SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT

OCUFLUR EYE DROPS (Flurbiprofen Sodium Ophthalmic Solution USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Flurbiprofen Sodium USP ……0.3% w/v
Phenylmercuric Nitrate (As Preservative) BP…….. 0.002%w/v
Water for Injection BP……q.s.

3. PHARMACEUTICAL FORM

Ophthalmic Solution

Description
A clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OCUFLUR Eye Drops is indicated for

- Inhibition of intraoperative miosis. OCUFLUR Eye Drops does not have intrinsic mydriatic properties and does not replace mydriatic agents.
- Management of post-operative and post-laser trabeculoplasty inflammation in the anterior segment of the eye in patients in whom steroid therapy is not recommended.

4.2 Posology and method of administration

For ocular use only
Adult: For the inhibition of intraoperative miosis, 1 drop is instilled every half hour starting 2 hours before surgery. The final drop should be given not less than 30 minutes before surgery.
To control post-operative and post-laser trabeculoplasty inflammation the dosing regimen above should be followed. Beginning twenty-four hours after surgery, one drop is administered four times daily for at least one week after laser trabeculoplasty or for two to three weeks after other surgery.

Paediatric population
The safety and efficacy of OCUFLUR Eye Drops in children has not been established.

Method of administration
OCUFLUR Eye Drops is administered topically by instillation into the conjunctival sac.
In accordance with standard practice, other topical medication should not be co-administered with OCUFLUR Eye Drops. When administering other topical medications, a minimum interval of 5 minutes between instillations is recommended.
Use the solution within one month after opening the vial.

4.3 Contraindications

OCUFLUR Eye Drops is contraindicated in the following:

- Hypersensitivity to the active substance or to any of the excipients.
- Epithelial herpes simplex keratitis (dendritic keratitis).

- The potential exists for cross-sensitivity to acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (NSAIDs). OCUFLUR Eye Drops is contraindicated in individuals who have previously exhibited sensitivities to these drugs.
- With NSAIDs, there exists the potential for increased bleeding due to interference with thromobocyte aggregation. The use of OCUFLUR Eye Drops is contraindicated in patients with known haemostatic defects or who are receiving other medications which may prolong bleeding time.
- OCUFLUR Eye Drops are contraindicated for intraocular use during surgical procedures.
- As with all NSAIDs, OCUFLUR Eye Drops is contraindicated in the third trimester of pregnancy.

4.4 Special warnings and precautions for use

Wound healing may be delayed with the use of OCUFLUR Eye Drops.

There have been reports that OCUFLUR Eye Drops may cause an increased bleeding tendency of ocular tissues in conjunction with surgery.

Patients with a history of herpes simplex keratitis should be monitored closely.

4.5 Interaction with other medicinal products and other forms of interaction

Although clinical studies with acetylcholine chloride and animal studies with acetylcholine chloride or carbachol revealed no interference, and there is no known pharmacological basis for an interaction, there have been reports that acetylcholine chloride and carbachol have been ineffective when used in some surgical patients treated with OCUFLUR Eye Drops.

4.6 Fertility, pregnancy and lactation

Pregnancy

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, OCUFLUR Eye Drops should not be given unless clearly necessary.

If OCUFLUR Eye Drops is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- Renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

At the end of pregnancy, all prostaglandin synthesis inhibitors may expose the mother and the neonate, to:

- Possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- Inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, OCUFLUR Eye Drops is contraindicated during the third trimester of pregnancy.

Brast Feeding

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

It is unknown whether flurbiprofen/metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Ocuflur Eye Drops therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

Studies have not been performed to evaluate the effect of topical ocular administration of flurbiprofen on human fertility.

4.7 Effects on ability to drive and use machines

Transient blurred vision can result after instillation. If this occurs, the patient should wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

The following adverse reactions were reported during the use of Ocuflur Eye Drops in clinical studies. 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) adverse reactions are presented according to MedDRA System organ class

System Organ Class	Very Common	Not known
Eye disorders	Eye irritation, eye pain, Hyphema*	Eye haemorrhage*, mydriasis (prolonged mydriasis), ocular hyperaemia

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.

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4.9 Overdose

Overdose by the topical ophthalmic route will not ordinarily cause acute problems. If accidentally ingested, treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory agents, non-steroids.
ATC code: SO1BC04

Mechanism of Action

Flurbiprofen sodium is a non steroidal anti inflammatory agent which inhibits prostaglandin synthesis by inhibition of the cyclo-oxygenase (COX) enzyme.

Pharmacodynamic Effects

Ophthalmic surgery causes prostaglandin release, with the effect that prostaglandin- mediated miosis may occur.Treatment with Ocuflur Eye Drops prior to surgery has been shown to inhibit intra-operative miosis and it is believed that this is brought about by inhibition of ocular prostaglandin release.

The sympathetic nervous system is not affected by this mechanism and acetylcholine- induced miosis has not been found to be inhibited in clinical trials.

Prostaglandins have also been shown to be mediators of certain kinds of intraocular inflammatory processes. In studies performed on animal eyes, prostaglandins have been shown to produce disruption of the blood-aqueous humour barrier, vasodilation, increased vascular permeability, leukocytosis and increased intraocular pressure.

5.2 Pharmacokinetic properties

Flurbiprofen concentrations of 213 ng/ml in aqueous humour have been reported following half hourly treatment for two hours preceding surgery.

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, carcinogenic potential and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenylmercuric Sodium, Sodium Chloride, Water for Injection

6.2 Incompatibilities

None known

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light.

6.5 Nature and contents of container

5 ml solution filled in 5 ml labeled LDPE vial with HIPS spike cap packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling

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

Handling of the container:

- Tighten the cap on the nozzle. The spike in the cap will perce the tip of the vial.
- Dispense drops with gentle pressure. Replace the cap after every use.
- Use the solution within one month after opening the vial.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

05372/07268/REN/2020

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Sep 29, 2020

10. DATE OF REVISION OF THE TEXT

August 2023