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. Flurbiprofen sodium is represented by the following structure formula:

![Structural formula of Flurbiprofen Sodium](https://example.com/flurbiprofen_sodium_structure)

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

Each mL Contains: ACTIVE: Flurbiprofen sodium 0.03%; INACTIVES: Citric Acid, Edetate Disodium, Polyvinyl Alcohol 1.4%, Potassium Chloride, Purified Water, Sodium Chloride, Sodium Citrate. Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (6.0 – 7.0).

**INDICATIONS**
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 this product.

**WARNINGS**
- With some 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 including hyphema in conjunction with ocular surgery.
- Flurbiprofen sodium ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Although clinical studies with acetylcholine chloride and animal studies with acetylcholine chloride or carbachol revealed no evidence of interference, and there is no evidence of pharmacologic activity in any interaction, there have been reports that acetylcholine chloride and carbachol have been ineffective when used in patients treated with flurbiprofen sodium ophthalmic solutions.
- Long-term studies in mice and/or rats have shown no evidence of carcinogenicity or impairment of fertility with flurbiprofen. There are no adequate and well-controlled studies in pregnant women. Flurbiprofen sodium ophthalmic solution is 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 300 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. Although clinical studies with acetylcholine chloride and animal studies with acetylcholine chloride or carbachol revealed no evidence of interference, and there is no evidence of pharmacologic activity in any interaction, there have been reports that acetylcholine chloride and carbachol have been ineffective when used in patients treated with flurbiprofen sodium ophthalmic solutions.

**PRECAUTIONS**
- Long-term studies in mice and/or rats have shown no evidence of carcinogenicity or impairment of fertility with flurbiprofen.
- There are no adequate and well-controlled studies in pregnancy. Flurbiprofen sodium ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Although clinical studies with acetylcholine chloride and animal studies with acetylcholine chloride or carbachol revealed no evidence of interference, and there is no evidence of pharmacologic activity in any interaction, there have been reports that acetylcholine chloride and carbachol have been ineffective when used in patients treated with flurbiprofen sodium ophthalmic solutions.

**ADVERSE REACTIONS**
- Flurbiprofen sodium ophthalmic solution is not expected to cause major side effects. The most commonly reported reactions with topical NSAIDS include: fibrosis, hyphema, miosis, mydriasis, and ocular hyperemia. Transient burning and stinging upon instillation and other minor symptoms of ocular irritation are reported with use of topical NSAIDS are expected as part of the pharmacologic effect. Transient periorbital edema, increased vascular permeability, leukocytosis, and increased intraocular pressure.

**DRUG INTERACTIONS**
- Interaction of flurbiprofen sodium ophthalmic solution with other topical ophthalmic medications has not been fully investigated. In some cases, a single ophthalmic product may mask the symptoms of infection or inflammation, allowing a pathogen to develop resistance. Flurbiprofen sodium ophthalmic solution, like other topical ophthalmic products, may interfere with the ocular effects of preservatives, including those of some of the traditional ocular medications used to treat glaucoma. The use of the same bottle of eye drops for both eyes is not recommended with ocular surgery.

**INFORMATION FOR PATIENTS**
- Patients should be instructed in the correct use of the topical solution and in the correct use of the ophthalmic solution. Patients should be instructed to avoid allowing the tip of the bottle to contact the eye or surrounding structures because this may cause the tip to become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

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

**Stability**: Store below 25°C (77°F). Bausch & Lomb Incorporated, Tampa, Florida 33627 (Sterile)

**DISCLAIMER**: This information is not intended to substitute for professional medical advice, diagnosis, or treatment.

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