

ENGERIX[®]-B

Hepatitis B Vaccine

CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about ENGERIX-B vaccine. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you having ENGERIX-B against the expected benefits.

If you have any concerns about receiving ENGERIX-B talk to your doctor, nurse or pharmacist.

Keep this leaflet with this vaccine. You may need to read it again.

WHAT ENGERIX-B IS USED FOR

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.

BEFORE RECEIVING ENGERIX-B

DO NOT HAVE ENGERIX-B IF :

- you have had an allergic reaction to ENGERIX-B, or any ingredient 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.

If you are not sure whether you should have ENGERIX-B, talk to your doctor, nurse or pharmacist. Do not give this vaccine to anyone else; your doctor has prescribed it specifically for you.

BEFORE YOU HAVE ENGERIX-B TELL YOUR DOCTOR IF:

- you have an allergy to yeast
- you are or think you may be pregnant, or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving ENGERIX-B during pregnancy.
- you are breastfeeding. 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.
- 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.

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).

- 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. You may need a higher dose of ENGERIX-B than normal.

Some vaccines may be affected by other vaccines or medicines. 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.

USE IN CHILDREN

ENGERIX-B can be given to newborns, infants and children of all ages.

HOW ENGERIX-B IS 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, 0.5mL (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 IS IT 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.

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

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

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 YOU MISS A DOSE

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

WHILE YOU ARE USING ENGERIX-B

THINGS YOU MUST DO:

Keep your follow up visits with the doctor or clinic. It is important the 2 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.

THINGS TO BE CAREFUL OF:

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. But in some people vaccination can cause dizziness or lightheadedness. 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.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if 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.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with ENGERIX-B are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site. Events reported following ENGERIX-B which may have been related to the vaccine are listed below.

MILD EVENTS

· **Tell your doctor if you notice any of the following**

that are troublesome or ongoing:

- ◆ pain, redness, swelling, a hard lump, bruising or itching around the injection site
- ◆ headache, unusual tiredness, dizziness or feeling generally unwell
- ◆ vomiting or feeling sick, stomach pains, loss of appetite or diarrhoea
- ◆ muscle aches and pains, back pain or neck stiffness
- ◆ coughing, sore throat, runny nose, mild fever, swollen glands in armpit or neck, fainting, sweating, flushing or chills
- ◆ disturbed sleep.

MORE SERIOUS EVENTS

· **Tell your doctor immediately if you notice any of the following:**

- ◆ difficulty in walking, numbness, weakness and/or fatigue in limbs, tingling in fingers or toes, pain, blurred vision or other visual changes
- ◆ drooping eyelid or sagging muscles on one side of the face, also called Bell's palsy
- ◆ aches or pains in joints, mild skin rash
- ◆ swelling with fluid in tissues
- ◆ difficulty in passing urine
- ◆ fever
- ◆ reddening of the skin, red swellings over the skin or in the mouth and on the lips, or other skin problems.

· **As with all vaccines given by injection there is a very small risk of serious allergic reaction. Contact your doctor immediately 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.

Allergy to ENGERIX-B is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Other rare events that have been reported with ENGERIX-B include:

- ◆ blood disorders or low blood pressure
- ◆ changes in liver function tests
- ◆ Guillain-Barre Syndrome (an inflammatory illness affecting nerves, resulting in weakness of muscles)
- ◆ Disease of the brain including infection and swelling
- ◆ Convulsions

Other side effects not listed above, can also occur during or soon after a dose of ENGERIX-B. **Check with your doctor if you notice any other effects.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

STORAGE

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 for it to be given.

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

PRODUCT DESCRIPTION

WHAT IT LOOKS LIKE

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

- 20 microgram in 1mL of liquid
- 10 microgram in 0.5mL of liquid

INGREDIENTS:

The active ingredient of ENGERIX-B is the 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.

Inactive ingredients in the vaccine are: aluminium hydroxide, sodium phosphate, sodium chloride (salt), sodium acid phosphate, polysorbate 20 and water. A very small amount of thiomersal may also be present.

ENGERIX-B is made without any human blood or blood products, or any other substances of human origin.

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.

FURTHER INFORMATION

ENGERIX-B is only available if prescribed by a doctor.

ENGERIX-B comes in the following packs:

20 microgram/1mL - Monodose vials in packs of 1 and 10 (AUST R 73477)

10 microgram/0.5mL - Monodose vials in packs of 1 and 10 (AUST R 73478)

MANUFACTURER

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