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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): bazedoxifene

Procedure No. EMEA/H/C/PSUSA/00000302/201510

Period covered by the PSUR: 17 October 2014 to 16 October 2015

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Scientific conclusions

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

Since further cases of eye disorders have been reported and “Eye disorders” have been recently re-classified as an important identified risk, the PRAC recommended that vision disorders/ocular events are included in the table of section 4.8 of the SmPC which covers both clinical trial and post-marketing data rather than presented outside the table. These events should be displayed under a frequency unknown. The package leaflet should be updated accordingly.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing bazedoxifene 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 bazedoxifene the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bazedoxifene 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.