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EPAR summary for the public

Combivir

lamivudine / zidovudine

This is a summary of the European Public Assessment Report (EPAR) for Combivir. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Combivir.

For practical information about using Combivir, patients should read the package leaflet or contact their doctor or pharmacist.

What is Combivir and what is it used for?

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

Combivir contains two active substances, lamivudine and zidovudine.

How is Combivir used?

Combivir is available as tablets containing lamivudine 150 mg and zidovudine 300 mg.

The recommended dose of Combivir 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 dose depends on their weight. Children weighing less than 14 kg will need to use separate oral solutions containing lamivudine and zidovudine. Children taking Combivir should be closely monitored and the doctor may need to adjust the dose in case of side effects on their digestive system.

Patients who cannot swallow tablets may crush the tablets, adding the powder to a small amount of food or drink and swallowing it 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.

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Treatment with Combivir should be started by a doctor who has experience in the management of HIV infection. The medicine can only be obtained with a prescription.

How does Combivir work?

Both active substances in Combivir, lamivudine and zidovudine, are nucleoside reverse transcriptase inhibitors (NRTIs). They work in similar ways by blocking the activity of reverse transcriptase, an enzyme made by the HIV virus that allows it to reproduce itself in the cells it has infected.

Combivir, 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. Combivir does not cure HIV infection or AIDS, but it may hold off 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.

What benefit of Combivir have been shown in studies?

Because lamivudine and zidovudine have been available in the EU for a number of years, the company presented information from earlier studies of the two substances taken together. The studies showed that the active substances taken together could reduce viral loads (the level of HIV in the blood) and allow CD4 cell counts to rise after up to one year of treatment. CD4 cells (also called CD4 T cells) are white blood cells that are important for fighting infections, but they are killed by HIV.

The company also compared Combivir to separate tablets of lamivudine and zidovudine in 75 patients aged over 12 years who had not taken treatment for HIV infection before. The main measures of effectiveness were the change in viral load and CD4 cell counts in the blood. Patients taking Combivir and those taking the two active substances separately had similar falls in viral load. After 12 weeks, the viral load had fallen by more than 95%. The two groups also had similar rises in CD4 cell counts. The company also compared how the body absorbed the Combivir combination tablet and the separate tablets. Combivir was absorbed in the same way as the separate tablets.

To support its recommendations for Combivir doses in children, the company presented studies of the levels of lamivudine and zidovudine in the blood of children taking the medicines separately. It also presented information on the predicted blood levels of the two substances in children taking the two substances combined in one tablet. The recommended doses of Combivir in children produced similar levels of the two active substances as in older patients.

What are the risks associated with Combivir?

The most common side effects with Combivir (which may affect more than 1 patient in 10) are diarrhoea and nausea (feeling sick).

Combivir must not be used by patients with low neutrophil counts (a type of white blood cell) or anaemia (low red blood cell counts). For the full list of all the side effects of Combivir and restrictions on its use, see the package leaflet.

Why is Combivir approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Combivir's benefits are greater than its risks and recommended that it be given marketing authorisation. The

CHMP considered that combining the active ingredients in a single tablet may be of advantage because it can improve how well patients stick to the prescribed treatment and this can help to prevent HIV becoming resistant to treatment.

What measures are being taken to ensure the safe and effective use of Combivir?

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

Other information about Combivir

The European Commission granted a marketing authorisation valid throughout the EU for Combivir on 18 March 1998.

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

This summary was last updated in 11-2016.