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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/00001988/202109

Period covered by the PSUR: 02 September 2016 to: 01 September 2021

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Scientific conclusions

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

In view of available data on erythema nodosum from the literature, spontaneous reports including in three cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC Rapporteur considers a causal relationship between mercaptopurine and erythema nodosum is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing mercaptopurine should be amended accordingly.

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 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.