



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

AUBAGIO

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: teriflunomide

Procedure No.: EMEA/H/C/002514/PSUV/0005

Period covered by the PSUR: 26 August 2013 – 25 February 2014





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Scientific conclusions

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

During the assessment period of this PSUR, the PRAC became aware of the recently identified Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) related to leflunomide, and the SmPC of leflunomide-containing medicinal products was updated. Although no cases of severe skins reactions have been reported with teriflunomide in the clinical trials, the PRAC considered it appropriate to request an update of the SmPC and include the information that in patients treated with leflunomide, the parent compound, very rare cases of DRESS have been reported.

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 AUBAGIO, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance teriflunomide is favourable subject to the proposed changes to the product information.

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

