



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

International Nonproprietary Name (INN): *ribavirin*

On 23 April 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 Pharma BV, 200 mg and 400 mg, 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 Teva Pharma BV.

The active substance of Ribavirin Teva Pharma BV 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 Pharma BV is a generic of Rebetol. Studies have demonstrated the satisfactory quality of Ribavirin Teva Pharma BV, 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 Pharma BV 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 Pharma BV, 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 favorable benefit to risk balance for Ribavirin Teva Pharma BV 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.