EMA/814315/2016
EMEA/H/C/001064

EPAR summary for the public

Ribavirin Teva Pharma B.V.

ribavirin

This is a summary of the European public assessment report (EPAR) for Ribavirin Teva Pharma B.V. 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 Ribavirin Teva Pharma B.V.

For practical information about using Ribavirin Teva Pharma B.V., patients should read the package leaflet or contact their doctor or pharmacist.

What is Ribavirin Teva Pharma B.V. and what is it used for?

Ribavirin Teva Pharma B.V. is a medicine 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 Teva Pharma B.V. must never be used on its own but only together with interferon alfa 2b (another medicine used in hepatitis).

Ribavirin Teva Pharma B.V. is used in patients who have not been treated before for all types of hepatitis C except for genotype 1, as long as the liver is still working normally and hepatitis C virus can be found in the blood. Ribavirin Teva Pharma B.V. can also be used in adults (aged 18 years and older) whose disease has come back after previous treatment.

Ribavirin Teva Pharma B.V. is a 'generic medicine'. This means that Ribavirin Teva Pharma B.V. contains the same active substance and works in the same way as 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.

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How is Ribavirin Teva Pharma B.V. used?

Ribavirin Teva Pharma B.V. can only be obtained with a prescription. Treatment should be started and monitored by a doctor who has experience in the management of chronic hepatitis C.

Ribavirin Teva Pharma B.V. available as tablets (200 and 400 mg). The dose and duration of treatment is based on the patient's body weight and on the medicine used in combination with it. Ribavirin Teva Pharma B.V. is taken with food each day in two divided doses (morning and evening). The dose may need to be adjusted for patients who experience side effects. For more information, see the package leaflet.

How does Ribavirin Teva Pharma B.V. work?

The active substance in Ribavirin Teva Pharma B.V., ribavirin, is an antiviral belonging to the class 'nucleoside analogues'. Ribavirin Teva Pharma B.V.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 Pharma B.V. on its own has no effect on eliminating the hepatitis C virus from the body.

How has Ribavirin Teva Pharma B.V. 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, Rebetol and do not need to be repeated for Ribavirin Teva Pharma B.V.

As for every medicine, the company provided studies on the quality of Ribavirin Teva Pharma B.V. The company also carried out studies 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 Ribavirin Teva Pharma B.V.?

Because Ribavirin Teva Pharma B.V. 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 Ribavirin Teva Pharma B.V. approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Ribavirin Teva Pharma B.V. has been shown to have comparable quality and to be bioequivalent to Rebetol. Therefore, the CHMP's view was that, as for Rebetol, the benefits outweigh the identified risks. The Committee recommended that Ribavirin Teva Pharma B.V. be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Ribavirin Teva Pharma B.V.?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ribavirin Teva Pharma B.V. have been included in the summary of product characteristics and the package leaflet.

Other information about Ribavirin Teva Pharma B.V.

The European Commission granted a marketing authorisation valid throughout the EU for Ribavirin Teva Pharma B.V. on 1 July 2009.

The full EPAR for Ribavirin Teva 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 Ribavirin Teva Pharma B.V., 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 12-2016.