EPAR summary for the public

Prezista
darunavir

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

What is Prezista?

Prezista is a medicine that contains the active substance darunavir. It is available as tablets (75, 150, 300, 400, 600, and 800 mg) and as an oral suspension (100 mg/ml).

What is Prezista used for?

Prezista is used together with low-dose ritonavir and other HIV medicines to treat adults and children aged three years or over who are infected with human immunodeficiency virus (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

In adults, Prezista is also used with another medicine, cobicistat, in combination with other HIV medicines to treat HIV-1 infection.

The medicine can only be obtained with a prescription.

How is Prezista used?

Treatment with Prezista should be started by a healthcare professional who has experience in the management of HIV infection. The medicine is always taken with cobicistat (in adults) or with low-dose ritonavir (in adults and children) plus other HIV medicines, and should be taken with food.

For adults who have not been treated before, the recommended dose is 800 mg once a day. For adults who have been treated before, the dose is 600 mg twice a day. A dose of 800 mg once a day can also
be taken by previously treated patients, provided that the patients are healthy enough and that the HIV virus causing their infection has been shown not to be resistant to Prezista.

For previously untreated children aged from 3 to 17 years and weighing at least 15 kg, the recommended dose varies between 600 and 800 mg once daily depending on the body weight. Previously treated children may be given similar once-daily doses, provided that their disease is not resistant to Prezista, but treatment is usually with a dose between 380 and 600 mg twice daily, depending on their weight.

The oral suspension is available for patients unable to swallow the tablets.

**How does Prezista work?**

The active substance in Prezista, darunavir, is a protease inhibitor. It blocks an enzyme called protease, which is involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally and its rate of replication slows down. Either ritonavir or cobicistat is used with Prezista as a ‘booster’. These booster medicines slow the rate at which darunavir is broken down, increasing the levels of darunavir in the blood. This allows a lower dose of darunavir to be used for the same antiviral effect.

Prezista, taken in combination with other HIV medicines, reduces the amount of HIV in the blood and keeps it at a low level. Prezista does not cure HIV infection or AIDS, but it may delay or reverse the damage to the immune system and the development of infections and diseases associated with AIDS.

**How has Prezista been studied?**

In adults, Prezista has been studied in six main studies. In all of the studies, the patients also took other HIV medicines. The main measures of effectiveness were based on the change in HIV levels in the blood (viral load).

One study compared ritonavir-boosted Prezista 800 mg once a day with ritonavir-boosted lopinavir (another protease inhibitor) in 691 adults who had not been treated for HIV before.

Three studies involved adults who had been treated before who received 600 mg Prezista twice a day. One study compared ritonavir-boosted Prezista with ritonavir-boosted lopinavir in 604 patients who had taken some anti-HIV medicines in the past. The other two studies compared ritonavir-boosted Prezista with other protease inhibitors chosen on the basis of the patient’s previous treatments and predicted response, in a total of 628 patients who had taken many anti-HIV medicines in the past.

The fifth study involved 590 adults who had been treated before and compared Prezista 800 mg once a day with Prezista 600 mg twice a day.

Prezista in combination with the booster cobicistat was evaluated in a study in 313 adult patients all of whom received 800 mg Prezista and 150 mg cobicistat once a day, in addition to two other HIV medicines. The study included both previously treated patients and those who had not received HIV medicines before.

Ritonavir-boosted Prezista has also been studied in 101 previously treated children aged between three and 18 years and 12 previously untreated children aged between 12 to 18 years who weighed at least 40 kg.
What benefit has Prezista shown during the studies?

In adults who had not been treated before, Prezista was as effective as lopinavir. After 48 weeks, 84% of the patients taking ritonavir-boosted Prezista had viral loads below 50 copies/ml (287 out of 343) compared with 78% of those taking ritonavir-boosted lopinavir (271 out of 346).

In adults who had been treated before, those taking Prezista achieved lower viral loads than those taking the comparator protease inhibitors. In patients who had taken some anti-HIV medicines in the past, 77% of those taking ritonavir-boosted Prezista had viral loads below 400 copies/ml after 48 weeks, compared with 68% of those taking ritonavir-boosted lopinavir. In adults who had received many anti-HIV medicines in the past, 70% of those taking the approved dose of ritonavir-boosted Prezista (92 out of 131) had at least a 90% reduction in viral load after 24 weeks, compared with 21% of those taking the comparator protease inhibitors (26 out of 124).

Prezista 800 mg once a day was as effective as Prezista 600 mg twice a day in patients who had been treated before: after 48 weeks, 72% of the patients taking Prezista 800 mg once day had viral loads below 50 copies/ml (212 out of 294) compared with 71% of those taking Prezista 600 mg twice a day (210 out of 296).

In the study looking at Prezista with cobicistat, around 81% (253 out of 313) of patients had viral loads below 50 copies/ml after 48 weeks.

Prezista was also effective in previously treated children: 74% of the previously treated children aged above six years (59 out of 80) had at least a 90% reduction in viral loads after 24 weeks of treatment; 81% of those aged between three and six (17 out of 21) had viral loads below 50 copies/ml after 48 weeks.

In the study of previously untreated children, 83% (10 out of 12) had viral loads below 50 copies/ml after 48 weeks of treatment.

What is the risk associated with Prezista?

In adults, the most common side effects with Prezista are diarrhoea, 'immune reconstitution syndrome', nausea (feeling sick), pyrexia (fever) and rash. Immune reconstitution syndrome happens when the patient’s immune system starts working again and fights existing infections, causing inflammation at the site of the infection. Side effects are similar in children and adolescents. For the full list of all side effects reported with Prezista, see the package leaflet.

Prezista must not be taken by patients who have severely reduced liver function, or who are taking certain other medicines which may decrease blood levels of darunavir, ritonavir or cobicistat, and therefore cause a lack of effect. For the full list of these medicines, see the package leaflet.

The 300- and 600-mg tablets contain a colouring agent called sunset yellow (E110), which can cause allergies. Patients who are allergic to this agent may need to take the lower strength tablets, which do not contain sunset yellow.

Why has Prezista been approved?

The CHMP decided that Prezista’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 Prezista?

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

Other information about Prezista

The European Commission granted a marketing authorisation valid throughout the European Union for Prezista on 12 February 2007.

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

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