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EMA/CHMP/166940/2014
Committee for Medicinal Products for Human Use (CHMP)

# Adenuric

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

International non-proprietary name: febuxostat

Procedure No. EMEA/H/C/000777/PSUV/0033

Period covered by the PSUR: 21 April 2012 – 20 April 2013

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**Scientific conclusions**

In view of data presented in the PSUR regarding hepatic events and serious hypersensitivity reactions associated with febuxostat treatment, the PRAC considers that changes to the product information are warranted.

During the current review period, one of the most commonly reported serious events was Drug reaction with eosinophilia and systemic symptoms (DRESS). There is evidence for a cross-sensitivity with allopurinol. Given that hypersensitivity reactions with febuxostat can manifest in many different ways, the inclusion of DRESS is warranted.

Considering the severity as well as the prognosis of TEN and the fact that the prompt withdrawal of the treatment is crucial, the PRAC considers that the update of the product information is necessary.

One of the most common serious adverse events was drug induced liver injury and this is not explicitly mentioned in the SmPC.

Therefore, changes to the product information are warranted as follows:

Section 4.4:

The existing warning on serious allergic/hypersensitivity reactions should be updated to include information on TEN and DRESS (see Annex I).

Section 4.8:

The addition of liver injury* (rare) and drug reaction with eosinophilia and systemic symptoms* (rare) is endorsed (*_Adverse reactions coming from post-marketing experience),_ see Annex I.

Additionally, the MAH should include following adverse reaction in section 4.8:

- TEN ( frequency to be estimated by MAH)

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 Adenuric, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance febuxostat is favourable subject to the proposed changes to the product information.

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