



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2010
EMA/CHMP/40892/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (initial authorisation)

Ribavirin BioPartners

Ribavirin

On 20 January 2010, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ribavirin BioPartners, 200mg, film-coated tablets, intended for the treatment of chronic hepatitis C infection as part of a combination regimen with peginterferon alfa-2b or interferon alfa-2b. The applicant for this medicinal product is BioPartners GmbH. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Ribavirin BioPartners is Ribavirin, a purine nucleoside analogue which is active against a number of DNA and RNA viruses. Several mechanisms of action are proposed for ribavirin.

Ribavirin BioPartners is a generic of Rebetol. Studies have demonstrated the satisfactory quality of Ribavirin BioPartners, and its bioequivalence with the reference product Rebetol. A question-and-answer document on generic medicines can be found [here](#)

A pharmacovigilance plan for Ribavirin BioPartners, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Ribavirin BioPartners is indicated for the treatment of chronic hepatitis C virus (HCV) infection and must only be used as part of a combination regimen with peginterferon alfa-2b (adults) or interferon alfa-2b (adults, children 3-years of age and older and adolescents) Ribavirin BioPartners monotherapy must not be used. There is no safety or efficacy information on the use of Ribavirin BioPartners with other forms of interferon (i.e., not alfa 2b)". It is proposed that Ribavirin BioPartners is prescribed by physicians experienced in the management of chronic hepatitis C.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and

¹ Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.



will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Ribavirin BioPartners and therefore recommends the granting of the marketing authorisation.

Medicinal product no longer authorised