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Ritonavir Viatris[1] (*ritonavir*)

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

What is Ritonavir Viatris and what is it used for?

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).

Ritonavir Viatris contains the active substance ritonavir.

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 Ritonavir Viatris is Norvir. For more information on generic medicines, see the question-and-answer document here.

How is Ritonavir Viatris used?

Ritonavir Viatris can only be obtained with a prescription and treatment should be given by a doctor who has experience in the treatment of HIV infection. It is available as tablets and should be taken with food.

Ritonavir Viatris can be used as a 'pharmacokinetic enhancer' (booster) to increase the blood levels of other antiviral medicines that belong to the same group (known as protease inhibitors); it can also be used in larger doses for a direct antiviral effect on HIV.

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

How does Ritonavir Viatris work?

As a 'booster', the active substance ritonavir slows the breakdown of other protease inhibitor antivirals. This increases the levels of these protease inhibitors in the blood and enhances their antiviral effect.

[1] Previously known as Ritonavir Mylan.

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At higher antiviral doses, it blocks a viral enzyme called protease, which is involved in the replication of HIV. When the enzyme is blocked, the virus can no longer replicate normally, slowing down the spread of infection. Ritonavir Viatris, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Ritonavir Viatris does not cure HIV infection or AIDS, but it may hold off damage to the immune system and the development of infections and diseases associated with AIDS.

How has Ritonavir Viatris been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Norvir, and do not need to be repeated for Ritonavir Viatris.

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

Because 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 Ritonavir Viatris authorised in the EU?

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

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

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

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

Other information about Ritonavir Viatris

Ritonavir Viatris received a marketing authorisation valid throughout the EU on 10 November 2017.

The name of the medicine was changed to Ritonavir Viatris on 17 July 2024.

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

This overview was last updated in 07-2024.