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Ziagen (*abacavir*)

An overview of Ziagen and why it is authorised in the EU

What is Ziagen and what is it used for?

Ziagen is used with other antiviral medicines to treat patients who are infected with human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS).

Ziagen contains the active substance abacavir.

How is Ziagen used?

Ziagen can only be obtained with a prescription and should be prescribed by a doctor who has experience in managing 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.

Ziagen is available as tablets (300 mg) and as an oral solution (20 mg/ml). The recommended dose 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.

For more information about using Ziagen, see the package leaflet or contact your doctor or pharmacist.

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 produced by HIV to make more copies of itself in the cells it has infected and so spread in the body. Ziagen, taken 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, but it holds off damage to the immune system and the development of infections and diseases associated with AIDS.

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What benefits of Ziagen have been shown in studies?

Six main studies found that Ziagen was more effective than placebo (a dummy treatment) and was as effective as other antiviral medicines at keeping HIV infection under control. The studies included 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. The main measures of effectiveness were changes in the level 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 help fight infections and are killed by HIV.

In all studies, Ziagen caused a decrease in viral loads in all age groups, particularly when taken with other antiviral medicines. In one of the studies, 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). Another study compared the effects of Ziagen taken once and twice a day in combination with lamivudine and efavirenz (other antiviral medicines) in 784 patients. Once daily and twice daily Ziagen had similar effects on viral load. Patients receiving Ziagen also had increases in their CD4 cell counts.

Studies were also carried out in HIV-infected patients aged between 3 months and 18 years. One study found that in patients aged over 1 year, Ziagen combined with either lamivudine or zidovudine was more effective than treatment with a combination of lamivudine and zidovudine.

In addition, studies were carried out to examine once daily versus twice daily dosing in children and found that once daily and twice daily Ziagen had similar effects on viral load.

What are the risks associated with Ziagen?

The most common side effects with Ziagen (which may affect up to 1 in 10 people) 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 6 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 (belly) pain, dyspnoea (difficulty breathing), cough, fever, lethargy, feeling unwell, headache, blood tests showing signs of liver damage and muscle pain. Treatment with Ziagen should be stopped promptly if the patient has a hypersensitivity reaction.

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

Why is Ziagen authorised in the EU?

The European Medicines Agency noted that the demonstration of the benefit of Ziagen was based on the results of studies mainly with the medicine taken twice a day in combination with other medicines. The Agency decided that Ziagen's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Ziagen are continuously monitored. Side effects reported with Ziagen are carefully evaluated and any necessary action taken to protect patients.

Other information about Ziagen

Ziagen received a marketing authorisation valid throughout the EU on 8 July 1999.

Further information on Ziagen can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ziagen.

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