

# FACO DROPS<sup>®</sup>

## Eye Drops (Flurbiprofen Eye Drops IP)

### COMPOSITION:

Flurbiprofen Sodium IP .....	0.03% w/v
Phenyl Mercuric Nitrate IP .....	0.001% w/v
(As preservative)	
Water for Injections IP .....	q.s.

### DESCRIPTION

**FACO DROPS<sup>®</sup>** (Flurbiprofen Eye Drops IP) 0.03% w/v is a sterile topical non-steroidal anti inflammatory product for ophthalmic use.

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

**Structural Formula:**  $C_{19}H_{15}FNaO_3 \cdot 2H_2O$  mol.Wt.302.27

**Contains active:** Flurbiprofen Sodium IP 0.03% w/v (0.3 mg/mL). **Preservative:** Phenyl Mercuric Nitrate IP 0.001% w/v

### CLINICAL PHARMACOLOGY

Flurbiprofen sodium is one of a series of phenylalkanoic acids that have shown analgesis, 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, leucocytosis, and increases 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 Eye Drops has been shown to inhibit the miosis induced during the course of cataract surgery. Results from clinical studies indicate the flurbiprofen sodium has no effect upon intraocular pressure.

### INDICATIONS AND USAGE

**FACO DROPS<sup>®</sup>** is indicated for the inhibition of intraoperative miosis.

### CONTRAINDICATIONS

**FACO DROPS<sup>®</sup>** ophthalmic solution is contraindicated in individuals who are hypersensitive to any components of the medication.

### WARNINGS

With some non-steroidal anti-inflammatory drugs, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that Flurbiprofen eye drops may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

There is the potential for cross-sensitivity to acetylsalicylic acid and other non-steroidal anti-inflammatory drugs. Therefore caution should be used when treating individuals who have previously exhibited sensitivities to the drugs.

### PRECAUTIONS

#### General

Topical non steroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and the topical steroids may increase the potential for healing problems. It is recommended that **FACO DROPS** be used in caution in surgical patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

#### Information for Patients

Patients should be instructed to avoid allowing the tip of the bottle to contact the eye or surrounding structure because this could 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

To avoid the potential for cross-contamination, the patient should be advised to use one bottle for each eye with bilateral ocular surgery. The use of the same bottle of eye drops for both eyes is not recommended with ocular surgery.

#### Drug interactions

Interaction of Flurbiprofen Eye Drops IP 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 eye drops.

#### **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 showed 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 300 times the human daily topical dose) and above.

There are no adequate and well-controlled studies in pregnant women. **FACO DROPS** 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 eye drops. Other adverse reactions reported with the use of Flurbiprofen eye drops include: fibrosis, hyphema, miosis, mydriasis, and ocular hyperemia. Increased bleeding tendency of ocular tissues in conjunction with ocular surgery has also been reported (see warnings).

#### **OVERDOSAGE:**

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

#### **DOSAGE AND ADMINISTRATION**

A total of four (4) drops of FACO DROPS ophthalmic solution should be administered by instilling one (1) drop approximately every ½ hour beginning 2 hours before surgery.

#### **Storage and handling instruction**

Store below 30°C, Don't freeze, Use the solutions within one month after opening the container.

Do not touch the tip of the container to any surface.

Replace cap after using .Protect from light.

#### **KEEP OUT OF REACH OF CHILDREN**

#### **NOT FOR INJECTION**

#### **FOR EXTERNAL USE ONLY**

#### **Presentation:**

**FACO Drops** is a clear colourless solution supplied in opaque plastic dropper bottle with a cap, containing 10 mL of solution.



Turn the tamper proof cap anti clockwise to break the seal and remove the cap.

Remove and discard the tamper proof ring from the container.

Tilt your head back. Gently pull your lower eyelid downwards to form a pocket between your eyelid and your eye, look up.



Turn the container upside down, place the dropper tip close to your eye but be careful not to touch your eye with it and gently press the container with thumb and index finger to dispense the drop.

Replace the cap by turning clockwise direction until it is firmly touching the bottle. Do not overtighten the cap.

Manufactured in INDIA by :

**Senses Pharmaceuticals Pvt. Ltd.,**

No.77, 3rd Road, Bommasandra Industrial Area,  
Bommasandra 4th Phase, Bengaluru - 560 099.

® Registered Trade Mark

FACPI-01