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EPAR summary for the public

Ziagen

abacavir

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

What is Ziagen?

Ziagen is a medicine that contains the active substance abacavir. It is available as tablets (300 mg) and as an oral solution (20 mg/ml).

What is Ziagen used for?

Ziagen is used in combination with other antiviral medicines to treat patients who are 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 Ziagen used?

Ziagen should be prescribed by a doctor who has experience in the management of HIV infection.

Before starting treatment with abacavir, all patients should have a test to find out if they have a gene called 'HLA-B (type 5701)'. Patients with this gene are at an increased risk of having an allergic reaction to abacavir, so they should not take Ziagen.

The recommended dose of Ziagen for adults and children weighing at least 25 kg is 600 mg daily. This can be taken either as a single daily dose or divided into 300 mg twice a day. In children weighing less than 25 kg the recommended dose depends on body weight. Patients who cannot swallow tablets should use the oral solution, or alternatively they may crush the tablets and add them to a small

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

amount of food or drink immediately before swallowing it. For more information, see the package leaflet.

How does Ziagen work?

The active substance in Ziagen, abacavir, 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. Ziagen, 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 the damage to the immune system and avoid the development of infections and diseases associated with AIDS.

How has Ziagen been studied?

Ziagen has been studied in six main studies including 1,843 HIV-infected adults (aged 18 years and over). Ziagen was taken alone, or added to the combination of lamivudine and zidovudine (other antiviral medicines) or the patients' existing HIV treatment. One study compared the effects of Ziagen taken once and twice a day, in combination with lamivudine and efavirenz (other antiviral medicines) in 784 patients.

Ziagen has also been studied in three main studies including 489 HIV-infected patients aged between three months and 18 years. In addition, studies were carried out to examine once daily versus twice daily dosing in children.

Ziagen's effects were compared with other antiviral medicines, placebo (a dummy treatment) or no treatment.

The main measures of effectiveness were 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.

What benefit has Ziagen shown during the studies?

In all of the studies, Ziagen caused a decrease in viral loads, particularly when taken with other antiviral medicines. It was more effective than placebo, and was as effective as other antiviral medicines in reducing viral loads in all age groups. In one of the studies in adults, 77% of the patients taking Ziagen with lamivudine and zidovudine had viral loads below 400 copies/ml after 16 weeks (67 out of 87), compared with 38% of the adults taking lamivudine and zidovudine without Ziagen (33 out of 86). Once- and twice-daily Ziagen had similar effects on viral load. Patients receiving Ziagen also had increases in their CD4 cell counts.

What is the risk associated with Ziagen?

The most common side effects with Ziagen (seen in between 1 and 10 patients in 100) are loss of appetite, headache, nausea (feeling sick), vomiting, diarrhoea, rash, fever, lethargy (lack of energy) and tiredness.

Hypersensitivity reactions (allergic reactions) occur in patients taking Ziagen, usually within the first six weeks of treatment, and can be life-threatening. The risk of hypersensitivity is higher in patients who have the HLA-B (type 5701) gene. Symptoms almost always include fever or rash, but also very commonly include nausea, vomiting, diarrhoea, abdominal pain (stomach ache), dyspnoea (difficulty

breathing), cough, fever, lethargy, malaise (feeling unwell), headache, signs of liver damage in the blood and myalgia (muscle pain). Treatment with Ziagen should be stopped promptly if the patient has a hypersensitivity reaction.

For the full list of all side effects and restrictions with Ziagen, see the package leaflet.

Why has Ziagen been approved?

The CHMP noted that the demonstration of the benefit of Ziagen was based on the results of studies mainly carried out with the medicine taken twice a day in combination with other medicines in adults who had not taken HIV treatment before. Based on its review of the quality, safety and effectiveness of the medicine, the Committee decided that Ziagen'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 Ziagen?

A risk management plan has been developed to ensure that Ziagen 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 Ziagen, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Ziagen provides educational materials for doctors about hypersensitivity reactions with the medicine, including the need to test patients for the HLA-B (type 5701) gene and to remind patients to contact their doctor immediately if they develop symptoms suggestive of hypersensitivity. Patients who take Ziagen will also receive an alert card summarising the key safety information on hypersensitivity with the medicine.

Other information about Ziagen:

The European Commission granted a marketing authorisation valid throughout the European Union for Ziagen on 8 July 1999.

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

This summary was last updated in 04-2016.