

ENGERIX-B

Consumer Medicine Information (CMI) summary

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

1. Why am I being given ENGERIX-B?

ENGERIX-B is 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 using ENGERIX-B?](#) in the full CMI.

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

Do not receive 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 the upper arm muscle. For babies, the vaccine may be given in the upper thigh muscle. For some people with bleeding problems, the vaccine 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 being given ENGERIX-B?

Things you should do	<ul style="list-style-type: none">• Check with your doctor if you or your child have an allergy to yeast, 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.
Things you should not do	<ul style="list-style-type: none">• Do not receive ENGERIX-B if you or your child has a severe infection with a high temperature.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your vaccine	<ul style="list-style-type: none">• 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 being given ENGERIX-B?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been most commonly reported include redness, swelling, a hard lump, soreness, bruising or itching around the injection site, irritability, headache. There is a rare risk of serious allergic reactions. Contact your doctor immediately or go to the emergency 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 ingredients: *Hepatitis B surface protein*

Consumer Medicine Information (CMI)

This leaflet provides important information about receiving ENGERIX-B. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about receiving 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 when 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 aiding your body to produce its own protection (antibodies) against this disease. The vaccine is not infectious and will not give you the hepatitis B virus.

ENGERIX-B can be given to adults, adolescents, children, infants and neonates (newborns). The vaccine can be given at any age from birth onwards.

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 enters your bloodstream. This can happen 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.

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

Some groups of people are at a higher risk of exposure to hepatitis B. Vaccination is recommended for these people:

- some healthcare workers
- abusers of injectable drugs
- people with many sexual partners
- homosexual men
- haemodialysis patients or people who receive certain blood products
- people with chronic liver disease or hepatitis C
- people in contact with a hepatitis B carrier or an infected person
- staff and residents of institutions or homes
- inmates and prison staff at some correctional institutions
- some travellers to areas where the incidence of hepatitis B is high.

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. It may also help reduce disease complications such as chronic active hepatitis and liver cirrhosis as well as incidence of a type of liver cancer known as primary hepatocellular carcinoma.

Immunoglobulins can protect you from hepatitis B straight away if you have been exposed but it is only effective for a short period of time (8 to 12 weeks).

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 receive ENGERIX-B if:

- you are/your child is 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
- you have/your child has a severe infection with a high temperature. A minor infection such as a cold should not be a problem, but talk to your doctor, nurse or pharmacist about this before being vaccinated
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Check with your doctor if you or your child:

- have an allergy to yeast
- 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)
- a nervous system illness
- have had ENGERIX-B before and become unwell, tell your doctor, nurse or pharmacist before receiving the next dose.

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

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

Sometimes ENGERIX-B may need to be given differently to people with:

- bleeding disorders
- immune deficiency (e.g. HIV positive people)
- kidney problems (e.g. dialysis patients) or liver problems. A higher dose may be used.

Tell your doctor if you or your child have recently 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.

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 breast-fed 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/your child is 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 ciclosporin.

ENGERIX-B can be given at the same time as other vaccines including hepatitis A, Haemophilus influenza b, diphtheria, measles-mumps-rubella vaccine, pertussis (whooping cough), tetanus and polio. It can also be given at the same time as human immunoglobulin. ENGERIX-B will always be given at a separate injection site from other injections.

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, nurse 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?

Your doctor, nurse or pharmacist will give ENGERIX-B as an injection.

If you have any concerns about this, talk to your doctor, nurse or pharmacist before you are given the vaccine.

How much is given

For adults and adolescents over 15 years of age:

- 1 mL (20 micrograms) is given.

For adolescents from the age of 10 up to and including 15 years of age:

- 0.5 mL (10 micrograms) is given.

Where compliance cannot be assured:

- 1 mL dose (20 micrograms) should be given.

For babies and children under 10 years of age:

- 0.5 mL (10 micrograms) is given, although if this is not available, a dose of 20 micrograms in 1 mL may be used.

How it is given

In adults and older children, ENGERIX-B will be injected into the upper arm muscle.

In babies and infants, the vaccine may be given in the upper thigh muscle.

For some people with bleeding problems, the vaccine may be given under the skin (subcutaneously).

ENGERIX-B should not be given directly into the veins (intravenously).

When it is given

ENGERIX-B is generally given as a single dose on an elected date.

ENGERIX-B may be given as a three-dose series for primary immunisation against hepatitis B. National guidelines should also be consulted prior to use of the vaccine.

Different recommendations are based on risk of infection:

In areas of low risk of infection:

- 1st dose: at elected date
- 2nd dose: 1 month later
- 3rd dose: 6 months from the date of the first dose

In areas of high risk of infection:

- 1st dose: at elected date
- 2nd dose: 1 month later
- 3rd dose: 2 months from the date of the first dose.

Use in exceptional circumstances in adults (e.g. travellers commencing hepatitis B primary vaccination within one month of departure):

- 1st dose: at elected date
- 2nd dose: 7 days later
- 3rd dose: 21 days from the date of the first dose.

If you or your child are travelling overseas, allow at least 3 weeks before departure for the final ENGERIX-B dose to be given. This is so the body has time to respond to the vaccine. If there is a risk of hepatitis B infection occurring before immunity develops, human immunoglobulin may need to be given at the same time as ENGERIX-B.

Depending on the dosing schedule that you/your child follows, a booster dose of ENGERIX-B, given 12 months to 5 years after the third dose, gives long-term protection. It is not known how long the booster dose protection lasts. Your doctor will advise on the need for a booster dose.

If a dose is missed

If you miss a scheduled dose, talk to your doctor, nurse or pharmacist 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 **0800 POISON** or **0800 764 766**), 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 when being given ENGERIX-B?

Things you should do

Keep your follow-up visits with your doctor or clinic. It is important that 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

- feel unwell during or after having had a dose of ENGERIX-B

Remind any doctor, dentist or pharmacist you visit shortly after you have had the vaccine that you have received ENGERIX-B.

Things you should not do

- do not miss follow up doses of ENGERIX-B

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. 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 for it to be given.

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

When to discard your vaccine

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

Getting rid of any unwanted vaccine

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

Do not receive this vaccine 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. 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
General disorders and administration site conditions: <ul style="list-style-type: none">• redness, swelling, a hard lump, soreness, bruising or itching around the injection site• generally unwell, fever or headache• irritability Gastrointestinal disorders: <ul style="list-style-type: none">• loss of appetite, or feeling sick (nausea), vomiting or diarrhoea Psychiatric disorders: <ul style="list-style-type: none">• irritability	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<p>Nervous system disorders:</p> <ul style="list-style-type: none"> difficulty in walking, numbness, weakness and/or fatigue in limbs, tingling in fingers, toes, or other body parts, pain drooping eyelids or sagging muscles on one side of the face, also called Bell's palsy <p>Musculoskeletal and connective tissue disorders</p> <ul style="list-style-type: none"> aches or pains in joints <p>Renal and urinary disorders</p> <ul style="list-style-type: none"> difficulty in passing urine <p>Lymphatic disorders:</p> <ul style="list-style-type: none"> swelling with fluid in tissues <p>Skin disorders:</p> <ul style="list-style-type: none"> mild skin rash reddening of the skin, red swellings over the skin or in the mouth and on the lips, or other skin problems <p>General disorders and administration site conditions:</p> <ul style="list-style-type: none"> fever <p>Infections and immune system disorders:</p> <ul style="list-style-type: none"> allergic reactions <ul style="list-style-type: none"> 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, muscular aches and pains fever, headache, dizziness <p>Allergy to ENGERIX-B is rare. Any such severe reactions will usually occur within the first few hours of vaccination</p>	<p>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.</p>

Tell your doctor, nurse 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 via <https://pophealth.my.site.com/carmreportnz/s/>

By reporting side effects, you can help provide more information on the safety of this medicine.

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

7. Product details

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

What ENGERIX-B contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> surface protein of the hepatitis B virus (derived from genetically engineered yeast cells)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> aluminium hydroxide hydrate sodium chloride dibasic sodium phosphate dihydrate monobasic sodium phosphate dihydrate water for injections traces of polysorbate 20

Do not receive this vaccine if you or your child are allergic to any of these ingredients.

What ENGERIX-B looks like

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

- 10 micrograms in 0.5 mL of liquid - monodose pre-filled syringe in a pack of 1 (TT50-4218a)
- 20 micrograms in 1 mL of liquid - monodose pre-filled syringe in packs of 1 and 10 (TT50-4218)

Not all packs may be available.

Who distributes ENGERIX-B

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