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EPAR summary for the public

Lamivudine Teva

lamivudine

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

What is Lamivudine Teva?

Lamivudine Teva is a medicine that contains the active substance lamivudine. It is available as tablets (100 mg).

Lamivudine Teva is a 'generic medicine'. This means that Lamivudine Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Zeffix. For more information on generic medicines, see the question-and-answer document here.

What is Lamivudine Teva used for?

Lamivudine Teva is used to treat adult patients who have chronic (long term) hepatitis B (a disease of the liver due to an infection by 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 Lamivudine Teva, the doctor should only consider prescribing Lamivudine Teva if other treatments that are less likely to lead to resistance cannot be used.

The medicine can only be obtained with a prescription.

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How is Lamivudine Teva used?

Treatment with Lamivudine Teva should be initiated by a doctor who has experience in the management of chronic hepatitis B. The recommended dose of Lamivudine Teva is 100 mg once a day. The dose needs to be lowered for patients who have problems with their kidneys. Lamivudine Teva is not suitable for patients who require doses below 100 mg. 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 changing treatment to reduce the risk of resistance. Patients infected with a virus that has the 'YMDD mutation' (a change in the virus's DNA that is often found after treatment with lamivudine) should take Lamivudine Teva in combination with another medicine against hepatitis B. For more information, please see the Summary of Product Characteristics (also part of the EPAR).

How does Lamivudine Teva work?

The active substance in Lamivudine Teva, lamivudine, is an antiviral agent belonging to the class of the nucleoside analogues. Lamivudine interferes with the action of a viral enzyme, 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 Lamivudine Teva been studied?

Because Lamivudine Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Zeffix. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Lamivudine Teva?

Because Lamivudine Teva is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine.

Why has Lamivudine Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Lamivudine Teva has been shown to have comparable quality and to be bioequivalent to Zeffix. Therefore, the CHMP's view was that, as for Zeffix, the benefit outweighs the identified risk. The Committee recommended that Lamivudine Teva be given marketing authorisation.

Other information about Lamivudine Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Lamivudine Teva on 23 October 2009.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 04-2012.