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Committee for Medicinal Products for Human Use (CHMP)

Xaluprine

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

International non-proprietary name: MERCAPTOPURINE

Procedure No. EMEA/H/C/002022/PSUV/0008

Period covered by the PSUR: 14 April 2013 – 13 September 2013

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Scientific conclusions

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

An article describing hypoglycaemia in a child treated with 6-mercaptopurine has been identified by the MAH. In addition, there are at least 5 other relevant articles describing hypoglycaemia in association with 6-mercaptopurine. A potential causal relationship of hypoglycaemia to Xaluprine is at least possible and therefore it is proposed to include hypoglycaemia as a warning in section 4.4 and as an adverse event in section 4.8 of the SmPC.

Some cases of 'photosensitivity reactions' in association with Xaluprine have been identified. Although the number of cases is limited there is at least one case (positive re-challenge) with a possible causality with 6-mercaptopurine. Taken this together the proposal is to update the SmPC to include photosensitivity reaction in section 4.8.

Therefore, in view of available data regarding hypoglycaemia and photosensitivity reactions, the PRAC considered that changes to the product information were warranted. 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 Xaluprine, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance mercaptopurine is favourable subject to the proposed changes to the product information.

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