24 October 2013
EMA/39286/2014
Committee for Medicinal Products for Human Use (CHMP)

Xaluprine

International non-proprietary name: mercaptopurine

Procedure No. EMEA/H/C/002022/PSUV/0006

Period covered by the PSUR: 14.09.2012 – 13.03.2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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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:

Xaluprine is indicated for the treatment of acute lymphoblastic leukaemia (ALL) in children, adolescents and adults.

This is the second 6-monthly PSUR relating to Xaluprine (20 mg/ml oral suspension of mercaptopurine as monohydrate) and covers the period between 14 September 2012 and 13 March 2013. The product is marketed in the UK, Ireland, Germany, Sweden, Denmark, Norway, Iceland and the Netherlands.

No new relevant information on efficacy and effectiveness in the authorised indication has become available during the reporting period covered by this PSUR.

However, a cumulative review by the MAH on hepatosplenic T cell lymphoma and lymphoproliferative disorders, due to signal detection in the EudraVigilance (EV) database, was included in this PSUR. There have been 27 cases (including 14 duplicates) submitted to EV up to 13 July 2011. In two cases mercaptopurine was given as monotherapy.

The originator product SmPC has a warning in section 4.4 and HSTCL labelled in section 4.8. The evaluation of the signal requires an update of the SmPC. The MAH should submit a detailed SmPC with an update of sections 4.4 and 4.8 in accordance with the recommended changes specified in Annex I. An update of the Patient leaflet is also proposed.

Review of the safety information received during the period covered by this PSUR indicates that the current risk / benefit ratio for Xaluprine remains acceptable.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

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.