22 March 2018
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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): ibuprofen (indicated in ductus arteriosus)

Procedure No. EMEA/H/C/PSUSA/00001712/201707

Period covered by the PSUR: 30 July 2014 - 29 July 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ibuprofen (indicated in ductus arteriosus), the scientific conclusions of CHMP are as follows:

Considering the morbidity and mortality associated with gastric perforation, the suspicion of causality attributed to Pedea by the reporters in 4/5 cases, the existence of a biologically plausible mechanism, and the rarity of the condition amongst all gastrointestinal perforations in the neonatal period, the MAH is requested to add the adverse reaction “gastric perforation” in section 4.8 of the SmPC with a frequency “unknown” in order to alert healthcare professionals to the possibility of this specific adverse drug reaction.

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 ibuprofen (indicated in ductus arteriosus) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ibuprofen (indicated in ductus arteriosus) 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.