EMA/198478/2015
EMEA/H/C/003823

EPAR summary for the public

Dutrebis

lamivudine / raltegravir

This is a summary of the European public assessment report (EPAR) for Dutrebis. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Dutrebis.

For practical information about using Dutrebis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Dutrebis and what is it used for?

Dutrebis is a medicine used to treat patients infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immunodeficiency syndrome (AIDS). It is used together with other HIV medicines and can be used in patients from 6 years of age and weighing at least 30 kg.

Dutrebis contains the active substances lamivudine and raltegravir and is only for use in patients whose infection is not resistant to these medicines or certain related antiviral medicines.

How is Dutrebis used?

Dutrebis can only be obtained with a prescription and treatment should be prescribed by a doctor who is experienced in managing HIV infections. Dutrebis is available as tablets containing 150 mg of lamivudine and 300 mg of raltegravir, and the recommended dose is one tablet twice a day. Dutrebis must be used in combination with other HIV medicines.

For further information, see the package leaflet.

How does Dutrebis work?

The two active substances in Dutrebis act by blocking different stages of the process by which the HIV virus replicates itself in the body. One active substance, lamivudine, is a 'nucleoside reverse-

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

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. The other active substance, raltegravir, is an 'integrase inhibitor'. It blocks an enzyme called integrase that is needed for the subsequent stage of virus replication.

Dutrebis 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.

The active substances in Dutrebis are already available in the European Union (EU) as single-component medicines: lamivudine as Epivir since 1996, and raltegravir as Isentress since 2007.

What benefits of Dutrebis have been shown in studies?

Because lamivudine and raltegravir are already approved individually to treat HIV infection, the company presented data from the studies used to approve these medicines, including a study involving 160 patients given raltegravir with lamivudine (plus another HIV medicine, tenofovir) for a total of 240 weeks. The main measure of effectiveness was the proportion of patients with a reduction of the levels of virus in the blood (viral load) to fewer than 50 copies of HIV RNA per ml, which was 68.8%.

The company also looked at the way Dutrebis was absorbed in the body in comparison with two separate tablets containing lamivudine and raltegravir. The results of the studies showed that Dutrebis produced similar levels lamivudine in the body to lamivudine taken separately; although the levels of raltegravir were slightly different, Dutrebis was shown to produce levels of raltegravir that were similarly effective in controlling the virus.

What are the risks associated with Dutrebis?

The most common side effects with lamivudine or raltegravir (which may affect up to 1 in 10 people) are headache and nausea (feeling sick). Other common side effects with lamivudine are malaise (feeling generally unwell), tiredness, nasal signs and symptoms, diarrhoea and cough.

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

Why is Dutrebis approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Dutrebis' benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee noted that the two active substances in Dutrebis are frequently taken together in clinical practice. Dutrebis allows them to be taken as a single tablet, although this will have to be taken twice daily and with other medicines for HIV. The effectiveness and safety are taken to be the same as that for the two individual active substances, which are well characterised and do not raise any particular concern.

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

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

Further information can be found in the summary of the risk management plan.

Other information about Dutrebis

The European Commission granted a marketing authorisation valid throughout the European Union for Dutrebis on 26 March 2015.

The full EPAR and risk management plan summary for Dutrebis 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 Dutrebis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2015.