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EPAR summary for the public

Fendrix

hepatitis B (rDNA) vaccine (adjuvanted, adsorbed)

This is a summary of the European public assessment report (EPAR) for Fendrix. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Fendrix.

What is Fendrix?

Fendrix is a vaccine, which is available as a suspension for injection. It contains parts of the hepatitis B virus as the active substance.

What is Fendrix used for?

Fendrix is used to protect patients with kidney problems against hepatitis B (a disease of the liver due to infection with the hepatitis B virus). It can be used in patients from the age of 15 years, including patients needing haemodialysis (a blood clearance technique used in patients with kidney disease).

The vaccine can only be obtained with a prescription.

How is Fendrix used?

The recommended vaccination schedule for Fendrix is four doses. There should be a gap of one month between the first and second, and between the second and third injections. The fourth injection is given four months after the third. It is recommended that individuals who receive the first dose should complete the course with Fendrix. The vaccine is injected into the shoulder muscle.

A booster dose of Fendrix may be given, according to official recommendations.

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How does Fendrix work?

Fendrix is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Fendrix contains small amounts of the 'surface antigen' (proteins from the surface) of the hepatitis B virus. When a patient is given the vaccine, the immune system recognises the surface antigens as 'foreign' and makes antibodies against them. In the future, the immune system will be able to make antibodies more quickly when it is exposed to the hepatitis B virus. The antibodies will help to protect against the disease caused by the virus.

The surface antigens are produced by a method known as 'recombinant DNA technology': they are made by a yeast that has received a gene (DNA), which makes it able to produce the proteins.

The active substance in Fendrix has been available in other vaccines that have been authorised in the European Union (EU) for a number of years. In Fendrix, it is used with an 'adjuvant system' which contains 'MPL', a purified fat from bacteria, and an aluminium compound. This system enhances the response of the immune system, which can help when vaccines are used in patients who may have a lower response, such as those with kidney problems.

How has Fendrix been studied?

Because the active substance in Fendrix has been available in the EU in other vaccines, some of the information used to support the use of the other vaccines was used to support the use of Fendrix.

Fendrix has also been studied in one main study involving 165 patients aged 15 years and above who had kidney disease and needed haemodialysis. Fendrix was compared with a double dose of Engerix B (another hepatitis B vaccine). The main measure of effectiveness was the proportion of patients who developed protective levels of antibodies against the hepatitis B virus.

The company also presented information on the use of Fendrix in liver transplant patients, but it withdrew the application for the use of Fendrix in these patients during the assessment of the vaccine.

What benefit has Fendrix shown during the studies?

Fendrix was as effective as a double dose of the comparator vaccine. One month after the last dose, 91% of the patients receiving Fendrix had protective levels of antibodies against the hepatitis B virus, compared with 84% of those receiving the comparator.

The effect of Fendrix lasted longer than that of the comparator vaccine: 80% of the patients receiving Fendrix maintained protective levels of antibody for up to three years, compared with 51% of those receiving the comparator.

What is the risk associated with Fendrix?

The most common side effects with Fendrix (seen in more than 1 patient in 10) are headache, pain, redness, swelling at the injection site and fatigue (tiredness). For the full list of side effects reported with Fendrix, see the package leaflet.

Fendrix must not be used in people who are hypersensitive (allergic) to the active substance or any of the other ingredients or have had an allergic reaction after being given a hepatitis B vaccine. Fendrix must not be given to patients with a severe sudden fever.

Why has Fendrix been approved?

The CHMP decided that Fendrix's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Fendrix

The European Commission granted a marketing authorisation valid throughout the European Union for Fendrix on 2 February 2005.

The full EPAR for Fendrix can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Fendrix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2014.