



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Yellox

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

International non-proprietary name: bromfenac

Procedure No. EMEA/H/C/001198/PSUV/0010

Period covered by the PSUR: 1 December 2013 – 30 May 2014



Scientific conclusions

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

Following a request from the PRAC as part of the previous PSUR, the MAH within this PSUR evaluated the signal of "rebound effect" and "macular oedema" and assessed whether an update of the SmPC is warranted.

Cumulatively, 29 cases reported rebound eye inflammation/macular oedema. Of these 26 cases were assessed as possibly related to bromfenac withdrawal, 2 cases were assessed as unlikely related, 1 case had insufficient information for a causality assessment.

The mechanism involved is suggested to be related to the effect of withdrawal of bromfenac. Once bromfenac is withdrawn, the anti-inflammatory effect seems to be removed and the underlying inflammatory mechanisms caused by tissue damage from the cataract surgery take over.

Based on the reported cases and the suggested mechanism it is deemed appropriate to warn the physician about this potential flare up of inflammation and the following sentence is proposed to be added to section 4.4 Special warnings and precautions for use of the SmPC:

"It has been observed in rare cases that upon withdrawal of Yellox, a flare-up of the inflammatory response, e.g. in the form of macular oedema, due to the cataract operation may occur."

The Patient Leaflet is updated accordingly.

Therefore, in view of available data, 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 Yellox, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance bromfenac is favourable subject to the proposed changes to the product information.

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