EMA/717174/2015
EMEA/H/C/001236

**EPAR summary for the public**

# Lamivudine/Zidovudine Teva

lamivudine/zidovudine



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

## What is Lamivudine/Zidovudine Teva?

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

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

## What is Lamivudine/Zidovudine Teva used for?

Lamivudine/Zidovudine Teva is used in combination with at least one other HIV medicine to treat patients 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/Zidovudine Teva used?

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

The recommended dose of Lamivudine/Zidovudine Teva for patients over 12 years of age who weigh at least 30 kg is one tablet taken twice a day. In children (below 12 years of age) weighing between 14 and 30 kg, the number of tablets and half tablets to take depends on their weight. Children weighing

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

less than 14 kg will need to use separate oral solutions containing lamivudine and zidovudine. Children taking Lamivudine/Zidovudine Teva should be closely monitored for side effects.

The tablets should ideally be swallowed without crushing. Patients who cannot swallow tablets may crush the tablets and add them to a small amount of food or drink immediately before swallowing it. 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 Teva work?

Both active substances in Lamivudine/Zidovudine Teva, 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 Teva, taken in combination with at least one other HIV medicine, reduces the amount of HIV in the blood and keeps it at a low level. Lamivudine/Zidovudine Teva 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.

Both active substances have been available in the EU for a number of years: lamivudine has been authorised as Epivir since 1996 and zidovudine has been available in the EU since the mid-1980s.

## How has Lamivudine Zidovudine Teva been studied?

Because Lamivudine/Zidovudine Teva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Combivir. 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/Zidovudine Teva?

Because Lamivudine/Zidovudine Teva is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

## Why has Lamivudine/Zidovudine Teva been approved?

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

## Other information about Lamivudine/Zidovudine Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Lamivudine/Zidovudine Teva on 28 February 2011.

The full EPAR for Lamivudine/Zidovudine 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/Zidovudine 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 11-2015.