10 November
EMA/33656/2017
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/00001353/201604

Period covered by the PSUR: 20 April 2015 to 20 April 2016

Scientific conclusions

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

The MAH had suggested including blood creatine phosphokinase increase in the SmPC and provided supportive data accordingly.

The PRAC agreed to include blood creatine phosphokinase increase in 4.8. of the SmPC, based on one case from literature and some evidence from clinical trials and in order to create awareness in medical staff to focus on elevated levels of CPK at an early stage.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing febuxostat were warranted.

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.