European Medicines Agency

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Ribavirin Teva
ribavirin

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Ribavirin Teva?
Ribavirin Teva is a medicine that contains the active substance ribavirin. It is available as white capsules (200 mg).
Ribavirin Teva is a 'generic medicine'. This means that it 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 Teva used for?
Ribavirin Teva is used to treat patients aged three years and older who have chronic (long-term) hepatitis C (a disease of the liver due to an infection with the hepatitis C virus). Ribavirin Teva must never be used on its own but only together with interferon alfa-2b (another medicine used in hepatitis). Ribavirin Teva can be used in 'naïve' patients (who have not been treated before) for all types of hepatitis C except for genotype 1 or 4. It can also be used in adults who previously responded to treatment with interferon alfa but whose disease has come back.
The medicine can only be obtained with a prescription.

How is Ribavirin Teva used?
Treatment with Ribavirin Teva should be started and monitored by a doctor who has experience in the management of chronic hepatitis C.
The dose of Ribavirin Teva is based on the patient's body weight, and ranges from three to seven capsules a day. It should only be taken by patients weighing at least 47 kg. Ribavirin Teva 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 24 weeks 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 Teva work?
The active substance in Ribavirin Teva, ribavirin, is an antiviral belonging to the class 'nucleoside analogues'. Ribavirin Teva is thought to interfere with the production or action of viral DNA and RNA, which are needed for viruses to survive and multiply. Ribavirin Teva on its own has no effect on eliminating the hepatitis C virus from the body.

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How has Ribavirin Teva been studied?
Because Ribavirin Teva is a generic medicine, studies have been limited to tests to demonstrate 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.

What are the benefit and risk of Ribavirin Teva?
Because Ribavirin Teva is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Ribavirin Teva been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Ribavirin Teva 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 Teva be given marketing authorisation.

Other information about Ribavirin Teva:
The European Commission granted a marketing authorisation valid throughout the EU for Ribavirin Teva to Teva Pharma B.V. on 31 March 2009.

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

This summary was last updated in 09-2009.