EMA/593111/2013
EMEA/H/C/002577

EPAR summary for the public

Vitekta

elvitegravir

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

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

What is Vitekta and what is it used for?

Vitekta is an antiviral medicine that contains the active substance elvitegravir. It is used to treat adults with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immunodeficiency syndrome (AIDS). It is used in combination with 'protease inhibitor' medicines taken together with ritonavir, and with other anti-HIV medicines in patients whose disease is not expected to be resistant to elvitegravir.

How is Vitekta used?

Vitekta can only be obtained with a prescription and treatment should be started by a doctor who is experienced in managing HIV infections. Vitekta is available as tablets (85 and 150 mg); the recommended dose is one tablet a day, taken with food. The choice of dose of Vitekta depends on which other medicines it is given with. Vitekta is taken either at the same time as a once-daily protease inhibitor, or with the first dose of a twice-daily protease inhibitor. For further information, see the package leaflet.

How does Vitekta work?

The active substance in Vitekta, elvitegravir, is a type of antiviral agent called an 'integrase inhibitor'. It blocks an enzyme called integrase, which is involved in a step in the reproduction of HIV. When the enzyme is blocked, the virus cannot reproduce normally, slowing down the spread of infection.

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Vitekta does not cure HIV-1 infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Vitekta have been shown in studies?

Vitekta has been investigated in one main study involving 712 patients with HIV-1 who had not been treated before with an integrase inhibitor. The main measure of effectiveness was based on the reduction in the levels of HIV in the blood (viral load). Patients who attained a viral load of less than 50 copies/ml after 48 weeks of treatment were considered to have responded to treatment.

In this study, Vitekta was at least as effective as raltegravir (another integrase inhibitor) when taken in combination with other anti-HIV medicines. After 48 weeks, around 59% of patients treated with Vitekta (207 out of 351) responded to treatment compared with around 58% of patients treated with raltegravir (203 out of 351).

What are the risks associated with Vitekta?

The most common side effects with Vitekta (which may affect up to 1 in 10 people) are headache, abdominal pain (stomach ache), diarrhoea, vomiting, nausea (feeling sick), rash, fatigue (tiredness). For the full list of all side effects reported with Vitekta, see the package leaflet.

Vitekta must not be used with certain other medicines that may reduce its effectiveness or increase the risks of resistance. For the full list of restrictions, see the package leaflet.

Why is Vitekta approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Vitekta's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP concluded that the benefits of Vitekta in reducing the levels of HIV in the blood had been clearly shown in studies. Regarding the safety profile of the medicine, this was not considered of concern, with side effects comparable to other similar medicines. The Committee also noted that there is a significant potential for interactions with other medicines, and this has been reflected in the product information.

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

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

Other information about Vitekta

The European Commission granted a marketing authorisation valid throughout the European Union for Vitekta on 13/11/2013.

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

This summary was last updated in 11/2013.