



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Prezista (*darunavir*)

An overview of Prezista and why it is authorised in the EU

### What is Prezista and what is it used for?

Prezista is used together with low-dose ritonavir and other HIV medicines to treat patients from 3 years of age (weighing at least 15 kg) who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

In adults and adolescents (12 years of age or more and weighing at least 40 kg), Prezista is also used with another medicine, cobicistat, in combination with other HIV medicines to treat HIV-1 infection.

Prezista contains the active substance darunavir.

### How is Prezista used?

Prezista can only be obtained with a prescription and treatment should be started by a healthcare professional who has experience in managing HIV infection.

Prezista is taken by mouth with or soon after a meal and it is available as tablets, or as a liquid (oral suspension) for patients unable to swallow tablets. The medicine is always taken with cobicistat (in adults or adolescents) or with low-dose ritonavir (in adults and children) plus other HIV medicines. If used with cobicistat the medicine is taken once daily; if used with ritonavir it is taken once or twice daily.

The dose of Prezista depends on previous HIV treatment, whether the virus has any resistance to the medicine, and the patient's age, weight and overall health. For more information about using Prezista, see the package leaflet or contact your doctor or pharmacist.

### 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 slowing down its multiplication in the body. Either ritonavir or cobicistat is used with Prezista as a 'booster'. These booster medicines slow darunavir's breakdown, increasing the levels of darunavir in the blood. This allows a lower dose of darunavir to be used for the same antiviral effect.

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Prezista, taken in combination with other HIV medicines, reduces the amount of HIV-1 in the blood and keeps it at a low level. Prezista does not cure HIV-1 infection, but it holds off damage to the immune system and the development of infections and diseases associated with AIDS.

## What benefits of Prezista have been shown in studies?

Six main studies in **adults** found that Prezista was effective at keeping HIV infection under control. In all of the studies, the patients also took other HIV medicines. The main measures of effectiveness were changes in the levels of HIV in the blood (viral load).

- One study compared ritonavir-boosted Prezista with ritonavir-boosted lopinavir (another protease inhibitor) in 691 adults who had not been treated for HIV before. 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).
- 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. 77% of those taking ritonavir-boosted Prezista had viral loads below 400 copies/ml after 48 weeks (211 of 274), compared with 68% of those taking ritonavir-boosted lopinavir (189 out of 280). 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. 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).
- The fifth study involving 590 adults who had been treated before found that Prezista 800 mg once a day was as effective as Prezista 600 mg twice a day: 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).
- 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. Around 81% (253 out of 313) of patients had viral loads below 50 copies/ml after 48 weeks.

Ritonavir-boosted Prezista has also been studied in 101 previously treated **children** aged between 3 and 18 years and 12 previously untreated children aged between 12 to 18 years who weighed at least 40 kg.

- Prezista was effective at keeping HIV infection under control in previously treated children: 74% of children aged above 6 years (59 out of 80) had at least a 90% reduction in viral loads after 24 weeks of treatment; 81% of those aged between 3 and 6 (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.

Blood levels of cobicistat-boosted Prezista were found to be similar in adults and adolescents and its effectiveness is therefore expected to be similar. In an ongoing study involving previously treated children and adolescents, of 7 patients aged 12 to 16 years and weighing at least 40 kg who were given cobicistat and Prezista, 6 had viral loads below 50 copies/ml after 48 weeks of treatment.

## **What are the risks associated with Prezista?**

In adults, the most common side effects with Prezista (which may affect more than 1 in 10 people) are diarrhoea, nausea (feeling sick) and vomiting, headache and rash. 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 medicines which may decrease its effect, or cause serious side effects if given with Prezista combinations. For the full list of these medicines, see the package leaflet.

## **Why is Prezista authorised in the EU?**

The European Medicines Agency decided that Prezista's benefits are greater than its risks and it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Prezista?**

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

As for all medicines, data on the use of Prezista are continuously monitored. Side effects reported with Prezista are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Prezista**

Prezista received a marketing authorisation valid throughout the EU on 12 February 2007.

Further information on Prezista can be found on the Agency's website [ema.europa.eu/medicines/human/EPAR/prezista](http://ema.europa.eu/medicines/human/EPAR/prezista)

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