EMA/284756/2024
EMEA/H/C/004025

Lopinavir/Ritonavir Viatris[1] (*lopinavir / ritonavir*)

An overview of Lopinavir/Ritonavir Viatris and why it is authorised in the EU

What is Lopinavir/Ritonavir Viatris and what is it used for?

Lopinavir/Ritonavir Viatris is used in combination with other medicines to treat patients over two years of age who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Lopinavir/Ritonavir Viatris contains the active substances lopinavir and ritonavir.

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

How is Lopinavir/Ritonavir Viatris used?

Lopinavir/Ritonavir Viatris can only be obtained with a prescription and treatment should be started by a doctor who is experienced in managing HIV infection. It is available as tablets to be taken by mouth.

For more information about using Lopinavir/Ritonavir Viatris, see the package leaflet or contact your doctor or pharmacist.

How does Lopinavir/Ritonavir Viatris work?

The active substances in this medicine, lopinavir and ritonavir, are protease inhibitors: they block an enzyme called protease that is involved in the replication of HIV. When the enzyme is blocked, the virus does not replicate normally, slowing down the spread of infection. In Lopinavir/Ritonavir Viatris, lopinavir provides the activity and ritonavir is used as a 'booster' that slows down the rate at which lopinavir is broken down by the liver. This increases the levels of lopinavir in the blood, allowing a lower dose of lopinavir to be used for the same antiviral effect.

[1] Previously known as Lopinavir/Ritonavir Mylan.

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Lopinavir/Ritonavir Viatris, taken with other HIV medicines, reduces HIV in the blood and keeps the virus at a low level. It does not cure HIV infection, but it can hold off damage to the immune system and avoid the development of infections and diseases associated with AIDS.

How has Lopinavir/Ritonavir Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Kaletra, and do not need to be repeated for Lopinavir/Ritonavir Viatris.

As for every medicine, the company provided studies on the quality of Lopinavir/Ritonavir 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 Lopinavir/Ritonavir Viatris?

Because Lopinavir/Ritonavir 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 Lopinavir/Ritonavir Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Lopinavir/Ritonavir Viatris has been shown to have comparable quality and to be bioequivalent to Kaletra. Therefore, the Agency's view was that, as for Kaletra, the benefit outweighs the identified risk and it can be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Lopinavir/Ritonavir Viatris?

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

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

Other information about Lopinavir/Ritonavir Viatris

Lopinavir/Ritonavir Mylan received a marketing authorisation valid throughout the EU on 14 January 2016.

The name of the medicine was changed to Lopinavir/Ritonavir Viatris on 13 June 2024.

Further information on Lopinavir/Ritonavir Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lopinavir-ritonavir-viatris.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 06-2024.