of vaccination, ENGERIX-B may not prevent the disease in these people.

## 2. What should I know before I am given ENGERIX-B?

### Warnings

**Do not use ENGERIX-B if:**

- you are allergic to ENGERIX-B, or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction may include skin rash, itchiness, shortness of breath, or swelling of the face, neck or tongue.
- If you had ENGERIX-B before and became unwell, tell your doctor, nurse or pharmacist before receiving the next dose.
- you have had an allergic reaction to H-B-Vax II, or another hepatitis B vaccine.
- you have a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor about this before being vaccinated.
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering

Always check the ingredients to make sure you can use this medicine.

### Check with your doctor if you:

- have an allergy to yeast
- you have any medical conditions, such as:
  - severe heart or lung disease
  - a bleeding disorder
  - a liver or kidney problem
  - an immune deficiency condition (e.g. are HIV positive)
  - or a nervous system illness.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you/your child fainted with a previous injection.

If your child has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).

Sometimes ENGERIX-B may need to be given differently (e.g. people with bleeding problems) or a higher dose used (e.g. dialysis patients, or HIV positive people) if

- you have allergies to any other medicines or substances, such as dyes, foods or preservatives.
- you have received another vaccine, or are taking any prescription or OTC (over-the-counter) medicines. In particular mention if you are taking medicines which suppress the immune system, such as steroids or cyclosporin.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if ENGERIX-B passes into breast milk, but as it can safely be given to infants, it is not expected to cause problems in nursing babies. However, the infant should be checked for any reactions.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with ENGERIX-B and affect how it works**, in particular medicines which suppress the immune system, such as steroids or cyclosporin.

Your doctor, nurse or pharmacist will be able to tell you what to do if ENGERIX-B is to be given with another vaccine or medicine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ENGERIX-B.**

### **4. How is ENGERIX-B given?**

The doctor or nurse will give ENGERIX-B as an injection.

If you have any concerns about this, talk to your doctor, nurse or pharmacist.

#### **How much is given**

Usually, for adults and adolescents over 19 years of age:  
1mL (20 microgram) is given.

For adolescents aged 10 up to and including 19 years of age:

0.5 mL (10 microgram) is given.

Where compliance cannot be assured a 1mL dose (20 microgram) should be given. For babies and children under 10 years of age: 0.5mL (10 microgram) is given.

People with some conditions may need to have higher dosages.

#### **How it is given**

ENGERIX-B will be injected into your upper arm muscle. For babies, the vaccine may be given in the upper thigh muscle. For some people with bleeding problems, the dose may need to be given under the skin (subcutaneously).

The vaccine should not be given directly into the veins (intravenously).

#### **When is it given**

ENGERIX-B is generally given as a total of three doses over 6 months. Each dose is given at a separate visit. The first dose will be given on an elected date. The remaining two doses will be given one month, and six months after the first dose.

It is important to return at the recommended times for follow up doses.

- First dose: at an elected date
- Second dose: 1 month later
- Third dose: 6 months after the first dose

For babies born to mothers infected with hepatitis B, the first dose of ENGERIX-B should be given at birth or shortly afterwards. Hepatitis B immunoglobulin can also be given at this time.

ENGERIX-B can also be given as a total of three doses over 3 months. This schedule may be given to people needing rapid protection (e.g. overseas travellers). The first dose will be given on an elected date. The remaining two doses will be given one month and two months after the first dose. A booster dose is recommended at 12 months.

For adults, ENGERIX-B can also be given as a total of three doses over 3 weeks (a 0, 7, 21 day schedule). However, the body's immune response to this rapid schedule may be reduced compared to the above two schedules. Therefore, this rapid schedule should only be used under special circumstances (e.g. travellers wanting to be vaccinated within one month of departure). A booster dose is recommended at 12 months.

For adolescents aged from 11 to 15 years, ENGERIX-B can also be given as a total of two adult (1 mL) doses 6 months apart. However, as protection against hepatitis B is only achieved after the second dose is given, this schedule should only be used when there is a relatively low risk of hepatitis B infection during the vaccination course and

when it can be anticipated that the complete course is given.

Your doctor will advise on the possible need for extra doses, and future booster dosing.

#### **If a dose is missed**

If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

If you are given too much ENGERIX-B

If you think that you have been given too much ENGERIX-B, you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while being given ENGERIX-B?**

### **Things you should do**

Keep your follow up visits with the doctor or clinic. It is important the two follow-up doses of ENGERIX-B are given at the correct times. This will ensure the best effect of the vaccine in protecting you or your child against hepatitis B

#### **Call your doctor straight away if you:**

- You do not feel well during or after having had a dose of ENGERIX-B.
- ENGERIX-B helps protect most people from hepatitis B, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment.

Remind any doctor, dentist or pharmacist you visit that you have been given ENGERIX-B.

### **Things you should not do**

- Do not miss follow up doses.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how ENGERIX-B affects you.**

ENGERIX-B should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or light-headedness. Make sure you know how you react to ENGERIX-B before you drive a car or operate machinery, or do anything that could be dangerous if you are dizzy or lightheaded.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

### **Looking after your medicine**

ENGERIX-B is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store ENGERIX-B always:

- Keep ENGERIX-B in the refrigerator stored between +2°C and +8°C. **THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- Keep the vaccine out of the reach of children.
- Keep ENGERIX-B in the original pack until it is time to be given.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

### **When to discard your medicine**

**Ask your pharmacist what to do with any leftover ENGERIX-B that has expired or has not been used.**

### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary and generally occur around the injection site.

However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

| Less serious side effects  | What to do  |
|--|---|
| <p><b>General disorders and administration site conditions:</b></p> <ul style="list-style-type: none"> <li>• Pain, redness, swelling, a hard lump, bruising or itching around the injection site</li> <li>• Headache, unusual tiredness, drowsiness, dizziness or feeling generally unwell</li> <li>• Fever</li> <li>• Fainting, or chills</li> </ul> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>• Vomiting or feeling sick, stomach pains or diarrhoea</li> </ul> <p><b>Metabolic disorders:</b></p> <ul style="list-style-type: none"> <li>• Loss of appetite</li> </ul> <p><b>Musculoskeletal disorders:</b></p> <ul style="list-style-type: none"> <li>• Muscle aches and pains, back pain or neck stiffness</li> <li>• Aches or pains in joints</li> </ul> <p><b>Lymphatic disorders:</b></p> <ul style="list-style-type: none"> <li>• Swollen glands in armpit or neck</li> </ul> <p><b>Psychiatric disorders:</b></p> <ul style="list-style-type: none"> <li>• Disturbed sleep, irritability</li> </ul> <p><b>Respiratory and mouth disorders:</b></p> <ul style="list-style-type: none"> <li>• Coughing, sore throat, runny nose</li> </ul> <p><b>Skin disorders:</b></p> <ul style="list-style-type: none"> <li>• Mild skin rash</li> <li>• Sweating, flushing</li> </ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

## Serious side effects

| Serious side effects   | What to do   |
|--|--|
| <p><b>Respiratory and mouth disorders:</b></p> <ul style="list-style-type: none"> <li>• Breathing difficulties in your child</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• Difficulty in walking, numbness, weakness and/or fatigue in limbs, tingling in fingers, toes, or other body parts, pain</li> <li>• Bowel or bladder problems</li> <li>• Guillain-Barre Syndrome (an inflammatory illness affecting nerves, resulting in weakness of muscles)</li> </ul> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

|   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• Disease of the brain including infection and swelling</li> <li>• Convulsions</li> </ul> <p><b>Eye disorders:</b></p> <ul style="list-style-type: none"> <li>• Blurred vision or other visual changes</li> <li>• Drooping eyelid or sagging muscles on one side of the face, also called Bell's palsy</li> </ul> <p><b>Lymphatic disorders:</b></p> <ul style="list-style-type: none"> <li>• Swelling with fluid in tissues</li> <li>• Swollen glands in neck, armpit or groin</li> </ul> <p><b>Skin disorders:</b></p> <ul style="list-style-type: none"> <li>• Reddening of the skin, red swellings over the skin or in the mouth and on the lips, or other skin problems</li> <li>• Bleeding or bruising more easily than normal</li> </ul> <p><b>Infections and immune system disorders:</b></p> <ul style="list-style-type: none"> <li>• Allergic reactions</li> <li>• Swelling of limbs, face, eyes, inside of nose, mouth or throat</li> <li>• Shortness of breath, breathing or swallowing difficulties</li> <li>• Hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions</li> <li>• Unusual tiredness or weakness that is sudden and severe</li> </ul> <p>Allergy to ENGERIX-B is rare. Any such severe reactions will usually occur within the first few hours of vaccination</p> <p><b>Blood disorders:</b></p> <ul style="list-style-type: none"> <li>• Blood disorders or low blood pressure</li> <li>• * narrowing or blockage of blood vessels</li> <li>• changes in liver function tests</li> </ul> |  |
|---|--|

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ENGERIX-B contains

|                            |   |
|----------------------------|---|
| <b>Active ingredient</b>   | Surface protein of the hepatitis B virus, derived from genetically engineered yeast cells. The vaccine is not infectious, and will not give you the hepatitis B virus.  |
| <b>Other ingredients</b>   | Aluminium hydroxide hydrate, dibasic sodium phosphate dihydrate, monobasic sodium phosphate, sodium chloride (salt), and water. ENGERIX-B contains no thiomersal.   |
| <b>Potential allergens</b> | The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.<br><br>ENGERIX-B is made without any human blood or blood products, or any other substances of human origin. |

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ENGERIX-B looks like

ENGERIX-B comes in glass prefilled syringes, as a white, slightly milky liquid. Two different vaccine dosages are available:

- 10 microgram in 0.5mL of liquid - Monodose pre-filled syringes in packs of 1 and 10
- 20 microgram in 1mL of liquid - Monodose pre-filled syringe in packs of 1 and 10

Not all presentations and packs may be available.

ENGERIX-B is Aust R 123712 and Aust R 123713.

## Who distributes ENGERIX-B

GlaxoSmithKline Australia Pty Ltd  
Level 4, 436 Johnston Street,  
Abbotsford, Victoria, 3067  
Phone: 1800 033 109  
[www.gsk.com.au](http://www.gsk.com.au)

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This leaflet was prepared in February 2024.

Version 6.0