Package Leaflet: Information for the User

Yellox® 0.9 mg/ml eye drops, solution

(bromfenac)

Your medicine is known by the above name, but will be referred to as Yellox® throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT YELLOX® IS AND WHAT IT IS USED FOR

Yellox® contains bromfenac and belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It works by blocking certain substances involved in causing inflammation.

Yellox® is used to reduce eye inflammation following cataract surgery in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE YELLOX®

Do not use Yellox®

- if you are allergic to bromfenac or to any of the other ingredients of this medicine (listed in section 6).
- if you have experienced asthma, skin allergy or intense inflammation in your nose when using other NSAIDs. Examples of NSAIDs are: acetylsalicylic acid, ibuprofen, ketoprofen, diclofenac.

Warning and precautions

Talk to your doctor or pharmacist before using this medicine

- if you are using topical steroids (e.g. cortisone), as this may cause unwanted side effects.
- if you have bleeding problems (e.g. haemophilia) or have had them in the past, or you are taking other medicines which may prolong bleeding time (e.g. warfarin, clopidogrel, acetylsalicylic acid).
- if you have eye problems (e.g. dry eye syndrome, corneal problems).
- if you have diabetes.
- if you have rheumatoid arthritis.
- if you had repeated eye surgery within a short period of time.

Wearing contact lenses is not recommended after cataract surgery. Therefore, do not wear contact lenses whilst using Yellox®.

Children and adolescents

Yellox® should not be used in children and adolescents.

Other medicines and Yellox®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you use Yellox®.

Yellox® should not be used during the last three months of pregnancy. The doctor may prescribe this medicine during pregnancy if expected benefit to mother outweigh possible risk to baby.

Yellox® may be prescribed to breast-feeding woman and have no important influence on fertility.

Driving and using machines

Your vision may be blurred for a short time after using this eye drops. If you experience blurred vision upon instillation, do not drive or use machines until your vision is clear.

Yellox® contains benzalkonium chloride

This medicine contains 0.00185 mg benzalkonium chloride in each drop which is equivalent to 0.05 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. HOW TO USE YELLOX®

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dose

The recommended dose is one drop of Yellox® in the affected eye(s) twice daily (morning and evening). Do not use more than one drop in the affected eye(s) 2 times daily.

Start using the drops the next day after your cataract surgery.

Method of administration

Yellox® is for ocular use.

- Wash your hands before using the eye drops.
- Put yourself in a comfortable and stable position.
- Twist off the bottle cap.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a clean finger.
- Bring the bottle tip close to the eye.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.
- Gently squeeze the bottle to release one drop of Yellox®.
- Close the bottle cap firmly immediately after use.
- Keep the bottle tightly closed when not in use.

If you use any other eye drops, wait at least five minutes between using Yellox® and the other drops.

Duration of treatment

Continue the drops through the first 2 weeks after your surgery. Do not use Yellox® longer than 2weeks.

If you use more Yellox® than you should

Rinse out your eye with warm water. Do not put in any more drops until it is time for your next regular dose. If Yellox® is accidentally swallowed, a glass of water or other fluid should be taken to water down the medicine.

If you forget to use Yellox®

Use a single dose as soon as you remember. If it is almost time for the next dose, leave out the missed dose. Continue with the next regularly scheduled dose. Do not use a double dose to make up for a forgotten dose.

If you stop using Yellox®

Do not stop using Yellox® without speaking to your doctor.

In rare cases upon withdrawal of Yellox®, a flare-up of the inflammatory response, e.g. in the form of retina swelling, due to the cataract operation has been observed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience decreased or blurred vision the week after the end of treatment, contact your doctor immediately.

If you notice any of the following side effects while using the drops, contact your doctor immediately:

Uncommon side effects (may affect up to 1 in 100 people)

Foreign body sensation in the eye, redness and inflammation of the eye, damage and inflammation of the surface of the eye, eye discharge, itching, irritation or pain of the eye, swelling or bleeding of the eyelid, impaired vision due to inflammation, floaters or moving spots before the eyes or diminishing vision that can indicate bleeding or damage of the back of the eye (retina), ocular discomfort, sensitivity to light, reduced or blurred vision, swelling of the face, cough, nosebleeding or runny nose.

Rare side effects (may affect up to 1 in 1,000 people)

Damage of the eye surface, redness of the eye, asthma.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE YELLOX®

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Discard the bottle 4 weeks after first opening to prevent infection even if there is solution remaining.
- Write the date of opening on the carton label in the space provided.
- If your medicine shows any signs of deterioration or discoloration, consult a pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Yellox® contains

The active substance is bromfenac.

Each ml of solution contains 0.9 mg bromfenac (as sodium sesquihydrate). One drop contains approximately 33 micrograms bromfenac.

The other ingredients are boric acid, borax, sodium sulphite anhydrous (E221), benzalkonium chloride (see section 2), tyloxapol, povidone (K30), disodium edetate, water for injection, sodium hydroxide (to keep acidity levels normal).

What Yellox® looks like and contents of the pack

Yellox® is a clear yellow liquid (solution) supplied in a pack containing one 5 ml plastic bottle with a screw cap.

Manufactured by Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH, Brunsbutteler Damm 165/173, 13581 Berlin, Germany.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

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