

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

ENGERIX B, SUSPENSION FOR INJECTION HEPATITIS B (RECOMBINANT DNA) VACCINE (ADSORBED)

Read all of this leaflet carefully before you start receiving

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Engerix B is and what it is used for
2. Before you receive Engerix B
3. How Engerix B is given
4. Possible side effects
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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.

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/your child 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/your child if you have already caught the hepatitis B virus. Engerix B can only help to protect you/your child against infection with hepatitis B virus.

2. BEFORE YOU RECEIVE ENGERIX B

Engerix B should not be given:

- if you/your child have previously had any allergic reaction to Engerix B, or any ingredient contained in this vaccine. The active substances and other ingredients in Engerix B are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Take special care with Engerix B:

Your doctor needs to know before you/your child are injected with Engerix B if you/your child:

- have a severe infection with a high temperature (over 38°C). In these cases, the vaccination will be postponed until you/your child are feeling better. A minor infection such as a cold should not be a problem, your doctor will advise whether you or your child can still be vaccinated with Engerix B.
- have a poor immune system due to illness or drug treatment.
- have a bleeding problem or bruise(s) easily

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).

As with all vaccines, not everyone who is vaccinated will be protected from getting the infection. Also, if you/your child have unknowingly been infected with hepatitis B virus before being vaccinated with Engerix B, the vaccine may not be able to prevent you or your child getting the disease.

A poor response to the vaccine, possibly without achieving protection against hepatitis B, is more common in older people, men rather than women, smokers, obese people, and people with long standing illnesses, or people on some type of drug treatments. Your doctor may advise you/your child to have a blood test after completing the course of vaccinations to check how effective the vaccination has been. It may be necessary to have extra doses of the vaccine. Your doctor will advise you.

Using other medicines or vaccines

Please tell your doctor if you/your child are taking or have recently taken any other medicines, including medicines obtained without a prescription or have recently received any other vaccine.

Pregnancy and breast-feeding

Tell your doctor if 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 having Engerix B during pregnancy.

It is not known if Engerix B passes into breast-milk, however the vaccine is not expected to cause problems in breast-fed babies.

3. HOW ENGERIX B IS GIVEN

Engerix B 10 micrograms (10 µg) is used to vaccinate children from birth and up to 15 years of age. The dose is 0.5 ml.

Engerix B 20 micrograms (20 µg) is used to vaccinate people from 16 years of age and above. The dose is 1 ml.

Engerix B is usually injected into the upper arm muscle in adults and children or into the thigh muscle in babies and young children. The vaccine must never be injected into a vein.

Engerix B is usually given as a total of three separate injections over 6 months as follows:

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

Engerix B can also be given as a total of three doses over 3 months as follows: (This schedule may be given to people needing rapid protection)

- First dose: at chosen date
- Second dose: 1 month later
- Third dose: 2 months after the first dose

A fourth dose is recommended 12 months after the first dose.

In infants this schedule will allow for simultaneous administration of hepatitis B with other childhood vaccines.

In adults only, Engerix B 20 µg can also be given as a total of three doses over 1-month as follows: (This schedule may be given only to adults needing a rapid protection (e.g. overseas travelers)).

- First dose: at date
- Second dose: 7 days later
- Third dose: 21 days after the first dose

A fourth dose is recommended 12 months after the first dose.

In children aged 11 to 15 years, Engerix B 20 µg (1 ml) may be given as a total of 2 doses as follows:

- First dose: at chosen date
- Second dose: 6 months after the first dose

However, in this case, protection against hepatitis B may not be obtained until after the second dose. This schedule may be given to children aged 11 to 15 years only if there is a low risk of having

hepatitis B during the vaccination and if it is sure that the two doses will be given. If not, then the three doses of Engerix B 10 µg must be given.

Depending on individual circumstances and particularly if you/your child had kidney disease, other vaccination schedules are also possible. You should follow the instructions from your doctor.

For maximum protection from getting infected by Hepatitis B virus, make sure you/your child complete the full vaccination course of injections. If you miss an injection arrange another appointment as soon as you can. Your doctor will advise on the possible need for extra doses, including future booster doses.

4. POSSIBLE SIDE EFFECTS

Like all vaccines, Engerix B can cause side effects, although not everybody gets them. This is a widely used vaccine. Side effects that have been reported are:

- **Very common** (these may occur with more than 1 in 10 doses of the vaccine):
 - Irritability
 - pain and redness at the injection site
 - tiredness
- **Common** (these may occur with up to 1 in 10 doses of the vaccine):
 - loss of appetite
 - headache, drowsiness
 - nausea, vomiting, diarrhoea, abdominal pain
 - hard lump and swelling at the injection site
 - fever, generally feeling unwell
- **Uncommon** (these may occur with up to 1 in 100 doses of the vaccine):
 - Dizziness
 - aching muscles
 - flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- **Rare** (these may occur with up to 1 in 1,000 doses of the vaccine):
 - swollen glands in the neck, armpit or groin
 - abnormal sensation such as of burning, prickling, tickling or tingling
 - rash, itching, hives
 - joint pain
- **Very Rare** (these may occur with up to 1 in 10,000 doses of the vaccine)

Side effects that occurred very rarely during routine use of Engerix B:

- Inflammation of the membrane around the brain (meningitis). The symptoms are fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light
- bleeding or bruising more easily than normal
- as with all injectable vaccines, there is an extremely small risk of severe allergic reactions.

These can be recognised by:

- itchy rash of the hands and feet
- swelling of the eyes and face
- difficulty in breathing or swallowing

These reactions will usually occur before leaving the doctor's surgery. However, if your child gets any of these symptoms you should contact a doctor urgently

- paralysis, convulsions, fits or seizures, loss of skin sensitivity to pain or touch, swelling or infection of the brain, numbness or weakness of the arms and legs, inflammation of nerves
- low blood pressure, narrowing or blockage of blood vessels
- purple or reddish-purple bumps on the skin, serious rashes
- joint pain and swelling, muscle weakness

If any of the side effects gets serious, or if 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 at 2°C - 8°C (in a refrigerator)

Do not freeze. Freezing destroys the vaccine.

Store in the original package in order to protect from light.

Do not use after the expiry date stated on the pack. The date for last use corresponds to the last day of the month mentioned.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Engerix B contains

The active substances are:

Engerix B 10 µg

1 dose (0.5 ml) contains:

Hepatitis B surface antigen ^{1,2}	10 micrograms
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¹ Adsorbed on aluminium hydroxide, hydrated	Total: 0.25 milligrams Al ³⁺
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²Produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology

Engerix B 20µg

1 dose (1 ml) contains:

Hepatitis B surface antigen^{1,2} 20 micrograms

¹ Adsorbed on aluminium hydroxide, hydrated	Total: 0.50 milligrams Al ³⁺
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²Produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology

The other ingredients in Engerix B 10 µg and Engerix B 20 µg are:

sodium chloride, sodium phosphate dehydrate, sodium dihydrogen phosphate and water for injections.

Multi-dose presentations of Engerix B 10 µg and Engerix B 20 µg contain 2-phenoxyethanol in addition to the ingredients listed above.

What Engerix B looks like and contents of the pack

Engerix B is a white and milky liquid presented in a glass prefilled syringe or glass vial.

Manufacturer

GlaxoSmithKline Biologicals s.a.

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Belgium.

This leaflet was last approved on

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