



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 February 2012
EMA/CHMP/114051/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

PegIntron

peginterferon alfa-2b

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 PegIntron. 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:

Adults (tritherapy):

PegIntron in combination with ribavirin and boceprevir (tritherapy) is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adult patients (18 years of age and older) with compensated liver disease who are previously untreated or who have failed previous therapy (see section 5.1).

Please refer to the ribavirin and boceprevir Summary of Product Characteristics (SmPCs) when PegIntron is to be used 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 PegIntron will be as follows²:

Adults (tritherapy):

PegIntron in combination with ribavirin and boceprevir (tritherapy) is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adult patients (18 years of age and older) with compensated liver disease who are previously untreated or who have failed previous therapy (see section 5.1).

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.



Please refer to the ribavirin and boceprevir Summary of Product Characteristics (SmPCs) when PegIntron is to be used in combination with these medicines.

Adults (bitherapy and monotherapy):

PegIntron is indicated for the treatment of adult patients (18 years of age and older) with CHC who are positive for hepatitis C virus RNA (HCV-RNA), including patients with compensated cirrhosis and/or co-infected with clinically stable HIV (see section 4.4).

PegIntron in combination with ribavirin (bitherapy) is indicated for the treatment of CHC infection in adult patients who are previously untreated including patients with clinically stable HIV co-infection and in adult patients who have failed previous treatment with interferon alpha (pegylated or nonpegylated) and ribavirin combination therapy or interferon alpha monotherapy (see section 5.1).

Interferon monotherapy, including PegIntron, is indicated mainly in case of intolerance or contraindication to ribavirin.

Please refer to the ribavirin SmPC when PegIntron is to be used in combination with ribavirin.

Paediatric population (bitherapy):

PegIntron is indicated in a combination regimen with ribavirin for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, previously untreated, without liver decompensation, and who are positive for HCV-RNA.

When deciding 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).

Please refer to the ribavirin SmPC for capsules or oral solution when PegIntron is to be used in combination with ribavirin.