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

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

Excipient(s) with known effect:
Each ml of solution contains 50 micrograms of benzalkonium chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.
Clear yellow solution.
pH: 8.1-8.5; osmolality: 270-330 mOsmol/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Yellox is indicated in adults for the treatment of postoperative ocular inflammation following cataract extraction .

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.

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

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

Method of administration
For ocular use.

If more than one topical ophtalmic 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

4.3 Contraindications

Hypersensitivity to bromfenac or to any of the excipients listed in section 6.1, 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.

Cross-sensitivity
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs. Therefore, treating individuals who have previously exhibited sensitivities to these medicinal products has to be avoided (see section 4.3).

Susceptible persons
In susceptible patients, continued use of topical NSAIDs, including bromfenac 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.

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.

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. 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

Yellox has minor influence on the ability to drive and use machines. Transient blurring of vision may occur on instillation. If blurred vision occurs at instillation patients should be advised to refrain from driving or using machines until vision is clear.

4.8 Undesirable effects

Summary of the safety profile
Based on clinical data available, a total of 3.4% of patients 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); 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.

MedDRA system organ	Frequency	Adverse reactions

class		
Eye disorders	Uncommon	Visual acuity reduced Haemorrhagic retinopathy Corneal epithelium defect** Corneal erosion (mild or moderate) Corneal epithelium disorder Corneal oedema Retinal exudates Eye pain Eyelid bleeding Vision blurred Photophobia Eyelid oedema Eye discharge Eye pruritus Eye irritation Eye redness Conjunctival hyperaemia Abnormal sensation in eye Ocular discomfort
	Rare	Corneal perforation* Corneal ulcer* Corneal erosion, serious* Scleromalacia* Corneal infiltrates* Corneal disorder * Corneal scar*
Respiratory, thoracic and mediastinal disorders	Uncommon	Epistaxis Cough Nasal sinus drainage
	Rare	Asthma*
General disorders and administrative site conditions	Uncommon	Face swelling

*Serious 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 be instructed to immediately discontinue use of Yellox and should be monitored closely for corneal health (see section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

No abnormal findings or adverse reactions of clinical concern were noted upon administration of two drops 2mg/ml solution four times a day for the period of up to 28 days. Accidental administration of more than one drop should not result in increased topical exposure as excessive volume would rinse out of the eye due to limited conjunctival sac capacity.

There is practically no risk of adverse effects due to accidental oral ingestion. Ingestion of the 5 ml bottle content corresponds to an oral dose of less than 5 mg bromfenac, which is 30 times lower than daily dose of bromfenac oral formulation formerly used.
If Yellox is accidentally ingested, fluids should be taken to dilute the medicinal product.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophtalmologicals, 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 pranoprofen (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 pranoprofen 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.

Elimination
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 (K30)
Benzalkonium chloride
Disodium edetate
Water for injections
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
After first opening: 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C.
Patients should be instructed to keep the bottle tightly closed when not in use.

6.5 Nature and contents of container

5 ml solution in a polyethylene 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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Fax.: +420 234 719 619
Email: czech.info@valeant.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/11/692/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18.05.2011
Date of latest renewal: 11.01.2016

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

ANNEX II

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

• Periodic Safety Update Reports

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

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

Risk Management Plan (RMP)
The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2. of the Marketing Authorisation Application and any subsequent updates of the RMP.

An updated RMP should be submitted:
• At the request of the European Medicines Agency;
• Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

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) (see the package leaflet for further information), 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 SIGHTAND REACH OF CHILDREN

Keep out of the sight and reach 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

PharmaSwiss Česká republika s.r.o.
Jankovcova 1569/2c
17000 Praha 7
Czech Republic

12. MARKETING AUTHORISATION NUMBER

EU/1/11/692/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Yellox

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Yellox 0.9 mg/ ml eye drops, solution
bromfenac
Ocular use

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

5 ml

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Yellox 0.9 mg/ml eye drops, solution
Bromfenac

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 sodium sulphite and benzalkonium chloride
- Sodium sulphite may cause allergic reactions or asthma attacks, which may sometimes be severe and life-threatening.
- Benzalkonium chloride is a preservative which may cause eye irritation or eye surface problems. Do not use Yellox while wearing contact lenses, since benzalkonium chloride is known to discolour them.

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 or pharmacist.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Yellow

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away of 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. 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 (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.

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Manufacturer
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