EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2014
EMA/CHMP/137969/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Olysio

simeprevir

On 20 March 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Olysio, 150 mg, hard capsules intended for the treatment of chronic hepatitis C (CHC). The applicant for this medicinal product is Janssen-Cilag International N.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Olysio is simeprevir, antivirals for systemic use (J05AE) and a specific inhibitor of the HCV NS3/4A serine protease.

The benefits with Olysio are its efficacy demonstrated in the treatment of chronic hepatitis C in adult patients when used in combination with other medicinal products. The most common side effects (incidence ≥ 5%) are were nausea, rash, pruritus, dyspnoea, blood bilirubin increase and photosensitivity reaction.

A pharmacovigilance plan for Olysio will be implemented as part of the marketing authorisation.

The approved indication is: "*OLYSIO is indicated in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adult patients (see sections 4.2, 4.4 and 5.1). For hepatitis C virus (HCV) genotype specific activity, see sections 4.4 and 5.1.*". It is proposed that Olysio be prescribed by physicians experienced in the treatment of chronic hepatitis C (CHC).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made 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 there to be a favourable benefit-to-risk balance for Olysio and therefore recommends the granting of the marketing authorisation.

[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.

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