17 March 2011
EMA/CHMP/204341/2011
Committee for medicinal products for human use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Yellox

## bromfenac sodium sesquihydrate

On 17 March 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Yellox, 1 mg/ml, eye drops, solution, intended for the treatment of postoperative ocular inflammation. The applicant for this medicinal product is Croma-Pharma GmbH. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Yellox is bromfenac, an anti-inflammatory agent, non-steroids, ATC code: S01BC11, with mechanism of action through blockage of the prostaglandin synthesis by inhibiting primarily cyclooxygenase 2 (COX-2).

The benefit with Yellox is its ability to be effective in the treatment of post-operative ocular inflammation in subjects undergoing cataract extraction with posterior intraocular chamber lens implantation.

The most common side effects are abnormal sensation in eye, corneal erosion (mild or moderate), eye pruritus, eye pain and eye redness.

A pharmacovigilance plan for Yellox will be implemented as part of the marketing authorisation.

The approved indication is: "Treatment of postoperative ocular inflammation following cataract extraction in adults".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Yellox and therefore recommends the granting of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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