Package leaflet: Information for the user

Fendrix suspension for injection
Hepatitis B (rDNA) vaccine (adjuvanted, adsorbed)

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fendrix is and what it is used for

Fendrix is a vaccine which prevents hepatitis B.
It is used for patients with kidney problems:
- patients having "haemo-dialysis"- where a "dialysis" machine removes waste products from the blood
- patients who are going to have "haemo-dialysis" in the future.

Fendrix is for adults and young people aged 15 years and above.

What is hepatitis B?

Hepatitis B is caused by a virus which makes the liver swollen.
- Signs may not be seen for 6 weeks to 6 months after infection.
- The main signs of the illness include mild signs of flu such as headache or fever, feeling very tired, dark urine, pale stools (faeces), yellow skin or eyes (jaundice). These or other signs may mean the person might need treatment in hospital. Most people fully recover from the illness.
- Some people with hepatitis B do not look or feel ill - they do not have any signs of illness.
- The virus is found in body fluids such as in the vagina, blood, semen, or saliva (spit).

Carriers of hepatitis B

- The hepatitis B virus stays in the body of some people all through their lives.
- This means they can still infect other people and are known as virus "carriers".
- Carriers of the virus are likely to get serious liver problems, such as "cirrhosis" or liver cancer.

How Fendrix works

- Fendrix helps your body to produce its own protection against the virus (antibodies). These antibodies will protect you against the disease.
- Fendrix contains two things called "MPL" (a non-toxic purified fat derivative from bacteria) and "aluminium phosphate". These make the vaccine work quicker, better and last for longer.
- As with all vaccines, a course of Fendrix cannot fully protect all people that are vaccinated.
- Fendrix may not protect you from being ill if you have already caught the hepatitis B virus.

- Fendrix can only help to protect you against infection with the hepatitis B virus. It cannot protect you against other infections that can affect the liver - even though these infections might have signs similar to those caused by the hepatitis B virus.

2. What you need to know before you receive Fendrix

Fendrix should not be given

- if you are allergic to the active substance, or any of the other ingredients of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue
- if you have ever had an allergic reaction to any vaccine against hepatitis B
- if you have a severe infection with a high temperature. The vaccine can be given after you have recovered. A minor infection such as a cold should not be a problem, but talk to your doctor first.

Fendrix should not be given if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before having Fendrix.

Warnings and precautions

Talk to your doctor or pharmacist before you are given Fendrix:

- if you have any known allergies
- if you have had any health problems after having a vaccine in the past.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you fainted with a previous injection.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before having Fendrix.

Other medicines and Fendrix

Tell your doctor if you are taking, have recently taken, might take any other medicines or have recently received any other vaccine.

- You should have a gap of at least 2 to 3 weeks between having Fendrix and any other vaccine.
- Fendrix may need to be given at the same time as an injection of hepatitis B "immuno-globulins". Your doctor will make sure that the vaccines are injected into different parts of the body.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this vaccine.

Driving and using machines

You may feel tired or get a headache after receiving Fendrix. If this happens, take special care while driving or using any tools or machines.

3. How Fendrix is given

How the vaccine is given
The doctor or nurse will give Fendrix as an injection into your muscle. This is usually in your upper arm.

How much is given
- You will have a series of four injections.
- The injections will be given within 6 months:
  - First injection - on a date agreed with your doctor.
  - Second injection - 1 month after the first injection.
  - Third injection - 2 months after the first injection.
  - Fourth injection - 6 months after the first injection.

- The doctor or nurse will tell you when you should come back for the next injections.

- Once you have had the first injection of Fendrix, the next injections need also to be Fendrix (not another sort of hepatitis B vaccine).

Your doctor will tell you if you need any extra or "booster" injections in the future. Fendrix can also be used as a booster after a course of a different type of hepatitis B vaccine.

If you miss a dose

- **If you miss an injection, talk to your doctor and arrange another visit.**
- Make sure you finish the complete course of four injections. If not, you may not be fully protected against the disease.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

The following side effects may happen with this vaccine. Their frequency is defined using the conventions listed below:

Very common (these may occur with more than 1 in 10 doses of the vaccine)
- headache
- feeling tired
- pain or discomfort where the injection was given.

Common (these may occur with up to 1 in 10 doses of the vaccine)
- redness or swelling where the injection was given
- fever
- stomach and digestion problems.

Uncommon (these may occur with up to 1 in 100 doses of the vaccine**)**
- chills
- red, raised skin rash
- other reactions where the injection was given.

Rare (these may occur with up to 1 in 1,000 doses of the vaccine)
- allergy
- hot flushes

- feeling dizzy
- feeling thirsty
- feeling nervous
- infection caused by a virus
- back pain, swelling of your tendons.

Additionally, the following side effects have also been reported with other hepatitis B vaccines:

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine)
- fits
- fainting
- problems with the nerves of your eye (optic neuritis)
- multiple sclerosis
- loss of feeling or problems moving some parts of your body
- severe headache with a stiff neck
- numbness or weakness of the arms and legs (neuropathy), inflammation of nerves (neuritis), weakness and paralysis in the extremities and often progressing to the chest and face (Guillain-Barré syndrome), swelling or infection of the brain (encephalitis, encephalopathy).
- allergic reactions, including anaphylactoid reactions. These may be local or widespread rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness. Such reactions may occur before leaving the doctor's surgery. However, you should seek immediate treatment in any event.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).
By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard.

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Tel: +353 1 6764971
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Website: www.hpra.ie
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5. How to store Fendrix

- Keep this vaccine out of the sight and reach of children.

- Do not use this vaccine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

- Store in a refrigerator (2°C - 8°C).
- Store in the original package in order to protect from light.
- Do not freeze. Freezing destroys the vaccine.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fendrix contains

- The active substance in 1 dose (0.5 ml) of Fendrix is:

Hepatitis B surface antigen [1, 2, 3]	20 micrograms

[1]adjuvanted by AS04C containing:

- 3-*O*-desacyl-4'- monophosphoryl lipid A (MPL) [2]	50 micrograms

[2]adsorbed on aluminium phosphate (0.5 milligrams Al^{3+} in total)

[3]produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology.

- The other ingredients in Fendrix are: sodium chloride, water for injections.

What Fendrix looks like and contents of the pack

- Suspension for injection in a prefilled syringe.
- Fendrix is a white, milky suspension presented in a glass prefilled syringe (0.5 ml).
- Fendrix is available in packs of 1 (with or without a separate needle) and in a pack size of 10 without needles.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

GlaxoSmithKline Biologicals s.a.
Rue de l'Institut 89
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For any information about this medicine, please contact the local representative of the Marketing Authorisation holder.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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The following information is intended for healthcare professionals only:

Upon storage, a fine white deposit with a clear colourless supernatant can be observed.

Before administration, the vaccine should be well shaken to obtain a slightly opaque, white suspension.

The vaccine should be visually inspected both before and after re-suspension for any foreign particulate matter and/or change in physical appearance. The vaccine must not be used if any change in the appearance of the vaccine has taken place.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Fendrix should not be given to subjects with hypersensitivity to the active substance or to any of the excipients.

Fendrix should not be given to subjects with hypersensitivity after previous administration of other hepatitis B vaccines.

Fendrix should not be given to subjects suffering from acute severe febrile illness. The presence of a minor infection such as a cold, is not a contraindication for immunisation.

Fendrix should be injected intramuscularly in the deltoid region.

Since intramuscular administration into the gluteal muscle could lead to a suboptimal response to the vaccine, this route should be avoided.

Fendrix should under no circumstances be administered intradermally or intravenously.

As pre-haemodialysis and haemodialysis patients are particularly exposed to HBV and have a higher risk to become chronically infected, a precautionary attitude should be considered i.e. giving a booster dose in order to ensure a protective antibody level as defined by national recommendations and guidelines.

Appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.