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EPAR summary for the public

Lamivudine Teva Pharma B.V.

lamivudine

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

What is Lamivudine Teva Pharma B.V.?

Lamivudine Teva Pharma B.V. is an antiviral medicine containing the active substance lamivudine. It is available as tablets (150 and 300 mg).

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

What is Lamivudine Teva Pharma B.V. used for?

Lamivudine Teva Pharma B.V. is used in combination with other antiviral medicines to treat adults and children infected with human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS).

The medicine can only be obtained with a prescription.

How is Lamivudine Teva Pharma B.V. used?

Treatment with Lamivudine Teva Pharma B.V. should be initiated by a doctor who has experience in the management of HIV infection.

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The recommended dose of Lamivudine Teva Pharma B.V. for adults and children weighing at least 25 kg is 300 mg a day. This can be taken either as a single daily dose or divided into 150 mg twice a day. In children weighing less than 25 kg the recommended dose depends on their weight.

Lamivudine Teva Pharma B.V. tablets should ideally be swallowed without crushing. Patients who cannot swallow tablets should use an oral solution of lamivudine, or alternatively they may crush the tablets and add them to a small amount of food or drink immediately before swallowing it. The dose of Lamivudine Teva Pharma B.V. needs to be adjusted in patients who have severe problems with their kidneys. An oral solution of lamivudine can be used to achieve the appropriate dose. For more information, see the package leaflet.

How does Lamivudine Teva Pharma B.V. work?

The active substance in Lamivudine Teva Pharma B.V., lamivudine, is a nucleoside reverse transcriptase inhibitor (NRTI). It works by blocking the activity of reverse transcriptase, an enzyme needed by HIV to produce the genetic instructions for making more viruses once it has infected the cell. Lamivudine Teva Pharma B.V., taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Lamivudine Teva Pharma B.V. does not cure HIV infection or AIDS, but it can hold off damage to the immune system and avoid the development of infections and diseases associated with AIDS.

How has Lamivudine Teva Pharma B.V. been studied?

Because Lamivudine Teva Pharma B.V. is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Epivir. 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 Pharma B.V.?

Because Lamivudine Teva Pharma B.V. is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Lamivudine Teva Pharma B.V. been approved?

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

What measures are being taken to ensure the safe and effective use of Lamivudine Teva Pharma B.V.?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lamivudine Teva Pharma B.V. have been included in the summary of product characteristics and the package leaflet.

Other information about Lamivudine Teva Pharma B.V.

The European Commission granted a marketing authorisation valid throughout the EU for Lamivudine Teva Pharma B.V. on 10 December 2009.

The full EPAR for Lamivudine Teva Pharma B.V. 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 Pharma B.V., 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 09-2016.