24 September 2015
EMA/CHMP/408137/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rebetol

ribavirin

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Rebetol. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme Limited.

The changes clarify which medicinal products may be used in combination with Rebetol, removing specific reference to peginterferon (PegIFN) alfa-2b in the indication. As a result, the new full indication of Rebetol will be as follows:

"Rebetol is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adults (see sections 4.2, 4.4, and 5.1).

Rebetol is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) for paediatric patients (children 3 years of age and older and adolescents) not previously treated and without liver decompensation (see sections 4.2, 4.4 and 5.1)."

In addition, the CHMP recommended an update of section 4.3, removing several contraindications. For information, the full contraindications for Rebetol will be as follows:

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Pregnancy (see sections 4.4, 4.6 and 5.3). In females of childbearing potential, Rebetol must not be initiated until a report of a negative pregnancy test has been obtained immediately prior to initiation of therapy.
Breast-feeding.
History of severe pre-existing cardiac disease, including unstable or uncontrolled cardiac disease, in the previous six months (see section 4.4).
Haemoglobinopathies (e.g., thalassemia, sickle-cell anaemia).

Please refer to the corresponding SmPC of medicinal products used in combination with Rebetol for contraindications specific to these products.

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Detailed recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.