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EPAR summary for the public

Zeffix

lamivudine

This document is a summary of the European public assessment report (EPAR) for Zeffix. 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 Zeffix.

What is Zeffix?

Zeffix is a medicine that contains the active substance lamivudine. It is available as tablets (100 mg) and an oral solution (5 mg/ml).

What is Zeffix used for?

Zeffix is used to treat adults (aged 18 years or over) who have chronic (long-term) hepatitis B (a disease of the liver due to infection with the hepatitis B virus). It is used in patients with:

- compensated liver disease (when the liver is damaged but works normally), who also show signs that the virus is still multiplying and have signs of liver damage (raised levels of the liver enzyme alanine aminotransferase [ALT] and signs of damage when liver tissue is examined under a microscope). Because the hepatitis B virus can become resistant to Zeffix, the doctor should only consider prescribing Zeffix if other treatments that are less likely to lead to resistance cannot be used;
- decompensated liver disease (when the liver does not work normally). To reduce the risk of resistance, Zeffix must be used in combination with another anti-hepatitis B medicine that does not cause resistance in the same way as Zeffix.

The medicine can only be obtained with a prescription.

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How is Zeffix used?

Treatment with Zeffix should be started by a doctor who has experience in the management of chronic hepatitis B.

The recommended dose of Zeffix is 100 mg once a day. The dose needs to be lower in patients who have reduced kidney function. Doses lower than 100 mg need to be given using the oral solution. The duration of treatment depends on the patient's condition and response to treatment.

If the hepatitis B virus can still be found in the blood after six months of treatment, the doctor should consider switching treatment or adding another medicine for hepatitis B to reduce the risk of resistance. For more information, see the summary of product characteristics (also part of the EPAR).

How does Zeffix work?

The active substance in Zeffix, lamivudine, is an antiviral agent that belongs to the class 'nucleoside analogues'. Lamivudine interferes with the action of a viral enzyme called DNA polymerase, which is involved in the formation of viral DNA. Lamivudine stops the virus making DNA and prevents it from multiplying and spreading.

How has Zeffix been studied?

Zeffix has been studied in five main studies involving a total of 1,083 adults with compensated liver disease due to chronic hepatitis B. Three studies compared Zeffix with placebo (a dummy treatment), one of which looked particularly at 'HBeAg-negative' patients. These are patients infected with hepatitis B virus that has mutated (changed), leading to a form of chronic hepatitis B that is more difficult to treat. The other two studies compared Zeffix taken on its own with alfa-interferon (another treatment used in chronic hepatitis B) on its own and with the combination of Zeffix and alfa-interferon.

In addition, information was presented on the use of Zeffix in patients with decompensated liver disease.

There were several measures of effectiveness in the studies. These included looking at how the liver damage had evolved after a year of treatment using a liver biopsy (when a small sample of liver tissue is taken and examined under a microscope), as well as measuring other signs of the disease such as the levels of ALT or of hepatitis B virus DNA circulating in the blood.

What benefit has Zeffix shown during the studies?

In patients with compensated liver disease, Zeffix was more effective than placebo in slowing down the progression of liver disease. About half of the patients taking Zeffix had an improvement in liver damage assessed in a biopsy, compared with about a quarter of the patients who took placebo. Zeffix was as effective as alfa-interferon.

In patients with decompensated liver disease, Zeffix also reduced levels of hepatitis B virus DNA and ALT.

What is the risk associated with Zeffix?

The most common side effect with Zeffix (seen in more than 1 patient in 10) is raised ALT levels. For the full list of all side effects or restrictions with Zeffix, see the package leaflet.

Why has Zeffix been approved?

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

Other information about Zeffix:

The European Commission granted a marketing authorisation valid throughout the European Union for Zeffix on 29 July 1999.

The full EPAR for Zeffix 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 Zeffix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2016.