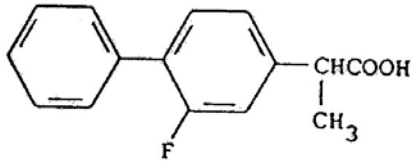


## OCUFEN® Eye Drops

### NAME OF THE DRUG

The active constituent of OCUFEN® Eye Drops is flurbiprofen sodium.



*(structure of flurbiprofen)*

### DESCRIPTION

Flurbiprofen sodium is a white or almost white crystalline powder. Practically insoluble in water; soluble 1 in 3 of alcohol, 1 in 4 of chloroform and 1 in 4.5 of ether.

**Chemical Name:** sodium (±)-2-(2-fluoro-4-biphenyl) propionate dihydrate.

**MW:** 303.3

**Empirical Formula:** C<sub>15</sub>H<sub>12</sub>FNaO<sub>2</sub>·2H<sub>2</sub>O

OCUFEN® Unit Dose Eye Drops contain flurbiprofen sodium 300 µg/mL with LIQUIFILM® (polyvinyl alcohol) 14 mg/mL, potassium chloride, sodium chloride, sodium citrate, citric acid, purified water and sodium hydroxide or hydrochloric acid if needed for pH adjustment.

### PHARMACOLOGY

Flurbiprofen sodium is one of a series of phenylalkanoic acids that have shown analgesic, antipyretic and anti-inflammatory activity in animal inflammatory diseases. Its mechanism of action is believed to be through inhibition of the cyclo-oxygenase enzyme that is essential in the biosynthesis of prostaglandins.

Prostaglandins have been shown in many animal models to be mediators of certain kinds of intraocular inflammation. 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.

Prostaglandins also appear to play a role in the miotic response produced during ocular surgery by constricting the iris sphincter independently of cholinergic mechanisms. In clinical studies, OCUFEN® Eye Drops have been shown to inhibit miosis induced during the course of cataract surgery.

Results from clinical studies indicate that flurbiprofen sodium has no significant effect upon the intraocular pressure in short term use. In one study in normal volunteers, decreases in mean intraocular pressure were reported after 5 and 30 days. Mydriasis was also reported in this study.

### INDICATIONS AND USE

OCUFEN® Eye Drops are indicated for the inhibition of intraoperative miosis.

## CONTRAINDICATIONS

OCUFEN® Eye Drops are contraindicated in epithelial *Herpes simplex* keratitis (dendritic keratitis) and in individuals who are hypersensitive to any components of the medication.

## PRECAUTIONS

There exists the potential for cross sensitivity to acetylsalicylic acid and other nonsteroidal anti-inflammatory drugs. Therefore caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

Acute infections of the eye may be masked by the use of topical inflammatory agents.

OCUFEN® Eye Drops possess no inherent antimicrobial activity. Use of OCUFEN® Eye Drops with an anti-infective drug in the presence of ocular infections should be monitored closely.

Patients with histories of *Herpes simplex* should be monitored closely.

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

**Use In Pregnancy:** Category C. The safety of this product for use in human pregnancy has not been established. Reproductive studies in rats showed that flurbiprofen had a significant effect on parturition at doses of  $\geq 0.4$  mg/kg/day. Additionally flurbiprofen was considered embryolethal at doses  $\geq 4.0$  mg/kg/day. Because of the known effects of prostaglandin-inhibiting drugs on the foetal cardiovascular system of rats (closure of the ductus arteriosus), the use of OCUFEN® Eye Drops during late pregnancy should be avoided. Flurbiprofen should only be used in pregnancy when the potential benefit to the patient outweighs the potential risk to the foetus.

**Use In Lactation:** It is not known whether flurbiprofen is excreted in human milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Use In Children:** Safety and effectiveness in children have not been established.

**Drug Interactions:** Although clinical trials with acetylcholine 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 patients treated with OCUFEN® Eye Drops.

It is known that some systemic absorption does occur with ocularly applied drugs and that non-steroidal anti-inflammatory drugs have been shown to increase bleeding time by interference with thrombocyte aggregation. There have been reports that OCUFEN® Eye Drops may cause an increased bleeding tendency of ocular tissues in conjunction with surgery. It is recommended that OCUFEN® Eye Drops be used with caution in surgical patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

## Effects on Ability to Drive and Use Machinery

As with any ocular medications, if transient blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

## **ADVERSE REACTIONS**

The most frequent adverse reactions reported with the use of OCUFEN® Eye Drops are transient burning and stinging upon instillation and other minor symptoms of ocular irritation. Severe discomfort is reported in approximately 3%.

Increased bleeding tendency of ocular tissue in conjunction with ocular surgery, . persistent mydriasis, not responsive promptly to intracameral miotics, ocular hyperaemia and hyphema have been reported. Allergic reactions have been reported infrequently.

## **DOSAGE AND ADMINISTRATION**

For the inhibition of intraoperative miosis, a total of four drops of OCUFEN® Eye Drops should be administered in the eye(s) by instilling one drop approximately every 1/2 hour beginning two hours before surgery.

In order to minimise systemic absorption of OCUFEN® Eye Drops, apply pressure to the tear duct immediately following administration of the drug.

## **OVERDOSAGE**

OCUFEN® Eye Drops are intended for topical use only. Overdosage will not ordinarily cause acute problems. Should accidental overdosage occur in the eye(s), flush the eye(s) with water or saline. If accidentally ingested, drink fluids to dilute the medication.

## **PRESENTATION**

Unit Dose Eye Drops: 0.4 mL (unit dose ampoule).  
Storage: Store below 25°C.  
Shelf life: 24 months.  
Discard the ampoule immediately after use.  
Any unused eye drops in the ampoule should be discarded.

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