Flurbiprofen sodium ophthalmic solution, USP 0.03%  

DESCRIPTION  
Flurbiprofen sodium ophthalmic solution 0.03% is a sterile topical non-steroidal anti-inflammatory product for ophthalmic use.  

Clinical Pharmacology  
Flurbiprofen is a member of the pyrazolopyridine class of nonsteroidal anti-inflammatory drugs (NSAIDs) and is a cyclooxygenase-2 (COX-2) specific inhibitor. Flurbiprofen selectively inhibits prostaglandin synthesis by irreversibly inhibiting the enzyme cyclooxygenase. This inhibition results in decreased synthesis of prostaglandins, which are known to contribute to the inflammation associated with ocular disease. Flurbiprofen sodium ophthalmic solution 0.03% is indicated for the treatment of ocular inflammation and pain associated with ocular surgery. In a study performed on animal eyes, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. In studies performed on animal eyes, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit the miosis induced during the course of cataract surgery. Results from clinical studies, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. During the course of cataract surgery, the miosis induced during the course of cataract surgery. Results from 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, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. In studies performed on animal eyes, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit the miosis induced during the course of cataract surgery. Results from clinical studies, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. 

CLINICAL PHARMACOLOGY  
Flurbiprofen sodium is a member of the pyrazolopyridine class of nonsteroidal anti-inflammatory drugs (NSAIDs). Flurbiprofen sodium ophthalmic solution 0.03% is a non-steroidal anti-inflammatory drug that functions by inhibiting the cyclooxygenase enzymes. Inhibition of these enzymes results in the inhibition of prostaglandin synthesis. Prostaglandins are known to play a role in the production of ocular inflammation and pain associated with ocular surgery. Inhibition of cyclooxygenase enzymes results in the inhibition of prostaglandin synthesis, which is known to contribute to the inflammation associated with ocular surgery. Flurbiprofen sodium ophthalmic solution 0.03% is indicated for the treatment of ocular inflammation and pain associated with ocular surgery. In a study performed on animal eyes, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. In studies performed on animal eyes, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit the miosis induced during the course of cataract surgery. Results from clinical studies, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. During the course of cataract surgery, the miosis induced during the course of cataract surgery. Results from clinical studies, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. During the course of cataract surgery, the miosis induced during the course of cataract surgery. Results from clinical studies, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. During the course of cataract surgery, the miosis induced during the course of cataract surgery. Results from clinical studies, flurbiprofen sodium ophthalmic solution 0.03% has been shown to inhibit intraocular inflammation. 

INDICATIONS AND USAGE  
Flurbiprofen sodium ophthalmic solution 0.03% is indicated for the treatment of intraocular inflammation. 

CONTRAINDICATIONS  
Flurbiprofen sodium ophthalmic solution 0.03% is contraindicated in individuals who are hypersensitive to any components of the medication. 

WARNINGS  
With some non-steroidal anti-inflammatory drugs (NSAIDs), there exists the potential for increased bleeding time due to interference with thromboxane aggregation. There have been reports that flurbiprofen sodium ophthalmic solution 0.03% may cause increased bleeding of ocular tissues in conjunction with ocular surgery. It is recommended that flurbiprofen sodium ophthalmic solution 0.03% be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time. 

PRECAUTIONS  
General  
Topical non-steroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concurrent use of topical NSAIDs and topical steroids may increase the potential for healing problems. 

Drug Interactions  
Interactions with flurbiprofen sodium ophthalmic solution 0.03% may be expected. 

ADVERSE REACTIONS  
No overall differences in safety or effectiveness have been observed between elderly and younger patients. There are no adequate and well-controlled studies in pregnant women. Flurbiprofen sodium ophthalmic solution 0.03% may cause increased bleeding of ocular tissues in conjunction with ocular surgery. Increased bleeding tendency of ocular tissues in conjunction with ocular surgery has also been reported (see Warnings). There are no adequate and well-controlled studies in pregnant women. Flurbiprofen sodium ophthalmic solution 0.03% has been reported to be embryocidal, delay parturition, prolong gestation, reduce weight, and/or slightly retard growth of fetus when given to rats in daily doses of 0.4 mg/kg (approximately 300 times the human daily topical dose) and above. 

Pregnancy Category C  
Flurbiprofen sodium ophthalmic solution 0.03% may cause increased bleeding of ocular tissues in conjunction with ocular surgery. Increased bleeding tendency of ocular tissues in conjunction with ocular surgery has also been reported (see Warnings). 

Pediatric Use  
In elderly patients, flurbiprofen sodium ophthalmic solution 0.03% may cause increased bleeding of ocular tissues in conjunction with ocular surgery. Increased bleeding tendency of ocular tissues in conjunction with ocular surgery has also been reported (see Warnings). 

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Drug Interactions  
Interaction of flurbiprofen sodium ophthalmic solution 0.03% with other topical ophthalmic medications has not been fully investigated. 

Although clinical studies with acetazolamide and animal studies with acetazolamide or contact lens revealed no interactions, there are no known pharmacological bases for such an interaction. Flurbiprofen sodium ophthalmic solution 0.03% has been reported to be embryocidal, delay parturition, prolong gestation, reduce weight, and/or slightly retard growth of fetus when given to rats in daily doses of 0.4 mg/kg (approximately 300 times the human daily topical dose) and above. 

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