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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): febuxostat

Procedure No. EMEA/H/C/PSUSA/00001353/201704

Period covered by the PSUR: 1 April 2016 - 20 April 2017

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Scientific conclusions

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

As a result of the request for close monitoring, the MAH has searched its global safety database using terms relating to Agranulocytosis Standardized MedDRA Query (SMQ, narrow). Cases with terms that matched the search criteria were retrieved from post-marketing sources. Cumulatively, there have been 13 cases reporting 13 Preferred Terms of Agranulocytosis from all post-marketing sources. This includes four cases from the current reporting interval. No cases have been retrieved from the clinical trials.

The MAH has calculated the frequency for agranulocytosis as "rare", using the 3/x rule. The section 4.8 of the SmPC is updated to add this new adverse event 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 febuxostat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing febuxostat 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.