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EPAR summary for the public

Ribavirin BioPartners

ribavirin

This document is a summary of the European Public Assessment Report (EPAR) for Ribavirin BioPartners. 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 BioPartners.

What is Ribavirin BioPartners?

Ribavirin BioPartners is a medicine that contains the active substance ribavirin. It is available as round, white tablets (200 mg).

Ribavirin BioPartners is a 'generic medicine'. This means that Ribavirin BioPartners 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 BioPartners used for?

Ribavirin BioPartners 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 BioPartners must never be used on its own but only together with peginterferon alfa 2b or interferon alfa 2b (other medicines used in hepatitis).

Ribavirin BioPartners 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. This includes adults (aged 18 years and older) who are also infected with human immunodeficiency virus (HIV). Ribavirin BioPartners 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

How is Ribavirin BioPartners used?

Treatment with Ribavirin BioPartners should be started and monitored by a doctor who has experience in the management of long-term hepatitis C. The dose of Ribavirin BioPartners is based on the patient's body weight, and ranges from three to seven tablets a day. It can only be used in patients who weigh more than 47 kg. Ribavirin BioPartners 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 BioPartners work?

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

How has Ribavirin BioPartners been studied?

Because Ribavirin BioPartners 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 BioPartners?

Because Ribavirin BioPartners 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 BioPartners been approved?

The CHMP concluded that, in accordance with EU requirements, Ribavirin BioPartners 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 BioPartners be given marketing authorisation.

Other information about Ribavirin BioPartners:

The European Commission granted a marketing authorisation valid throughout the European Union for Ribavirin BioPartners to BioPartners GmbH on 6 April 2010.

The full EPAR for Ribavirin BioPartners can be found here. For more information about treatment with Ribavirin BioPartners, read the Package Leaflet (also part of the EPAR).

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 02-2010.