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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): interferon alpha-2b

Procedure No. EMEA/H/C/PSUSA/00001758/201609

Period covered by the PSUR: 21 Sept 2011 – 20 Sept 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for interferon alpha-2b, the scientific conclusions of CHMP are as follows:

Based on a cumulative review of cases of tongue hyperpigmentation previously assessed by the PRAC within the PSUSA procedure for peginterferon alfa-2b, the PRAC concluded on a causal relationship with the drug and recommended the relevant update of the SmPC. The possible mechanism behind it is an upregulation of the alpha-melanocyte–stimulating hormone receptors on melanocytes induced by interferon alpha leading to an increase in melanin production. This can be considered as a class effect. As a result, tongue pigmentation should be considered as an adverse drug reaction also for interferon alfa 2b containing products.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for interferon alpha-2b the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing interferon alpha-2b is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.