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EPAR summary for the public

Hepsera

adefovir dipivoxil

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

What is Hepsera?

Hepsera is a medicine that contains the active substance adefovir dipivoxil. It is available as tablets (10 mg).

What is Hepsera used for?

Hepsera is used to treat adults with 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 functions 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 Hepsera, the doctor should only consider prescribing Hepsera if other treatments that are less likely to lead to resistance cannot be used;
- decompensated liver disease (when the liver is damaged and does not function normally. To reduce the risk of resistance, Hepsera must be used in combination with another anti-hepatitis B medicine that does not cause resistance in the same way as Hepsera.

The medicine can only be obtained with a prescription.

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How is Hepsera used?

Treatment with Hepsera should be started by a doctor who has experience in the management of chronic hepatitis B. The recommended dose is 10 mg once a day. The duration of treatment depends on the patient's condition and response to treatment. These should be monitored every six months. Patients who have problems with their kidneys should take Hepsera less frequently.

Hepsera is not recommended for use in patients with severe kidney disease or who are on dialysis (a blood clearing technique) – its use should only be considered in these patients if its potential benefits are greater than its potential risks.

For more information, see the summary of product characteristics (also part of the EPAR).

How does Hepsera work?

The active substance in Hepsera, adefovir dipivoxil, is a 'prodrug' that is converted into adefovir in the body. Adefovir is an antiviral belonging to the class 'nucleoside analogues'. Adefovir interferes with the action of a viral enzyme called DNA polymerase, which is involved in the formation of viral DNA. Adefovir stops the virus making DNA and prevents it from multiplying and spreading.

How has Hepsera been studied?

Hepsera has been studied in two main studies, in which it was compared with placebo (a dummy treatment). The first study included 511 patients who were 'HBeAg positive' (infected with the common type of the hepatitis B virus) and the second included 184 patients who were 'HBeAg negative' (infected with a virus that has mutated [changed], leading to a form of chronic hepatitis B that is more difficult to treat). In both studies, the effectiveness was measured by looking at how the liver damage had evolved after 48 weeks of treatment using a liver biopsy (when a sample of liver tissue is taken and examined under a microscope).

What benefit has Hepsera shown during the studies?

Hepsera was more effective than placebo in slowing down the progression of liver disease. Among those who took Hepsera, 53% of the HBeAg-positive and 64% of the HBeAg-negative patients had an improvement in liver damage as assessed in a biopsy, compared with 25% and 33%, respectively, in the patients who took placebo.

What is the risk associated with Hepsera?

The most common side effects with Hepsera (seen in more than 1 patient in 10) are raised creatinine (a marker of kidney problems) and asthenia (weakness). For the full list of all side effects reported with Hepsera, see the package leaflet.

Hepsera must not be used in people who are hypersensitive (allergic) to adefovir dipivoxil or any of the other ingredients.

Why has Hepsera been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Hepsera's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Hepsera

The European Commission granted a marketing authorisation valid throughout the European Union for Hepsera on 6 March 2003.

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

This summary was last updated in 05-2013.