16 February 2012
EMA/CHMP/114050/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rebetol

ribavirin

On 16 February 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Rebetol. The marketing authorisation holder for this medicinal product is Schering-Plough Europe. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:

Tritherapy:
Rebetol in combination with boceprevir and peginterferon alfa-2b is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults patients (18 years of age and older) with compensated liver disease who are previously untreated or who have failed previous therapy.

Please refer to peginterferon alfa -2b and boceprevir SmPCs when using Rebetol in combination with these medicines.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Rebetol will be as follows[2]:

Tritherapy:
Rebetol in combination with boceprevir and peginterferon alfa-2b is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults patients (18 years of age and older) with compensated liver disease who are previously untreated or who have failed previous therapy.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Please refer to peginterferon alfa -2b and boceprevir SmPCs when using Rebetol in combination with these medicines.

Bitherapy:
Rebetol is indicated for the treatment of chronic hepatitis C virus infection in adults, children 3 years of age and older and adolescents and must only be used as part of a combination regimen with peginterferon alfa-2b or interferon alfa-2b. Rebetol monotherapy must not be used.

Please refer to interferon alfa-2b and peginterferon alfa-2b SmPCs when using Rebetol in combination with these medicines.

There is no safety or efficacy information on the use of Rebetol with other forms of interferon (i.e., not alfa-2b).

Previously untreated (naïve) patients

Adult patients (18 years of age or older): Rebetol is indicated for:

- tritherapy - in combination with peginterferon alfa-2b and boceprevir for the treatment of adult patients with chronic hepatitis C genotype 1 infection with compensated cirrhosis.
- bitherapy - in combination with interferon alfa-2b or peginterferon alfa-2b, for the treatment of adult patients with chronic hepatitis C, not previously treated, without liver decompensation, with elevated alanine aminotransferase (ALT), who are positive for hepatitis C viral ribonucleic acid (HCV-RNA).
- bitherapy – for the treatment of CHC infection in combination with peginterferon alfa-2b for patients with compensated cirrhosis and/or clinically stable HIV co-infection (see section 4.4).

Bitherapy

Paediatric patients (children 3 years of age and older and adolescents): Rebetol is indicated, in a combination regimen with peginterferon alfa-2b or interferon alfa-2b, for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA.

When deciding to not to defer treatment until adulthood, it is important to consider that the combination therapy induced a growth inhibition. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case by case basis (see section 4.4).

Previously treated patients

Adult patients: Rebetol is indicated for:

- tritherapy - in combination with peginterferon alfa-2b and boceprevir for the treatment of adult patients having CHC genotype 1 infection with compensated cirrhosis.
- bitherapy - in combination with peginterferon alfa-2b, for the treatment of patients with chronic hepatitis C who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination with ribavirin (see section 5.1).
- biotherapy - in combination with interferon alfa-2b, for the treatment of patients with chronic hepatitis C who have previously responded (with normalisation of ALT at the end of treatment) to interferon alfa monotherapy but who have subsequently relapsed.