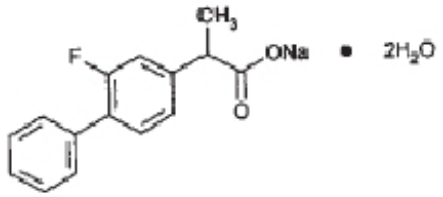
FLURBIPROFEN SODIUM- flurbiprofen sodium solution/ drops
Rebel Distributors Corp

Flurbiprofen Sodium Ophthalmic Solution USP, 0.03%

DESCRIPTION

Flurbiprofen Sodium Ophthalmic Solution USP, 0.03% is a sterile topical nonsteroidal anti-inflammatory product for ophthalmic use. Flurbiprofen sodium is represented by the following structural formula:



$C_{15}H_{12}FNaO_2 \cdot 2H_2O$

Mol. Wt. 302.27

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

Each mL Contains: ACTIVE: Flurbiprofen sodium 0.03%;

INACTIVES: Sodium Citrate, Polyvinyl Alcohol 1.4%, Edetate Disodium, Potassium Chloride, Sodium Chloride, Citric Acid, Purified Water. Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (6.0 – 7.0).

PRESERVATIVE ADDED: Thimerosal 0.005%.

CLINICAL PHARMACOLOGY

Flurbiprofen sodium is one of a series of phenylalkanoic acids that have shown analgesic antipyretic, and antiinflammatory 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 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 is indicated for the inhibition of intraoperative miosis.

CONTRAINDICATIONS

Flurbiprofen sodium 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 flurbiprofen sodium ophthalmic solution may cause increased bleeding of ocular tissues 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.

It is recommended that flurbiprofen sodium ophthalmic solution 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 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.

Carcinogenesis, mutagenesis, impairment of fertility

Long-term studies in mice and/or rats have shown no evidence of carcinogenicity or impairment of fertility 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 67 times the human daily topical dose) and above. There are no adequate and well-controlled studies in pregnant women. Flurbiprofen sodium 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 flurbiprofen sodium ophthalmic solution. Other adverse reactions reported with the use of flurbiprofen sodium ophthalmic solution 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 should be administered by instilling 1 drop approximately every 1/2 hour beginning 2 hours before surgery.

HOW SUPPLIED

Flurbiprofen Sodium Ophthalmic Solution USP, 0.03% is supplied in a plastic bottle with a controlled drop tip in the following size:

2.5 mL - Prod. No. 31404

DO NOT USE IF IMPRINTED “Protective Seal” WITH YELLOW IS NOT INTACT.

Storage

Store between 15°–30°C (59°–86°F).

Rx only

FOR OPHTHALMIC USE ONLY

Manufacturer Information

Bausch & Lomb Incorporated

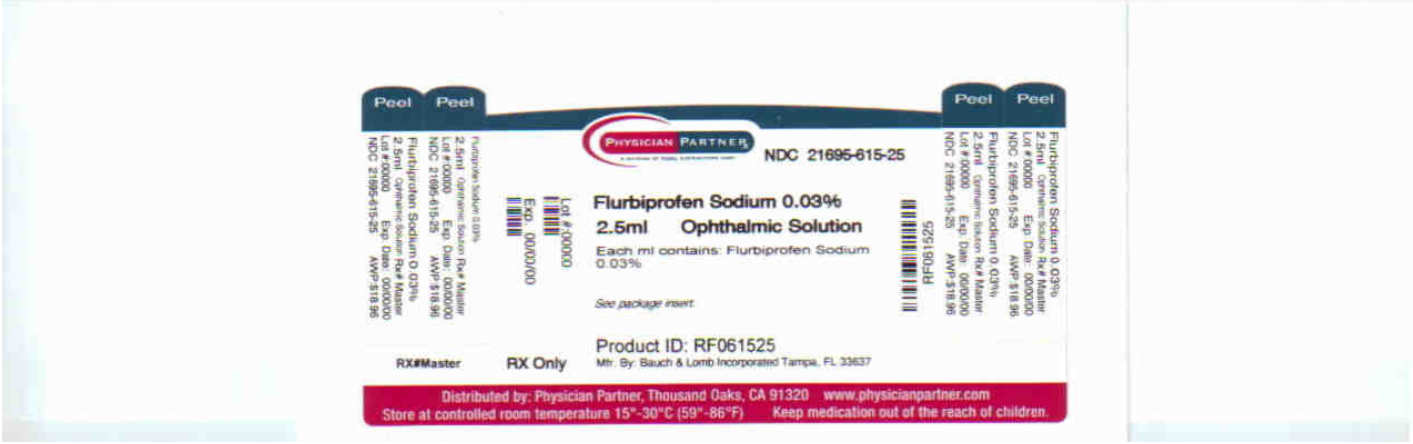
Tampa, Florida 33637

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

Principal Display Panel



FLURBIPROFEN SODIUM

flurbiprofen sodium solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21695-615(NDC:24208-314)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Flurbiprofen Sodium (UNII: Z5B97MU9K4) (FLURBIPROFEN - UNII:5GRO578KLP)	Flurbiprofen Sodium	0.242 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Citric Acid (UNII: 2968PHW8QP)	
Edetate Disodium (UNII: 7FLD91C86K)	
Hydrochloric Acid (UNII: QTT17582CB)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
Potassium Chloride (UNII: 660YQ98I10)	
Water (UNII: 059QF0KO0R)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Thimerosal (UNII: 2225PI3MOV)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:21695-615-25	2.5 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA074447	01/04/1995	

Labeler - Rebel Distributors Corp (118802834)

Establishment

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

Revised: 9/2010 Rebel Distributors Corp