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EMA/CHMP/717110/2014
Committee for Medicinal Products for Human Use (CHMP)

Fasturtec

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

International non-proprietary name: rasburicase

Procedure No. EMEA/H/C/000331/PSUV/0041

Period covered by the PSUR: 01 March 2011 – 23 February 2014

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Scientific conclusions

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

In view of available data regarding the risk of convulsion (comprising spontaneous and study reports, including a well-documented case involving a positive re-challenge), and of available data regarding the risk of involuntary muscle contraction (including a well-documented literature report), the following ADRs should be included in section 4.8 of the SmPC under the SOC Nervous system disorders: "convulsion" with the frequency category "uncommon" based on the MAH's calculation using the incidence observed across clinical studies and "muscle contraction involuntary" with the frequency category "unknown" . The PL should be updated accordingly.

Therefore, in view of available data regarding convulsion and involuntary muscle contraction, 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 Fasturtec, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance rasburicase is favourable subject to the proposed changes to the product information.

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