



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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



## **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.