EMA/629356/2010
EMEA/H/W/000672

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

EPAR summary for the public

Lamivudine/Zidovudine ViiV[1]

lamivudine/zidovudine

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

What is Lamivudine/Zidovudine ViiV?

Lamivudine/Zidovudine ViiV is a medicine that contains two active substances, lamivudine (150 mg) and zidovudine (300 mg). It is available as red capsule-shaped tablets.

What is Lamivudine/Zidovudine ViiV used for?

Lamivudine/Zidovudine ViiV is an antiviral medicine. It is used in combination with at least one other antiviral medicine to treat patients who are infected with human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS).

Lamivudine/Zidovudine ViiV is identical to a medicine already authorised in the European Union (EU) called Combivir, 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/Zidovudine GSK.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How is Lamivudine/Zidovudine ViiV used?

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

In adults and adolescents weighing at least 30 kg, the recommended dose of Lamivudine/Zidovudine ViiV is one tablet taken twice a day. In children weighing between 14 and 30 kg, the number of tablets and half tablets to take depends on body weight. Children weighing less than 14 kg will need to use separate medicines containing lamivudine and zidovudine. Children taking Lamivudine/Zidovudine ViiV should be closely monitored for side effects.

Lamivudine/Zidovudine ViiV can be taken with or without food. 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. If patients need to stop taking lamivudine or zidovudine, or need to take different doses because of problems with their kidneys, liver or blood, they will need to take medicines containing lamivudine or zidovudine separately.

For more information, see the package leaflet.

How does Lamivudine/Zidovudine ViiV work?

Both active substances in Lamivudine/Zidovudine ViiV, lamivudine and zidovudine, are nucleoside reverse transcriptase inhibitors (NRTIs). They both work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and make more viruses. Lamivudine/Zidovudine ViiV, taken in combination with at least one other antiviral medicine, reduces the amount of HIV in the blood and keeps it at a low level. Lamivudine/Zidovudine 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/Zidovudine ViiV been studied?

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

What benefit has Lamivudine/Zidovudine ViiV shown during the studies?

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

What is the risk associated with Lamivudine/Zidovudine ViiV?

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

Why has Lamivudine/Zidovudine ViiV been approved?

Lamivudine/Zidovudine ViiV is to be used in the same indication, with the same dose and conditions of use as Combivir. The only differences from Combivir 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/Zidovudine ViiV's benefits are greater than its risks.

Other information about Lamivudine/Zidovudine ViiV

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

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

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

This summary was last updated in 09-2010.