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EPAR summary for the public

Epivir

lamivudine

This document is a summary of the European Public Assessment Report (EPAR) for Epivir. 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 Epivir.

What is Epivir?

Epivir is a medicine containing the active substance lamivudine. It is available as tablets (150 and 300 mg) and as an oral solution (10 mg/ml).

What is Epivir used for?

Epivir is used in combination with other antiviral medicines 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 Epivir used?

Treatment with Epivir should be started by a doctor who has experience in the management of HIV infection.

The recommended dose of Epivir 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.

Patients who cannot swallow tablets should use the oral solution, 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 Epivir needs to be adjusted in patients who have severe kidney problems. The oral solution can be used to achieve the appropriate dose. For further information, see the package leaflet.

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How does Epivir work?

The active substance in Epivir, 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. Epivir, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. It 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 Epivir been studied?

Epivir has been studied in five main studies involving almost 3,000 adults (aged 18 years or over).

Four of these studies compared Epivir in combination with zidovudine (another antiviral medicine) to either Epivir or zidovudine alone, or to the combination of Epivir and zalcitabine (another antiviral medicine). The studies examined the effects of Epivir on the levels of HIV in the blood (viral load) and the number of CD4 T-cells in the blood (CD4 cell count). CD4 T-cells are white blood cells that are important in helping to fight infections, but which are killed by HIV.

The fifth study compared the effects of adding Epivir or placebo (a dummy treatment) to existing treatment for HIV infection in 1,895 adults who had been taking antiviral medicines for at least four weeks. This study looked at how many patients had developed an illness associated with AIDS or had died after a year's treatment.

Epivir has also been studied in 615 patients aged between nine months and 15 years. The study compared the effects of Epivir taken with zidovudine to didanosine (another antiviral medicine) taken alone. The study measured how long the patients lived without their disease getting worse.

What benefit has Epivir shown during the studies?

All of the studies found that combinations including Epivir were more effective than the comparator medicines.

In the first four studies in adults, Epivir, taken in combination with zidovudine, increased CD4 cell counts more than the comparator medicines after 24 weeks of treatment. The combination also reduced viral loads in all studies after two to four weeks of treatment, but this effect was temporary.

In the fifth adult study, adding Epivir to existing treatment reduced the risk of disease progression or death: after a year, 9% of the patients taking Epivir had developed an AIDS-related illness or died (128 out of 1,369), compared with 20% of those taking placebo (95 out of 471).

Similar results were seen in HIV-infected patients aged under 15 years.

What is the risk associated with Epivir?

The most common side effects with Epivir (seen in between 1 and 10 patients in 100) are diarrhoea, nausea (feeling sick), vomiting, headache, insomnia (difficulty sleeping), cough, nasal symptoms, rash, muscle disorders, arthralgia (joint pain), alopecia (hair loss), fever, abdominal pain (stomach ache) or cramps, malaise (feeling unwell) and fatigue (tiredness). For the full list of all side effects and restrictions with Epivir, see the package leaflet.

Why has Epivir been approved?

The CHMP decided that Epivir's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Epivir is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Epivir, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Epivir

The European Commission granted a marketing authorisation valid throughout the European Union for Epivir on 8 August 1996.

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

This summary was last updated in 02-2015.