ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE MEDICINAL PRODUCT
Yellox 0.9 mg/ml eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
One ml of solution contains 0.9 mg bromfenac (as sodium sesquihydrate).
One drop contains approximately 33 micrograms bromfenac.

Excipient:
Each ml of solution contains 50 micrograms of benzalkonium chloride.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Eye drops, solution.
Clear yellow solution.
P.H.: 8.1-8.5; osmolality: 270-330 mOsmol/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Treatment of postoperative ocular inflammation following cataract extraction in adults.

4.2 Posology and method of administration

Posology
Use in adults, including the elderly
The dose is one drop of Yellox in the affected eye(s) twice daily, beginning the next day after cataract surgery and continuing through the first 2 weeks of the postoperative period.

The treatment should not exceed 2 weeks as safety data beyond this is not available.

Paediatric population
The safety and efficacy of bromfenac in paediatric patients has not been established. No data are available.

Hepatic and renal impairment
Yellox has not been studied in patients with hepatic disease or renal impairment.

Method of administration
For ocular use.

If more than one topical ophthalmic medicinal product is being used, each one should be administered at least 5 minutes apart.

To prevent contamination of the dropper-tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper-tip of the bottle. Instruct patient to keep the bottle tightly closed when not in use. Contact lenses should not be worn during treatment with Yellox (see section 4.4).
4.3 Contraindications

Yellox must not be used in patients with known hypersensitivity to bromfenac, to any of the excipients, or to other non-steroidal anti-inflammatory medicinal products (NSAIDs). Yellox is contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or by other medicinal products with prostaglandin synthetase inhibiting activity.

4.4 Special warnings and precautions for use

All topical NSAIDs may slow or delay healing like topical corticosteroids. Concomitant use of NSAIDs and topical steroids may increase the potential for healing problems.

Yellox contains sodium sulphite which may cause allergic-type reactions including anaphylactic symptoms and less severe asthmatic episodes in susceptible patients.

Cross-sensitivity
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these medicinal products and potential risks and benefit should be carefully evaluated.

Susceptible persons
In susceptible patients, continued use of topical NSAIDs, including Yellox may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs and should be closely monitored for corneal health. Consequently in at risk patients concomitant use of ophthalmic corticosteroids with NSAIDs may lead to a higher risk of corneal adverse events.

Postmarketing experience
Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus and ocular surface diseases e.g. dry eye syndrome, rheumatoid arthritis or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse reactions which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

There have been reports that ophthalmic NSAIDs may cause increased bleeding of ocular tissues (including hyphaema) in conjunction with ocular surgery. Yellox should be used with caution in patients with known bleeding tendencies or who are receiving other medicinal products which may prolong bleeding time.

Ocular infection
An acute ocular infection may be masked by the topical use of anti-inflammatory medicinal products.

Use of contact lenses
In general, contact lens wear is not recommended during the postoperative period following cataract surgery. Therefore, patients should be advised not to wear contact lenses during treatment with Yellox.

Excipients
Since Yellox contains benzalkonium chloride, close monitoring is required with frequent or prolonged use. Benzalkonium chloride is known to discolour soft contact lenses. Contact with soft contact lenses must be avoided. Benzalkonium chloride has been reported to cause eye irritation, punctuate keratopathy and/or toxic ulcerative keratopathy.
4.5 Interaction with other medicinal products and other forms of interaction

Formal interaction studies have not been performed, but no interactions with antibiotic eye drops used in conjunction with surgery have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of bromfenac in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown. Since the systemic exposure in non-pregnant women is negligible after treatment with Yellox, the risk during pregnancy could be considered low.

However, because of the known effects of prostaglandin biosynthesis-inhibiting medicinal products on the foetal cardiovascular system (closure of ductus arteriosus), the use of Yellox during third trimester pregnancy should be avoided. The use of Yellox is in general not recommended during pregnancy unless the benefit outweighs the potential risk.

Breast-feeding
It is unknown whether bromfenac or its metabolites are excreted in human milk. Animal studies have shown excretion of bromfenac in the milk of rats following very high oral doses (see section 5.3). No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to bromfenac is negligible. Yellox can be used during breast-feeding.

Fertility
No effects of bromfenac on the fertility were observed in animal studies. In addition the systemic exposure to bromfenac is negligible; for this reason no pregnancy testing or contraceptive measures are required.

4.7 Effects on ability to drive and use machines

Transient blurring of vision may occur on instillation. If blurred vision occurs at instillation refrain from driving or using machines until vision is clear.

4.8 Undesirable effects

Summary of the safety profile
Based on an analysis of all patients receiving Yellox in a clinical trial for treatment of post-operative inflammation following cataract surgery (n = 973, whereof n=356 in studies performed in the U.S and n=617 in studies performed in Japan), a total of 3.4% of patients (6.7% in U.S. studies and 1.3% in Japanese studies) experienced one or more adverse reactions. The most common or most important reactions in the pooled studies were abnormal sensation in eye (0.5%), corneal erosion (mild or moderate) (0.4%), eye pruritus (0.4%), eye pain (0.3%) and eye redness (0.3%). Corneal adverse reactions were only observed in the Japanese population. Adverse reactions rarely led to withdrawal, with a total of 8 (0.8%) patients who prematurely discontinued treatment in a study due to an adverse reaction. These comprised 3 (0.3%) patients with mild corneal erosion, 2 (0.2%) patients with eyelid oedema and 1 (0.1%) patient each with abnormal sensation in eye, corneal oedema, or eye pruritus.

Tabulated list of adverse reactions
The following adverse reactions were classified according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), or very rare (<1/10,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

The table below describes adverse reactions by system organ class and frequency.
<table>
<thead>
<tr>
<th>MedDRA system organ class</th>
<th>Frequency</th>
<th>Adverse reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye disorders</td>
<td>Uncommon</td>
<td>Visual acuity reduced</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Haemorrhagic retinopathy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal epithelium defect**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal erosion (mild or moderate)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal epithelium disorder</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal oedema</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retinal exudates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eyelid bleeding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vision blurred</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Photophobia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eyelid oedema</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye pruritus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation</td>
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<tr>
<td></td>
<td></td>
<td>Eye redness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Conjunctival hyperaemia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Abnormal sensation in eye</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ocular discomfort</td>
</tr>
<tr>
<td></td>
<td>Rare</td>
<td>Corneal perforation*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal ulcer*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal erosion, serious*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Scleromalacia*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal infiltrates*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal disorder *</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corneal scar*</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Uncommon</td>
<td>Epistaxis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cough</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nasal sinus drainage</td>
</tr>
<tr>
<td></td>
<td>Rare</td>
<td>Asthma*</td>
</tr>
<tr>
<td>General disorders and administrative site conditions</td>
<td>Uncommon</td>
<td>Face swelling</td>
</tr>
</tbody>
</table>

*Serious, isolated reports from post-marketing experience of more than 20 million patients
** Observed with four times daily dose

Patients with evidence of corneal epithelial breakdown should immediately discontinue use of Yellox and should be monitored closely for corneal health (see section 4.4).

4.9 **Overdose**

If Yellox is accidentally ingested, fluids should be taken to dilute the medicinal product.
5.  PHARMACOLOGICAL PROPERTIES

5.1  Pharmacodynamic properties

Pharmacotherapeutic group: Ophtalmologics, Antiinflammatory agents, non-steroids, ATC code: S01BC11

**Mechanism of action**
Bromfenac is a non-steroidal anti-inflammatory drug (NSAID) that has anti-inflammatory activity which is thought to be due to its ability to block prostaglandin synthesis by inhibiting primarily cyclooxygenase 2 (COX-2). Cyclooxygenase 1 (COX-1) is only inhibited to a small extent. *In vitro*, bromfenac inhibited the synthesis of prostaglandins in the rabbit iris ciliary body. The IC50-values were lower for Bromfenac (1.1 μM) than for indometacin (4.2 μM) and pronaprofen (11.9 μM). Bromfenac at concentrations of 0.02%, 0.05%, 0.1% and 0.2% inhibited almost all signs of ocular inflammation in an experimental uveitis model in rabbits.

**Clinical efficacy**
Two Phase II multicentre, randomised, double-masked, parallel group studies were conducted in Japan, and two Phase III multicentre, randomised (2:1), double-masked, parallel group, placebo-controlled studies were conducted in the US to assess the clinical safety and efficacy of Yellox dosed twice daily in the treatment of post-operative inflammation in patients undergoing cataract surgery. In these studies, study substance was administered approximately 24 hours after cataract surgery and continued for up to 14 days. Treatment effect was evaluated up to 29 days. A significantly greater proportion of patients in the Yellox group 64.0% vs. 43.3% in the placebo group (p<0.0001) experienced complete clearance of ocular inflammation at study day 15. There was significantly less anterior chamber cells and flare within the first 2 weeks post-surgery (85.1% of patients with flare score of ≤1) vs. placebo (52%). The difference in the rate of inflammation clearance showed as early as day 3.

In a large, well controlled study that was conducted in Japan, Yellox was shown to be as effective as pronaprofen ophthalmic solution.

**Paediatric population**
The European Medicines Agency has waived the obligation to submit the results of studies with Yellox in all subsets of the paediatric population in postoperative ocular inflammation (see section 4.2 for information on paediatric use)

5.2  Pharmacokinetic properties

**Absorption**
Bromfenac efficiently permeates the cornea of cataract patients: A single dose resulted in a mean peak aqueous humour concentrations of 79±68 ng/ml at 150-180 minutes after dosing. Concentrations were maintained for 12 hours in aqueous humour with measurable levels up to 24 hours in major ocular tissues including the retina. Following twice daily dosing with bromfenac eye drops plasma concentrations were not quantifiable.

**Distribution**
Bromfenac shows high binding to plasma proteins. *In vitro*, the 99.8% were bound to proteins in human plasma.

No biological relevant melanin binding was observed *in vitro*.

Studies in rabbits using radio-labelled bromfenac have demonstrated that highest concentrations after topical administration are observed in the cornea followed by the conjunctiva and the aqueous humour. Only low concentrations were observed in the lens and vitreous.
Biotransformation

_In vitro_ studies indicate that bromfenac is mainly metabolised by CYP2C9, which is absent in both iris-ciliary body and retina/choroid and the level of this enzyme in the cornea is less than 1% compared to the corresponding hepatic level.

In orally treated humans unchanged parent compound is the major component in plasma. Several conjugated and unconjugated metabolites have been identified with the cyclic amide being the major urinary metabolite.

Excretion

After ocular administration the half-life of bromfenac in aqueous humour is 1.4 h indicating rapid elimination.

After oral administration of 14C-bromfenac to healthy volunteers, urinary excretion was found to be the major route of radioactive excretions, accounting for approximately 82% while faecal excretion represented approximately 13% of the dose.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety, pharmacology, 'repeated-dose' toxicity, genotoxicity and carcinogenic potential. However, 0.9 mg/kg/day in rats at oral doses (900 times the recommended ophthalmic dose) caused embryo-foetal lethality, increased neonatal mortality, and reduced postnatal growth. Pregnant rabbits treated orally with 7.5 mg/kg/day (7500 times the recommended ophthalmic dose) caused increased post-implantation loss (see section 4.6).

Animal studies have shown excretion of bromfenac in breast milk when applied orally at doses of 2.35 mg/kg which is 2350 times the recommended ophthalmic dose. However, following ocular administration plasma levels were not detectable (see section 5.2).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Boric acid
- Borax
- Sodium sulphite, anhydrous (E221)
- Tyloxapol
- Povidone
- Benzalkonium chloride
- Disodium edetate
- Water for injections
- Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 17 months
Discard any unused contents 4 weeks after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container
5 ml solution in a polyethylene plastic squeeze bottle with a dropper-tip and a polyethylene screw cap. Pack of 1 bottle.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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A-2100 Leobendorf
Austria
Tel.: +43 (0)22 62 684 68 0
Fax.: +43 (0)22 62 684 68 15
Email: office@croma.at

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency [http://www.ema.europa.eu](http://www.ema.europa.eu)
ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION
A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Croma-Pharma GmbH
Industriezeile 6
A-2100 Leobendorf
Österreich

Dr. Gerhard Mann
Chem.-pharm. Fabrik GmbH
Brunsbütteler Damm 165–173
13581 Berlin
Germany

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OF THE MARKETING AUTHORISATION

- CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER

Medicinal product subject to medical prescription.

- CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable.

- OTHER CONDITIONS

Pharmacovigilance system
The MAH must ensure that the system of pharmacovigilance presented in Module 1.8.1. of the Marketing Authorisation Application is in place and functioning before and whilst the product is on the market.

Risk Management Plan
The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version 5.0 dated 8 March 2011 of the Risk Management Plan (RMP) presented in Module 1.8.2. of the Marketing Authorisation Application and any subsequent updates of the RMP agreed by the CHMP.

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the following Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted:
- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached
- At the request of the European Medicines Agency
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON FOR SINGLE BOTTLE 5 ML

1. NAME OF THE MEDICINAL PRODUCT

Yellox 0.9 mg/ml eye drops, solution
Bromfenac

2. STATEMENT OF ACTIVE SUBSTANCE(S)

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

3. LIST OF EXCIPIENTS

Boric acid, borax, sodium sulphite anhydrous (E221), tyloxapol, povidone, disodium edetate, benzalkonium chloride (see the package leaflet for further information), water for injections, sodium hydroxide (for pH adjustment)

4. PHARMACEUTICAL FORM AND CONTENTS

eye drops, solution
1x5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Ocular use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP
Discard any unused contents 4 weeks after first opening.
Opened:
9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Croma-Pharma GmbH
Industriezeile 6
A-2100 Leobendorf
Austria

12. MARKETING AUTHORISATION NUMBER

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Yellox
### Minimum Particulars to Appear on Small Immediate Packaging Units

#### Bottle Label

<table>
<thead>
<tr>
<th>1. Name of the Medicinal Product and Route(s) of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellox 0.9 mg/ml eye drops, solution</td>
</tr>
<tr>
<td>Bromfenac</td>
</tr>
<tr>
<td>Ocular use</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Method of Administration</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>3. Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Batch Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Contents by Weight, by Volume or by Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 ml</td>
</tr>
</tbody>
</table>
B. PACKAGE LEAFLET
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. Therefore, Yellox is used to reduce eye inflammation following cataract surgery in adults.

2. **BEFORE YOU USE YELLOX**

**Do not use Yellox**
- if you are allergic (hypersensitive) to bromfenac or to any of the other ingredients of Yellox (see section “Further information” at the end of this leaflet).
- 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.

**Take special care with Yellox**
- 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.
- 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.

**Children and adolescents**
Yellox should not be used in children and adolescents.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.
Pregnancy and breastfeeding
If you are pregnant or breastfeeding, talk to your doctor before you use Yellox. Yellox should not be used during the last three months of pregnancy.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Your vision may be blurred for a short time after using Yellox. If you experience blurred vision upon using Yellox, do not drive or use machines until your vision is clear.

Important information about some of the ingredients of Yellox
Yellox contains sodium sulphite which may cause allergic reactions.
Yellox contains benzalkonium chloride, a preservative which may cause eye irritation. Do not use Yellox while wearing contact lenses, since benzalkonium chloride is known to discolour them.
Additionally, wearing contact lenses is not recommended after cataract surgery. Therefore, do not wear contact lenses whilst using Yellox.

3. HOW TO USE YELLOX
Always use Yellox exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dose and duration of treatment
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 taking Yellox the next day after your cataract surgery. Continue the drops through the first 2 weeks after your surgery. Do not use Yellox longer than 2 weeks.

Administration
- 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.

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 ingested, fluids (e.g. a glass of water) should be taken to dilute 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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Yellox can cause side effects, although not everybody gets them.
If you experience decreased or blurred vision the week after the end of treatment, you should contact your doctor immediately.

The frequency of possible side effects listed below is defined using the following convention:

- **Very common** Affects more than 1 user out of 10
- **Common** Affects 1 to 10 users in 100
- **Uncommon** Affects 1 to 10 users in 1,000
- **Rare** Affects 1 to 10 users in 10,000
- **Very rare** Affects less than 1 user in 10,000
- **Not known** Frequency cannot be estimated from the available data

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

**Uncommon side effects (Affects 1 to 10 users in 1,000)**
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 (Affects 1 to 10 users in 10,000)**
Damage of the eye surface, redness of the eye, asthma.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE YELLOX

Keep out of the reach and sight of children.

Do not use Yellox after the expiry date which is stated on the bottle and outer carton 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
6. FURTHER INFORMATION

What Yellox contains

- The active substance is bromfenac. One 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, tyloxapol, povidone, 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.

Marketing Authorisation Holder and Manufacturer

Croma-Pharma GmbH
Industriezeile 6
A-2100 Leobendorf
Austria
office@croma.at

Manufacturer

Dr. Gerhard Mann
Chem.-pharm. Fabrik GmbH
Brunsbütteler Damm 165-173
13581 Berlin
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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