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Darunavir Viatris[1] (*darunavir)*

An overview of Darunavir Viatris and why it is authorised in the EU

What is Darunavir Viatris and what is it used for?

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

Darunavir Viatris contains the active substance darunavir and is a 'generic medicine'. This means that Darunavir Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Darunavir Viatris is Prezista. For more information on generic medicines, see the question-and-answer document here.

How is Darunavir Viatris used?

Darunavir Viatris 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 Viatris is available as tablets. 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.

For more information about using Darunavir Viatris, see the package leaflet or contact your doctor or pharmacist

How does Darunavir Viatris work?

The active substance in Darunavir Viatris, 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 Viatris 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.

[1] Previously known as Darunavir Mylan.

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

As for every medicine, the company provided studies on the quality of Darunavir Viatris. 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 Viatris?

Because Darunavir Viatris 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 Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Darunavir Viatris 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 and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Darunavir Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Prezista also apply to Duranavir Viatris where appropriate.

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

Other information about Darunavir Viatris

The European Commission granted a marketing authorisation valid throughout the European Union for Darunavir Mylan on 4 January 2017.

The name of the medicine was changed to Duranavir Viatris on 5 July 2024.

Further information on Duranavir Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/duranavir-viatris. Information on the reference medicine can also be found on the Agency's website.

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