EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: mecasermin

Procedure No. EMEA/H/C/PSUSA/00001942/201408

Period covered by the PSUR: 01 September 2013 – 31 August 2014

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Scientific conclusions

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

A search of the MAHs Global Safety Database cumulative to 20 January 2015 identified 1 unique case of treatment emergent femoral epiphysiolysis and 3 unique cases of treatment emergent avascular necrosis (AVN) of the femoral head.

Given (i) the medical importance of AVN, (ii) that AVN is a recognised complication of slipped capital femoral epiphysis (SCFE), (iii) that the risk of SCFE is higher in patients with growth hormone (GH) abnormalities, (iv) and that both SCFE and AVN are noted in Section 4.4 Special warnings and precautions for use and/or Section 4.8 Undesirable effects of UK SmPCs for human Growth Hormone, it is considered necessary to revise the wording of Section 4.4 of the EU SmPC.

Therefore, in view of available data regarding mecasermin, the PRAC considered that changes to the product information were warranted.

Furthermore, the MAH is asked to address this issue in the relevant sections of the EU RMP in the next regulatory procedure affecting the RMP.

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 mecasermin the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing mecasermin is favourable subject to the proposed changes to the product information

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