OCUFEN®

(flurbiprofen sodium ophthalmic solution, USP) 0.03%

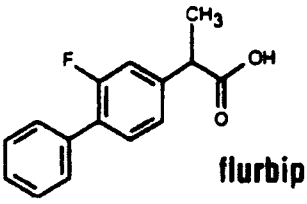
sterile

DESCRIPTION

OCUFEN® (flurbiprofen sodium ophthalmic solution, USP) 0.03% is a sterile topical nonsteroidal anti-inflammatory product for ophthalmic use.

Chemical Name: Sodium (±)-2-(2-fluoro-4-biphenylyl) propionate dihydrate.

Structural Formula:



flurbiprofen sodium

Contains:

Active: flurbiprofen sodium 0.03% (0.3 mg/mL).

Preservative: thimerosal 0.005%.

Inactives: polyvinyl alcohol 1.4%; edetate disodium; potassium chloride; sodium chloride; sodium citrate; citric acid; and purified water. May also contain hydrochloric acid and/or sodium hydroxide to adjust the pH.

The pH of OCUFEN® ophthalmic solution is 6.0 to 7.0.

CLINICAL 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 humor barrier, vasodilatation, 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.

INDICATIONS AND USAGE

OCUFEN® ophthalmic solution is indicated for the inhibition of intraoperative miosis.

CONTRAINDICATIONS

OCUFEN® ophthalmic solution is contraindicated in individuals who are hypersensitive to any components of the medication.

WARNINGS

With nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding due to interference with thrombocyte aggregation. There have been reports that OCUFEN® ophthalmic solution may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

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.

PRECAUTIONS

General: Wound healing may be delayed with the use of OCUFEN® (flurbiprofen sodium ophthalmic solution, USP) 0.03%.

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.

Drug interactions: Interaction of OCUFEN® ophthalmic solution with other topical ophthalmic medications has not been fully investigated.

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 patients treated with OCUFEN®.

Carcinogenesis, Mutagenesis, Impairment of fertility: Long-term studies in mice and/or rats have shown no evidence of carcinogenicity with flurbiprofen.

Long-term mutagenicity studies in animals have not been performed.

Pregnancy:

Pregnancy category C: Flurbiprofen has been shown to be embryocidal, delay parturition, prolong gestation, reduce weight, and/or slightly retard growth of fetuses when given to rats in daily oral doses of 0.4 mg/kg (approximately 190 times the human daily topical dose) and above. There are no adequate and well-controlled studies in pregnant women.

OCUFEN® ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from flurbiprofen sodium, 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.

Pediatric use: Safety and effectiveness in pediatric patients have not been established.

Geriatric use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

Transient burning and stinging upon instillation and other minor symptoms of ocular irritation have been reported with the use of OCUFEN® ophthalmic solution. Other adverse reactions reported with the use of OCUFEN® include: fibrosis, miosis, and mydriasis.

Increased bleeding tendency of ocular tissues in conjunction with ocular surgery has also been reported.

OVERDOSAGE

Overdosage will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

DOSAGE AND ADMINISTRATION

A total of four (4) drops of OCUFEN® ophthalmic solution should be administered by instilling one (1) drop approximately every 1/2 hour beginning 2 hours before surgery.

HOW SUPPLIED

OCUFEN® (flurbiprofen sodium ophthalmic solution, USP) is available for topical ophthalmic administration as a 0.03% sterile solution, and is supplied in a white opaque low density polyethylene bottle with a controlled dropper tip and a white high impact polystyrene cap in the following size:

2.5 mL - NDC 11980-801-03

Note: Store at room temperature.

Rx only

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Allergan, Inc. Irvine, California 92612, U.S.A.

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/s/

Linda Ng

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