Kaletra
Lopinavir / ritonavir

This document is a summary of the European Public Assessment Report (EPAR) for Kaletra. 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 Kaletra.

What is Kaletra?

Kaletra is a medicine that contains two active substances, lopinavir and ritonavir. It is available as capsules (133.3 mg lopinavir and 33.3 mg ritonavir), an oral solution (80 mg lopinavir and 20 mg ritonavir per millilitre) and tablets (100 mg lopinavir and 25 mg ritonavir; 200 mg lopinavir and 50 mg ritonavir).

What is Kaletra used for?

Kaletra is used together with other anti-HIV medicines to treat patients over two years of age who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

The medicine can only be obtained with a prescription.

How is Kaletra used?

Treatment with Kaletra should be prescribed by a doctor who has experience in the management of HIV infection.

In adults and adolescents (aged 12 years and over), the recommended dose of Kaletra is three capsules or two 200/50-mg tablets twice a day. This dose as tablets is also suitable for children (aged between two and 12 years) provided that they weigh more than 40 kg and have a body surface area
(calculated using the child’s height and weight) over 1.4 m². The dose for smaller children depends on the child’s body surface area and the other medicines that the child is taking.

If necessary, adults (aged 18 years or over) can take the full dose of four tablets as a single daily dose if they are infected with HIV that is likely to respond to most medicines in the same class as Kaletra (protease inhibitors). When deciding to use once-daily dosing, the doctor should consider the fact that it might not be as effective as twice-daily dosing at keeping HIV levels low in the long term and may increase the risk of diarrhoea.

The oral solution is for patients who cannot take the tablets or capsules and is recommended for use in children (aged 12 years and under) because it allows for a more accurate dosing. The capsules and oral solution must be taken with food, but the tablets can be taken with or without food. Kaletra tablets should be swallowed whole and not chewed, broken or crushed. For more information, see the package leaflet.

**How does Kaletra work?**

Kaletra contains two active substances, lopinavir and ritonavir. Both substances 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 the spread of infection. In Kaletra, lopinavir provides the activity and ritonavir is used as a ‘booster’ that slows down the rate at which lopinavir is broken down by the liver. This increases the levels of lopinavir in the blood, allowing a lower dose of lopinavir to be used for the same antiviral effect. Kaletra does not cure HIV infection or AIDS, but it may delay the damage to the immune system, and the development of infections and diseases associated with AIDS.

**How has Kaletra been studied?**

There have been two main studies of Kaletra taken twice a day in adults and one in children. The first study included 653 adults who had not been treated for HIV before and compared Kaletra capsules with nelfinavir (another antiviral medicine). The second study included 118 adults who had taken another protease inhibitor in the past and compared Kaletra capsules with a protease inhibitor chosen by the study investigator on a patient-by-patient basis. The third study involved 100 children, who were given one of two doses of Kaletra oral solution. In all three studies, Kaletra and the comparator medicines were combined with other antiviral medicines. The main measure of effectiveness was the number of patients who had undetectable levels of HIV-1 in their blood (below 400 copies/ml) after treatment.

Additional studies have been carried out to compare the levels of the active substances produced in the blood by the tablets and the capsules, and to compare once- and twice-daily dosing with Kaletra in adults.

**What benefit has Kaletra shown during the studies?**

In all three main studies, Kaletra reduced viral load (the amount of virus found in the blood). In the study of adults who had not been treated for HIV before, 79% of the patients taking Kaletra (259 out of 326) had viral loads below 400 copies/ml after 24 weeks, compared with 71% of the patients taking nelfinavir (233 out of 327). In the study of adults who had previously taken a protease inhibitor, 73% of the patients taking Kaletra (43 out of 59) had viral loads below 400 copies/ml after 16 weeks, compared with 54% of the patients taking the comparator medicines (32 out of 59). Similar results were seen with both doses of Kaletra in the study of children, with around 70% having viral loads...
below 400 copies/ml after 12 weeks, but there were too few children aged below two years to support the use of Kaletra in this age group.

The additional studies showed that the tablets produced somewhat higher levels of the active substances in the blood than the capsules. Once- and twice-daily dosing with Kaletra tablets were also of similar effectiveness in adults over a period of one to two years, but the studies suggested that once-daily dosing might not be as effective as twice-daily dosing at keeping HIV levels low in the long term.

**What is the risk 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 in people who are hypersensitive (allergic) to lopinavir, ritonavir or any of the other ingredients. 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 has Kaletra been approved?**

The CHMP decided that Kaletra’s benefits are greater than its risks and recommended that it be given marketing authorisation.

**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](http://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.

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