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**EPAR summary for the public**

# Darunavir Krka d.d.

darunavir

This is a summary of the European public assessment report (EPAR) for Darunavir Krka d.d. 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 Darunavir Krka d.d.

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

## What is Darunavir Krka d.d. and what is it used for?

Darunavir Krka d.d. is an antiviral medicine used with other HIV medicines to treat patients with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is given with low-dose ritonavir or, in adults, with cobicistat. Darunavir Krka d.d. may be given to adults or children from 3 years of age and weighing at least 15 kg.

Darunavir Krka d.d. contains the active substance darunavir.

Darunavir Krka d.d. is a 'generic medicine'. This means that Darunavir Krka d.d. contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Prezista. For more information on generic medicines, see the question-and-answer document here.

## How is Darunavir Krka d.d. used?

Darunavir Krka d.d. can only be obtained with a prescription and treatment should be started by a healthcare professional who has experience in the management of HIV.

Darunavir Krka d.d. is available as tablets. The medicine is to be taken with low-dose ritonavir or, as an alternative in adults, with cobicistat and with other HIV medicines, and should be taken with food.



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## How does Darunavir Krka d.d. work?

The active substance in Darunavir Krka d.d., darunavir, is a protease inhibitor. It blocks protease, an enzyme involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally, slowing down its multiplication in the body. Darunavir Krka d.d. is always given with ritonavir. Ritonavir reduces the breakdown of darunavir, increasing the levels of darunavir in the blood. This allows effective treatment while avoiding a higher dose of darunavir.

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

## How has Darunavir Krka d.d. been studied?

Studies on the benefits and risks of the active substance in the approved use have already been carried out with the reference medicine, Prezista, and do not need to be repeated for Darunavir Krka d.d.

As for every medicine, the company provided studies on the quality of Darunavir Krka d.d. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

## What are the benefits and risks of Darunavir Krka d.d.?

Because Darunavir Krka d.d. is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

## Why is Darunavir Krka d.d. approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Darunavir Krka d.d. has been shown to have comparable quality and to be bioequivalent to Prezista. Therefore, the Agency's view was that, as for Prezista, the benefit outweighs the identified risk. The Agency recommended that Darunavir Krka d.d. be approved for use in the EU.

## What measures are being taken to ensure the safe and effective use of Darunavir Krka d.d.?

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

## Other information about Darunavir Krka d.d.

The European Commission granted a marketing authorisation valid throughout the European Union for Darunavir Krka d.d. on 18 January 2018.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 01-2018.