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EPAR summary for the public

Sebivo

telbivudine

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

What is Sebivo?

Sebivo is a medicine that contains the active substance telbivudine. It is available as tablets (600 mg) and as an oral solution (20 mg/ml).

What is Sebivo used for?

Sebivo is used to treat adults with chronic (long-term) hepatitis B, a disease of the liver caused by infection with the hepatitis B virus. It is used in patients who have compensated liver disease (when the liver is damaged but is still able to work normally), who also show signs that the virus is still multiplying, and have signs of liver damage (raised liver enzymes in the blood or signs of damage when liver tissue is examined under a microscope).

Starting treatment with Sebivo should only be considered when it is not possible or appropriate to use an alternative medicine which the hepatitis B virus is less likely to develop resistance to.

The medicine can only be obtained with a prescription.

How is Sebivo used?

Treatment with Sebivo should be started by a doctor who has experience in the management of chronic hepatitis B. The recommended dose of Sebivo is 600 mg (one tablet) once a day. The oral solution can be considered for patients who have difficulty swallowing tablets.

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Patients who have problems with their kidneys may need to take a lower daily dose using the oral solution. If this is not possible, they should take the tablets less often. Patients with kidney problems should be closely monitored. See the summary of product characteristics (also part of the EPAR) for full details.

The patient's blood should be monitored every six months for the presence of DNA from the hepatitis B virus. A change of treatment should be considered if viral DNA is found.

How does Sebivo work?

The active substance in Sebivo, telbivudine, is an antiviral medicine that belongs to the class 'nucleoside analogues'. Telbivudine interferes with the action of a viral enzyme called DNA polymerase, which is involved in the formation of viral DNA. By stopping the virus making DNA, telbivudine prevents it from multiplying and spreading.

How has Sebivo been studied?

Sebivo tablets were compared with lamivudine (another medicine used in chronic hepatitis B) in a two-year study involving 1,367 patients. The patients were mainly of Asian origin and had an average age of 36 years. None of the patients had been treated with nucleoside analogues before. The main measure of effectiveness was the number of patients who had responded to treatment after a year. A response was defined as low levels of viral DNA in the blood, together with either the levels of a liver enzyme called alanine aminotransferase (ALT) returning to normal or the marker for the hepatitis B virus disappearing from the blood.

The company also presented the results of a study showing that the oral solution produced the same levels of the active substance in the blood as the tablets.

What benefit has Sebivo shown during the studies?

Overall, Sebivo was at least as effective as lamivudine, with about three-quarters of the patients responding to treatment after a year.

The results were also calculated separately between 'HBeAg-positive' patients (infected with the common hepatitis B virus) and 'HBeAg-negative' patients (infected with a virus that has mutated, leading to a form of chronic hepatitis B that is more difficult to treat). After one year of treatment, Sebivo was more effective than lamivudine in the HBeAg-positive patients, with 75% responding to Sebivo and 67% to lamivudine. In the HBeAg-negative patients, Sebivo was as effective as lamivudine (75% and 77% responding, respectively).

What is the risk associated with Sebivo?

The most common side effects with Sebivo (seen in between 1 and 10 patients in 100) are dizziness, headache, cough, increased levels of some enzymes in the blood (amylase, lipase, creatine phosphokinase and alanine aminotransferase), diarrhoea, nausea (feeling sick), abdominal pain (stomach ache), skin rash and fatigue (tiredness). Because creatine phosphokinase is an enzyme that is raised when muscles are damaged, doctors need to monitor all muscle-related side effects closely. For the full list of all side effects reported with Sebivo, see the package leaflet.

Sebivo must not be used in people who are hypersensitive (allergic) to telbivudine or to any of the other ingredients. Sebivo must not be used in combination with pegylated or standard interferon alfa (other medicines used in the treatment of hepatitis).

Why has Sebivo been approved?

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

Other information about Sebivo

The European Commission granted a marketing authorisation valid throughout the European Union for Sebivo on 24 April 2007.

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

This summary was last updated in 04-2012.