EMA/274452/2016
EMEA/H/C/000581

EPAR summary for the public

Kivexa

abacavir and lamivudine

This document is a summary of the European public assessment report (EPAR) for Kivexa. 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 Kivexa.

What is Kivexa?

Kivexa is a medicine that contains two active substances, abacavir (600 mg) and lamivudine (300 mg). It is available as tablets.

What is Kivexa used for?

Kivexa is used in combination 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).

The medicine can only be obtained with a prescription.

How is Kivexa used?

Kivexa 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 Kivexa.

Kivexa is taken as one tablet once a day. It should only be given to patients who weigh at least 25 kg. Patients who need to adjust the dose of abacavir or lamivudine should take the medicines separately.

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

How does Kivexa work?

Both active substances in Kivexa, abacavir and lamivudine, are nucleoside reverse transcriptase inhibitors (NRTIs). They both work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and make more viruses. Kivexa, taken in combination 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 or AIDS, but can delay the 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.

How has Kivexa been studied?

Kivexa has been studied 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. Two studies used the active substances taken as separate medicines, while the third used a combination tablet for the once-daily dose. 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.

What benefit has Kivexa shown during the studies?

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 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 combination tablet taken once a day was also as effective as the medicines taken separately twice a day in reducing viral loads over 24 weeks of treatment.

What is the risk associated with Kivexa?

The most common side effects with Kivexa (seen in between 1 and 10 patients in 100) are hypersensitivity (allergic reactions), rash, nausea (feeling sick), vomiting, diarrhoea, abdominal pain (stomach ache), headache, arthralgia (joint pain), muscle disorders, cough, nasal symptoms (nose problems, such as irritation and runny nose), fever, lethargy (lack of energy), tiredness, insomnia (difficulty sleeping), malaise (feeling unwell), loss of appetite and alopecia (hair loss). For the full list of all side effects reported with Kivexa, see the package leaflet.

Hypersensitivity reactions occur in patients taking Kivexa, 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, dyspnoea (difficulty breathing), cough, lethargy, malaise, headache, signs of liver damage in the blood and myalgia (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 has Kivexa been approved?

The CHMP decided that Kivexa'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 Kivexa?

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

In addition, the company that makes Kivexa will provide educational material for all doctors who are expected to prescribe this medicine to increase awareness of the risk of hypersensitivity reactions and to provide guidance on how to manage it. Patients will also receive an alert card summarising key safety information on hypersensitivity reactions with this medicine.

Other information about Kivexa

The European Commission granted a marketing authorisation valid throughout the European Union for Kivexa on 17 December 2004.

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

This summary was last updated in 04-2016.