

NEW ZEALAND DATA SHEET

NAME OF MEDICINE:

OCUFEN[®] flurbiprofen sodium 0.03%

PRESENTATION:

OCUFEN[®] eye drops: each mL contains flurbiprofen sodium 0.3mg with Liquifilm[®] (polyvinyl alcohol) 14mg, potassium chloride, sodium chloride, sodium citrate, citric acid, purified water and sodium hydroxide or hydrochloric acid if needed for pH adjustment.

USES: Actions

Clinical Pharmacology

Flurbiprofen sodium is one of a series of phenylalkanoic acids that have shown analgesic, antipyretic and anti-inflammatory activity in anti-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 humor 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[®] has been shown to inhibit the miosis induced during the course of cataract surgery.

Results from clinical studies indicate that flurbiprofen sodium has no significant effect upon intraocular pressure.

Pharmacokinetics

An orally administered dose of flurbiprofen is rapidly absorbed, metabolised in the liver and quickly and evenly distributed to most tissues other than those of the central nervous system. The mean half-life of elimination was seen with three times daily dosing of 50 mg for 10 days. Urinary excretion of unchanged drug (23.2%) and metabolites in humans accounts for 100% of the dose administered. Although all metabolites have been identified in laboratory animals, 3 metabolites conjugated as glucuronides or sulphates were recovered from urine of volunteers. More than 99.5% of flurbiprofen binds to serum protein, specifically to one site in serum albumin, over the therapeutic dosage range.

INDICATIONS

OCUFEN[®] eye drops are indicated for the inhibition of intraoperative miosis.

DOSAGE AND ADMINISTRATION

Adults

Intraoperative miosis: A total of four drops of OCUFEN[®] should be administered in the eye(s) by instilling one drop approximately every half hour beginning two hours before surgery.

Post surgical procedures: One drop should be instilled into the conjunctival sac every four hours for one week following laser trabeculoplasty or two to three weeks after other surgical procedures.

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 ≥ 0.4 mg/kg/day. Additionally flurbiprofen was considered embryo-lethal at doses ≥ 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.

Children: Not recommended for use in children.

Elderly: Refer adult dose regimen.

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.

WARNINGS AND PRECAUTIONS

There exists the potential for cross sensitivity to acetylsalicylic acid and other non-steroidal 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 anti-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 keratitis should be monitored closely.

Wound healing may be delayed with the use of OCUFEN[®] eye drops.

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 EFFECTS

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%.

Persistent mydriasis, not responsive promptly to intracameral miotics, ocular hyperaemia and hyphema have been reported. Allergic reactions have been reported infrequently.

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 ocularly applied OCUFEN[®] eye drops may cause an increased bleeding tendency of ocular tissues in conjunction with surgery. It is recommended that OCUFEN[®] be used with caution in surgical patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

INTERACTIONS

Drug 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 surgical patients treated with OCUFEN[®] eye drops.

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.

PHARMACEUTICAL PRECAUTIONS

Store at less than 25°C.

FURTHER INFORMATION

Chemical Name: sodium (\pm)-2-(2-fluoro-4-biphenyl) propionate dihydrate.

MW: 303.3 **Empirical Formula:** C₁₅H₁₂FNaO₂2H₂O

PACKAGE QUANTITIES

OCUFEN[®] Unit Dose eye drops (flurbiprofen sodium 0.03%) are supplied in 0.4mL single dose vials in packs of 5.

MEDICINE CLASSIFICATION

Prescription Medicine

NAME AND ADDRESS

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