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**EPAR summary for the public**

# Yellox

bromfenac

This is a summary of the European public assessment report (EPAR) for Yellox. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Yellox.

For practical information about using Yellox, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Yellox and what is it used for?

Yellox is a medicine used in adults to treat inflammation in the eye that can occur after an operation to remove a cataract (clouding of the lens).

Yellox contains the active substance bromfenac.

## How is Yellox used?

Yellox is available as an eye drop solution and the recommended dose is one drop into the affected eye(s) twice a day. Treatment begins the day after the cataract operation and continues for two weeks.

If more than one eye medicine is being used, they should be given at least five minutes apart.

The medicine can only be obtained with a prescription. For more information see the package leaflet.

## How does Yellox work?

The active substance in Yellox, bromfenac, is a non-steroidal anti-inflammatory drug (NSAID). It works by blocking an enzyme called cyclo-oxygenase, which produces prostaglandins, substances that are involved in the inflammation process. By reducing the production of prostaglandins in the eye, Yellox can reduce the inflammation caused by eye surgery.

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## What benefits of Yellox have been shown during the studies?

Yellox was found to be more effective than placebo (a dummy treatment) at relieving inflammation in the eye following cataract surgery in two main studies involving a total of 527 patients undergoing cataract surgery. In both studies, the main measure of effectiveness was the number of patients with no sign of inflammation after two weeks. In one study, 66% of patients treated with Yellox (104 out of 158) had no signs of inflammation after two weeks compared with 48% of patients receiving placebo (35 out of 73). In the second study, the figures were: 63% (124 out of 198) for patients treated with Yellox and 40% (39 out of 98) for those treated with placebo.

## What are the risks associated with Yellox?

The most common or most important side effects seen with Yellox are abnormal sensation in eye (0.5%), mild or moderate erosion of the cornea (the transparent layer in front of the eye) (0.4%), eye pruritus (itching) (0.4%), eye pain (0.3%) and eye redness (0.3%). For the full list of all side effects reported with Yellox, see the package leaflet.

Yellox must not be used in people who are hypersensitive (allergic) to bromfenac, to any of the other ingredients or to other NSAIDs. It must not be used in patients who get asthma attacks, urticaria (itchy rash) or acute rhinitis (stuffy and runny nose) from taking acetylsalicylic acid (aspirin) or other NSAIDs.

## Why is Yellox approved?

The European Medicines Agency decided that Yellox's benefits are greater than its risks and recommended that it be given marketing authorisation.

## What measures are being taken to ensure the safe and effective use of Yellox?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Yellox have been included in the summary of product characteristics and the package leaflet.

## Other information about Yellox

The European Commission granted a marketing authorisation valid throughout the European Union for Yellox on 18 May 2011.

The full EPAR for Yellox can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Yellox, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.