European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 22 January 2009
Doc. Ref. EMEA/CHMP/34493/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
RIBAVIRIN TEVA

International Nonproprietary Name (INN): ***ribavirin***

On 22 January 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Ribavirin Teva 200 mg hard capsule 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 TEVA Pharma B.V.

The active substance of Ribavirin Teva 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 Teva is a generic of Rebetol. Studies have demonstrated the satisfactory quality of Ribavirin Teva, and its bioequivalence with the reference product Rebetol. A question-and-answer document on generic medicines can be found here.

The approved indication is as follows: "Ribavirin Teva is indicated for the treatment of chronic hepatitis C 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 or older), and adolescents). Ribavirin monotherapy must not be used. There is no safety or efficacy information on the use of Ribavirin with other forms of interferon (i.e., not alfa-2b), or on the use of Ribavirin with peginterferon alfa-2b in children or adolescents."

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

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and 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 that there is a favourable benefit to risk balance for Ribavirin Teva and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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