



Clofenac[®] Eye Drops

Diclofenac Sodium

Anti-inflammatory Eye drops

COMPOSITION

Clofenac[®] Eye Drops : Each ml contains Diclofenac Sodium BP 1.0 mg.

PHARMACOLOGY

Clofenac[®] Eye Drops contains Diclofenac Sodium, a potent non-steroidal anti-inflammatory drug with analgesic property. Diclofenac Sodium produces anti-inflammatory effect by inhibiting cyclooxygenase activity with a reduction in the tissue prostaglandin (such as PgE2 and Pg F2 α) .

INDICATION

1. Post-traumatic inflammation (as an adjuvant to local anti-infective therapy).
2. Post-operative inflammation after cataract surgery and other surgical procedures.
3. Non-infectious inflammatory conditions affecting the anterior region of the eye (e.g. chronic non-infectious conjunctivitis).
4. Pain in corneal epithelial defects after photorefractive keratectomy (PRK).
5. Inhibition of miosis during and after cataract surgery.

DOSAGE AND ADMINISTRATION

Adult: For the prophylaxis of pre-operative miosis: One drop four times during 2 hours prior to surgery.

For the control of post-operative inflammation: One drop four times daily for up to 28 days.

For the control of post-PRK pain and discomfort : one drop two times in the hour prior to surgery, one drop two times five minutes apart immediately after PRK-surgery and then post-operatively one drop every 2-5 hours while awake for up to 24 hours.

Children: Safety and efficacy in children has not yet been established.

CONTRAINDICATION AND PRECAUTION

Diclofenac Sodium is contraindicated to patients with known hypersensitivity to any of the ingredients of the formulation. Like other non-steroidal anti-inflammatory agents, Diclofenac Sodium is also contraindicated to patients in whom attacks of asthma, urticaria, or acute rhinitis have been observed following application of acetyl salicylic acid or other cyclo-oxygenase inhibitors.

Topical NSAIDs used in ophthalmologic surgery can retard the bleeding

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time. Therefore, patients tending toward uncontrolled bleeding or under therapy with anti-coagulants should use Diclofenac Sodium with caution. If infection is present or there is a risk of infection, appropriate treatment (e.g. with antibiotics) should be given concomitantly. If the response to treatment is inadequate, the diagnosis should be re-evaluated. Contact lenses must be removed before the application and should be inserted at least 15 minutes after application.

SIDE EFFECT

Retardation of wound healing.

Occasional: Nausea, Vomiting.

Rare: Systemic hypersensitivity reactions like asthma, urticaria, itching, acute rhinitis and photosensitivity.

DRUG INTERACTION

Not reported to date. Diclofenac Sodium can be combined with eye drops containing steroids, if necessary, as confirmed by clinical findings.

To prevent the active substance being washed out by farther doses, an interval of at least 5 minutes between each application should be adhered to.

USE IN PREGNANCY AND LACTATION

There is no experience concerning the safety of Diclofenac Sodium in human pregnancy. Administration during pregnancy and lactation is therefore not recommended except for justified reasons.

OVERDOSE

Accidental ingestion of Diclofenac Sodium presents virtually no risk of unwanted effects, since one 5 ml bottle of eye drop solution contains only 5 mg of Diclofenac Sodium, which is equivalent to about 3% of the recommended maximum oral dose for adults.

STORAGE CONDITION

Close the bottle immediately after use. Do not use for more than four weeks after opening. All medicines should be kept out of the reach of children. Store at room temperature.

HOW SUPPLIED

Clofenac[®] 0.1% Eye Drops : Dropper bottle containing 5 ml of sterile solution.

