



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/CHMP/322798/2014  
Committee for Medicinal Products for Human Use (CHMP)

## ViraferonPeg

International non-proprietary name: PEGINTERFERON ALFA-2B

Procedure No. EMEA/H/C/000329/PSUV/0110

Period covered by the PSUR: 25.07.2013 to 24.07.2013

**Scientific conclusions and grounds recommending the variation to  
the terms of the Marketing Authorisation**

Medicinal product no longer authorised



## Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for ViraferonPeg, the scientific conclusions of PRAC are as follows:

The overall benefit of ViraferonPeg in the authorised indications was not altered as a result of new information that became available during the reporting period of this PSUR.

Based on a review of data concerning tongue pigmentation provided in this PSUR as well as similar data provided in the PSUR of another peginterferon alfa containing product, the PRAC considered that tongue pigmentation should be added as an Adverse Drug Reaction to section 4.8 of the SmPC and that the package leaflet be updated accordingly.

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

## Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for ViraferonPeg, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance Peginterferon alfa-2b is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.

Medicinal product no longer authorised