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Kivexa (*abacavir / lamivudine*)

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

What is Kivexa and what is it used for?

Kivexa is used with at least one other antiviral medicine to treat adults and children weighing at least 25 kg who are infected with human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS).

Kivexa contains two active substances, abacavir and lamivudine.

How is Kivexa used?

Kivexa can only be obtained with a prescription and should be prescribed by a doctor who has experience in managing HIV infection. It is available as tablets, each containing abacavir 600 mg and lamivudine 300 mg.

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 Kivexa.

The dose of Kivexa is one tablet once a day. Patients who need to adjust the dose of abacavir or lamivudine should take the medicines separately.

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

How does Kivexa work?

Both active substances in Kivexa, abacavir and lamivudine, are nucleoside reverse transcriptase inhibitors (NRTIs). They work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to make more copies of itself in the cells it has infected and so spread in the body. Kivexa, taken with at least one other HIV medicine, reduces the amount of HIV in the blood and keeps it at a low level. Kivexa does not cure HIV infection, but it holds off damage to the immune system and the development of infections and diseases associated with AIDS.

Both active substances have been available in the European Union (EU) since the late 1990s: abacavir has been authorised as Ziagen since 1999, and lamivudine has been authorised as Epivir since 1996.

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What benefits of Kivexa have been shown in studies?

Kivexa was shown to be effective against HIV in three main studies involving a total of 1,230 patients. At the time of Kivexa's authorisation, abacavir was authorised at a dose of 300 mg twice a day. Therefore, the studies compared abacavir taken at a dose of 600 mg once a day and at a dose of 300 mg twice a day, in combination with lamivudine and one or two other antiviral medicines. The main measure of effectiveness was the change in the level of HIV in the blood (viral load) after 24 or 48 weeks of treatment.

Two studies used the active substances, abacavir and lamivudine, taken as separate medicines. Both doses of abacavir, taken in combination with lamivudine and other antiviral medicines, were equally effective in reducing viral loads. In the first study, 66% (253 out of 384) of the patients taking abacavir once a day had undetectable viral loads (below 50 copies/ml) after 48 weeks of treatment, compared with 68% (261 out of 386) of the patients taking it twice a day.

The third study used a combination tablet for the once-daily dose. The combination tablet taken once a day was as effective as the medicines taken separately twice a day in reducing viral loads over 24 weeks of treatment.

What are the risks associated with Kivexa?

The most common side effects with Kivexa (which may affect up to 1 in 10 people) are hypersensitivity (allergic reactions), rash, nausea (feeling sick), vomiting, diarrhoea, abdominal (belly) pain, headache, joint pain, muscle disorders, cough, nasal symptoms (nose problems, such as irritation and runny nose), fever, lethargy (lack of energy), tiredness, insomnia (difficulty sleeping), feeling unwell, loss of appetite and hair loss. For the full list of side effects of Kivexa, see the package leaflet.

Hypersensitivity reactions occur in patients taking Kivexa, 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 pain, dyspnoea (difficulty breathing), cough, lethargy, feeling unwell, headache, blood tests showing signs of liver damage and muscle pain. Treatment with Kivexa should be stopped promptly if the patient has a hypersensitivity reaction. For more information and the full list of restrictions, see the package leaflet.

Why is Kivexa authorised in the EU?

The European Medicines Agency decided that Kivexa'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 Kivexa?

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

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

Other information about Kivexa

Kivexa received a marketing authorisation valid throughout the EU on 17 December 2004.

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

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