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EPAR summary for the public

Darunavir Mylan

darunavir

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

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

What is Darunavir Mylan and what is it used for?

Darunavir Mylan 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 Mylan may be given to adults or children from 3 years of age and weighing at least 15 kg.

Darunavir Mylan contains the active substance darunavir.

Darunavir Mylan is a 'generic medicine'. This means that Darunavir Mylan 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 Mylan used?

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

Darunavir Mylan is available as tablets (75, 150, 300, 400, 600 and 800 mg). The medicine is always taken either with cobicistat (in adults) or with low-dose ritonavir (in adults and children) and with other HIV medicines, and should be taken with food.

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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. Previously treated patients can also take a dose of 800 mg once a day provided that their HIV infection is well controlled and is not likely to be resistant to darunavir.

For children aged 3 to 17 years and weighing at least 15 kg who have not be treated before, the recommended dose varies between 600 and 800 mg once daily depending on their weight. For previously treated children the usually recommended dose varies between 375 and 600 mg twice a day depending on their weight.

For further information, see the package leaflet.

How does Darunavir Mylan work?

The active substance in Darunavir Mylan, 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 Mylan is always given with ritonavir or cobicistat. Ritonavir and cobicistat reduce the breakdown of darunavir, increasing the levels of darunavir in the blood. This allows effective treatment while avoiding a higher dose of darunavir.

Darunavir Mylan, taken in combination with other HIV medicines, reduces the amount of HIV in the blood and keeps it at a low level. Darunavir Mylan 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 Mylan 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 Mylan.

As for every medicine, the company provided studies on the quality of Darunavir Mylan. The company also carried out studies 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 Mylan?

Because Darunavir Mylan 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 Mylan approved?

The Agency’s Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Darunavir Mylan has been shown to have comparable quality and to be bioequivalent to Prezista. Therefore, the CHMP’s view was that, as for Prezista, the benefit outweighs the identified risk. The Committee recommended that Darunavir Mylan be approved for use in the EU.

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

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

Other information about Darunavir Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Darunavir Mylan on 04 January 2017.

The full EPAR for Darunavir Mylan 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 Mylan, 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 01-2017.