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EPAR summary for the public

Kaletra

lopinavir / ritonavir

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

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

What is Kaletra and what is it used for?

Kaletra is an HIV medicine used in combination with other medicines to treat adults and children from over 14 days of age who are infected with HIV-1. HIV is the virus that causes acquired immune deficiency syndrome (AIDS).

Kaletra contains two active substances, lopinavir and ritonavir.

How is Kaletra used?

Kaletra is available as tablets, capsules and oral liquid. The capsules and liquid must be taken with food, but the tablets can be taken with or without food.

The medicine is taken once or twice daily in adults, and the dose depends on the type of virus the patient is infected with. In children, the dose depends on body weight and height.

Kaletra can only be obtained with a prescription and should be prescribed by a doctor with experience treating HIV infection. For further information, see the package leaflet.

How does Kaletra work?

Both active substances in Kaletra are protease inhibitors: they block an enzyme called protease that is involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally slowing down its multiplication in the body. In Kaletra, lopinavir provides the activity against

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the virus while ritonavir mainly works as a 'booster' to slow down the rate at which lopinavir is broken down by the liver. Kaletra does not cure HIV infection or AIDS, but it may hold off damage to the immune system, and the development of infections and diseases associated with AIDS.

What benefits of Kaletra have been shown in studies?

Studies have shown that Kaletra is effective at reducing viral load (the amount of virus found in the blood) to very low levels (below 400 copies/ml).

In one study of adults who had not been treated for HIV before, 79% of the patients taking Kaletra (259 out of 326) had very low levels of the virus after 24 weeks, compared with 71% of the patients taking nelfinavir (233 out of 327).

A second adult study in patients who had previously taken a protease inhibitor, 73% of the patients taking Kaletra (43 out of 59) had very low levels of the virus after 16 weeks, compared with 54% of the patients taking the comparator medicines (32 out of 59).

Studies in children from 14 days of age showed between 71% and 85% of patients having very low levels of the virus after 48 weeks of treatment with Kaletra.

What are the risks associated with Kaletra?

The most common side effects with Kaletra in adults (seen in more than 1 patient in 10) are upper respiratory tract infection (colds), nausea (feeling sick) and diarrhoea. Side effects are similar in children. For the full list of all side effects reported with Kaletra, see the package leaflet.

Kaletra must not be used by patients with severe liver disease or by patients who are taking St John's wort (a herbal preparation used to treat depression) or medicines that are broken down in the same way as Kaletra and are harmful at high levels in the blood. For the full list of restrictions, see the package leaflet.

Why is Kaletra approved?

Kaletra is effective at reducing HIV viral loads to below 400 copies/ml in the majority of adults and children from 14 days of age. The medicine is also well tolerated and its side effects are manageable. The European Medicines Agency (EMA) therefore concluded that the benefits of Kaletra outweigh its risks and recommended that it be given marketing authorisation in the EU.

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

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

Other information about Kaletra

The European Commission granted a marketing authorisation valid throughout the European Union for Kaletra on 20 March 2001.

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

This summary was last updated in 07-2017.