30 May 2024
EMA/240603/2024
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): teriflunomide

Procedure No. EMEA/H/C/PSUSA/00010135/202309

Period covered by the PSUR: 09 November 2022 To: 12 September 2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for teriflunomide, the scientific conclusions of PRAC are as follows:

In view of available data on herpes virus infections from clinical trial(s), the literature and spontaneous reports, including in some cases a plausible temporal relationship, a positive de-challenge and/or re-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between teriflunomide and herpes virus infections is at least a reasonable possibility. The PRAC concluded that the product information of products containing teriflunomide should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for teriflunomide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing teriflunomide 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.