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European Public Assessment Report on a scientific opinion in cooperation with the World Health Organization

EPAR summary for the public

Lamivudine ViiV[1]

lamivudine

This is a summary of the European public assessment report (EPAR) for Lamivudine ViiV. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion and its recommendations on the conditions of use for Lamivudine ViiV.

What is Lamivudine ViiV?

Lamivudine ViiV is a medicine containing the active substance lamivudine. It is available as red, diamond-shaped tablets (150 mg).

What is Lamivudine ViiV used for?

Lamivudine ViiV is an antiviral medicine. It 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).

Lamivudine ViiV is identical to a medicine already authorised in the European Union (EU) called Epivir, except for the appearance of the tablets. It has been developed in the context of co operation with the World Health Organization (WHO) because it can be used against a WHO target disease (HIV/AIDS). It is to be used exclusively in markets outside the EU.

The medicine can only be obtained with a prescription.

[1] Previously known as Lamivudine GSK.

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How is Lamivudine ViiV used?

Treatment with Lamivudine ViiV should be initiated by a doctor who has experience in the management of HIV infection.

The recommended dose of Lamivudine ViiV for patients over 12 years of age is two tablets once a day or one tablet twice a day. In children weighing more than 30 kg, the adult dose of one tablet twice a day should be used. In children weighing between 14 and 30 kg, the number of tablets and half tablets to take depends on body weight. The tablets should ideally be swallowed without crushing, although patients who cannot swallow tablets may crush and add them to a small amount of food or drink, before taking the dose immediately.

The dose of Lamivudine ViiV needs to be adjusted in patients who have severe problems with their kidneys. Lamivudine ViiV can be taken with or without food.

For more information, see the package leaflet.

How does Lamivudine ViiV work?

The active substance in Lamivudine ViiV, lamivudine, is a nucleoside reverse transcriptase inhibitor (NRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and make more viruses. Lamivudine ViiV, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Lamivudine ViiV does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Lamivudine ViiV been studied?

The changes in the appearance of the tablets have no impact on the product compared to Epivir. Because Lamivudine ViiV can be considered identical to Epivir, and both medicines are used in the same indication and at the same doses, the clinical studies performed with Epivir also apply to Lamivudine ViiV.

What benefit has Lamivudine ViiV shown during the studies?

The benefit associated with Lamivudine ViiV is identical to that of Epivir (see below for a link to information on Epivir).

What is the risk associated with Lamivudine ViiV?

The risk associated with Lamivudine ViiV is identical to that of Epivir (see below for a link to information on Epivir). Additionally, the dye used to colour Lamivudine ViiV tablets contains sunset yellow (E110), which may cause allergic reactions.

Why has Lamivudine ViiV been approved?

Lamivudine ViiV is to be used in the same indication, with the same dose and conditions of use as Epivir. The only differences from Epivir relate to the appearance of the tablets. The CHMP agreed that these changes would not have any impact on the benefit/risk ratio. Therefore, the Committee decided that Lamivudine ViiV's benefits are greater than its risks.

Other information about Lamivudine ViiV

The CHMP granted a positive scientific opinion in the context of cooperation with the WHO on 17 November 2005 for Lamivudine ViiV. The opinion has been assigned to ViiV Healthcare UK Limited.

For reference, the full EPAR for Epivir can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

The full EPAR for Lamivudine ViiV can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/Medicines for use outside the EU. For more information about treatment with Lamivudine ViiV, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2010.