25 April 2024
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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): mercaptopurine

Procedure No. EMEA/H/C/PSUSA/00001988/202309

Period covered by the PSUR: 2 September 2021 to 1 September 2023

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Scientific conclusions

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

In view of available data from the literature, spontaneous reports including in some cases a close 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 mercaptopurine and *stomatitis, cheilitis, mucosal inflammation, pellagra, cholestasis of pregnancy* and *coagulation factors decreased* is at least a reasonable possibility. The PRAC concluded that the product information of products containing mercaptopurine 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 mercaptopurine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing mercaptopurine 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.