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EPAR summary for the public

Ribavirin Mylan[1]

ribavirin

This document is a summary of the European Public Assessment Report (EPAR) for Ribavirin Mylan. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ribavirin Mylan.

What is Ribavirin Mylan?

Ribavirin Mylan is a medicine that contains the active substance ribavirin. It is available as white capsules (200 mg).

Ribavirin Mylan is a 'generic medicine'. This means that Ribavirin Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Rebetol. For more information on generic medicines, see the question-and-answer document here.

What is Ribavirin Mylan used for?

Ribavirin Mylan is used to treat long-term hepatitis C (a disease of the liver due to infection with the hepatitis C virus) in patients aged three years and older. Ribavirin Mylan must never be used on its own but only together with interferon alfa-2b (another medicine used in hepatitis).

Ribavirin Mylan is used in patients who have not been treated before, as long as the liver is still working and hepatitis C virus can be found in the blood. Ribavirin Mylan can also be used in adults whose disease has come back after previous treatment or whose previous treatment failed.

The medicine can only be obtained with a prescription.

[1] Previously known as Ribavirin Three Rivers

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How is Ribavirin Mylan used?

Treatment with Ribavirin Mylan should be started and monitored by a doctor who has experience in the management of long-term hepatitis C. The dose of Ribavirin Mylan is based on the patient's body weight, and ranges from three to seven capsules a day. It can only be used in patients who weigh more than 47 kg. Ribavirin Mylan is taken with food each day in two divided doses (morning and evening). The duration of treatment depends on the patient's condition and response to treatment, and ranges from six months to a year. The dose may need to be adjusted for patients who experience side effects. For more information, see the Package Leaflet.

How does Ribavirin Mylan work?

The active substance in Ribavirin Mylan, ribavirin, is an antiviral belonging to the class 'nucleoside analogues'. Ribavirin Mylan is thought to interfere with the production or action of viral DNA and RNA, which are needed for viruses to survive and multiply. Ribavirin Mylan on its own has no effect on eliminating the hepatitis C virus from the body.

How has Ribavirin Mylan been studied?

Because Ribavirin Mylan is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Rebetol. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefit and risk of Ribavirin Mylan?

Because Ribavirin Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine.

Why has Ribavirin Mylan been approved?

The CHMP concluded that, in accordance with EU requirements, Ribavirin Mylan has been shown to have comparable quality and to be bioequivalent to Rebetol. Therefore, the CHMP's view was that, as for Rebetol, the benefit outweighs the identified risk. The Committee recommended that Ribavirin Mylan be given marketing authorisation.

Other information about Ribavirin Mylan:

The European Commission granted a marketing authorisation valid throughout the EU for Ribavirin Three Rivers on 16 June 2010. The name of the medicine was changed to Ribavirin Mylan on 27 January 2011. The marketing authorisation is valid for five years, after which it can be renewed. The marketing authorisation holder is Generics [UK] Ltd.

The full EPAR for Ribavirin Mylan can be found here. For more information about treatment with Ribavirin 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 02-2011.