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EPAR summary for the public

Ritonavir Mylan

ritonavir

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

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

What is Ritonavir Mylan and what is it used for?

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

How is Ritonavir Mylan used?

Ritonavir Mylan can only be obtained with a prescription and treatment with Ritonavir Mylan should be given by a doctor who has experience in the treatment of HIV infection. It is available as tablets (100 mg) and should be taken with food.

Ritonavir Mylan can be used as a 'pharmacokinetic enhancer' (booster) to increase the blood levels of other antiviral medicines that belong to the same group as Ritonavir Mylan (protease inhibitors) including amprenavir, atazanavir, darunavir, fosamprenavir, lopinavir, saquinavir, and tipranavir. The usual dose of Ritonavir Mylan for adults is 100 or 200 mg, once or twice a day. The dose depends on

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which other protease inhibitor is being taken. For more information, see the package leaflet provided with the other medicine.

Ritonavir Mylan can also be used in larger doses for a direct antiviral effect on HIV. The recommended dose for adults (aged 18 years or over) is 600 mg twice a day. For younger patients, the recommended dose depends on the patient's height and weight. Treatment should start with a low dose that is gradually increased over the first 14 days of treatment.

How does Ritonavir Mylan 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.

At higher antiviral doses, ritonavir is a 'protease inhibitor'. This means that it blocks a viral enzyme called protease, which is involved in the multiplication of HIV. When the enzyme is blocked, the virus can no longer multiply normally, slowing down its spread. Ritonavir Mylan, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Ritonavir Mylan 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 Mylan 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 Mylan.

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

Because Ritonavir 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 Ritonavir Mylan approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Ritonavir Mylan 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 Mylan be approved for use in the EU.

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

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

Other information about Ritonavir Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Ritonavir Mylan on 10 November 2017.

The full EPAR for Ritonavir 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 Ritonavir 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 11-2017.