

FLURBIPROFEN SODIUM- flurbiprofen sodium solution/ drops
Rebel Distributors Corp

Flurbiprofen Sodium
Ophthalmic Solution, USP 0.03%

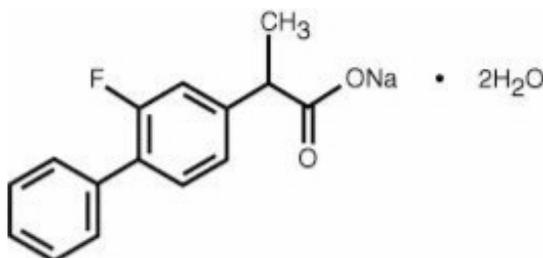
Sterile

DESCRIPTION

Flurbiprofen sodium ophthalmic solution, USP 0.03% is a sterile topical nonsteroidal anti-inflammatory product for ophthalmic use.

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

Structural Formula:



flurbiprofen sodium

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

Preservative: thimerosal 0.005%. **Inactives:** citric acid; edetate disodium; polyvinyl alcohol 1.4%; potassium chloride; purified water; sodium chloride; and sodium citrate. May also contain hydrochloric acid and/or sodium hydroxide to adjust the pH. The pH of flurbiprofen sodium ophthalmic solution 0.03% is 6.0 to 7.0. It has an osmolality of 260 - 330 mOsm/kg.

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, flurbiprofen sodium ophthalmic solution 0.03% 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

Flurbiprofen sodium ophthalmic solution 0.03% is indicated for the inhibition of intraoperative miosis.

CONTRAINDICATIONS

Flurbiprofen sodium ophthalmic solution 0.03% 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 flurbiprofen sodium ophthalmic solution 0.03% 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 flurbiprofen sodium ophthalmic solution 0.03%.

It is recommended that flurbiprofen sodium ophthalmic solution 0.03% 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 flurbiprofen sodium ophthalmic solution 0.03% 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 flurbiprofen sodium ophthalmic solution 0.03%.

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 333 times the human daily topical dose) and above.

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 flurbiprofen sodium ophthalmic solution 0.03%. Other adverse reactions reported with the use of flurbiprofen sodium ophthalmic solution 0.03% 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 flurbiprofen sodium ophthalmic solution 0.03% should be administered by instilling one (1) drop approximately every 1/2 hour beginning 2 hours before surgery.

HOW SUPPLIED

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 gray high impact polystyrene cap in the following size:

2.5 mL in 5 mL bottle - NDC 42254-023-25

Note: Store at 15°-25°C (59°-77°F).

Rx Only

Revised January 2004

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Irvine, CA 92612, U.S.A.



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Relabeled by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

Principal Display Panel

PHYSICIAN PARTNER
A DIVISION OF BEEL DISTRIBUTORS CORP.

NDC 42254-023-25

Flurbiprofen Sodium 0.03%
2.5ml Ophthalmic Solution

Each ml contains: Flurbiprofen Sodium 0.03%

See package insert.

Product ID: SF002325

Mfr. By: Pacific Pharma Irvine, CA 92612 U.S.A.

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

Peel

Flurbiprofen Sodium 0.03% Rx# Master
2.5ml Ophthalmic Solution
Lot #:00000 Exp. Date: 00/00/00
NDC 42254-023-25 AWP:\$18.96

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FLURBIPROFEN SODIUM

flurbiprofen sodium solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42254-023(NDC:60758-910)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
flurbiprofen sodium (UNII: Z5B97MU9K4) (flurbiprofen - UNII:5GRO578KLP)	flurbiprofen sodium	0.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
thimerosal (UNII: 2225PIBMOV)	
citric acid monohydrate (UNII: 2968PHW8QP)	
edetate disodium (UNII: 7FLD91C86K)	
polyvinyl alcohol (UNII: 532B59J990)	
potassium chloride (UNII: 660YQ98I10)	
water (UNII: 059QF0K00R)	

sodium chloride (UNII: 451W47IQ8X)	
sodium citrate (UNII: 1Q73Q2JULR)	
hydrochloric acid (UNII: QTT17582CB)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-023-25	1 in 1 CARTON		
1		2.5 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA019404	05/29/1997	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 12/2011

Rebel Distributors Corp