RUFENAL

Eye Drops

Composition
Each ml contains 1 mg Diclofenac sodium

Action
Diclofenac sodium is one of a series of phenylacetic acids that have demonstrated anti-inflammatory and analgesic properties in pharmacological studies. It is thought to inhibit the enzyme cyclooxygenase, which 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 in animal eyes, prostaglandins have been shown to produce disruption of the blood-aqueous humor barrier, vasodilation, 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, Diclofenac sodium ophthalmic has been shown to decrease the signs and symptoms of inflammation resulting from cataract surgery.

Results from clinical studies indicate that Rufenal ophthalmic has no significant effect upon intraocular pressure; however, elevations in intraocular pressure may occur following cataract surgery.

Rufenal ophthalmic has been safely administered in conjunction with other ophthalmic medications such as antibiotics, beta-blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics.

Indications
Rufenal ophthalmic is indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction and for the treatment of photophobia in patients undergoing incisional refractive surgery.

Contraindications
- Diclofenac sodium ophthalmic is contraindicated in patients concurrently wearing soft contact lenses and in patients who are hypersensitive to any component of the medication. Patients wearing hydrogel soft contact lenses who have received Diclofenac sodium ophthalmic concurrently have experienced ocular irritation manifested by redness and burning.
- Diclofenac sodium is contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis have been observed following application of acetyl salicylic acid or other cyclo-oxygenase inhibitors.

Warnings
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

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

Adverse Reactions
Ocular
Transient burning and stinging were reported in approximately 15% of patients across all studies with the use of Diclofenac sodium ophthalmic.

In ocular surgery studies, keratitis was reported in up to 28% of patients receiving Diclofenac sodium ophthalmic, although in many of these cases keratitis was initially noted prior to the initiation of treatment. Elevated intraocular pressure following cataract surgery was reported in approximately 15% of patients undergoing cataract surgery. Dry eye complaints were reported in approximately 12% of case studies undergoing incisional refractive surgery.

The following adverse reactions were reported in less than 3% of the patients: discharge, corneal deposits, corneal lesions, ocular allergy, itching, irritation, and blurred vision.
The following adverse reactions were reported in less than 1% of the patients: corneal edema, corneal opacity, eyelid disorder, iritis, injection, and lacrimation disorder.

Systemic
The following adverse reactions were reported in less than 3% of the patients: fever, pain, nausea, and insomnia. The following adverse reactions were reported in less than 1% of the patients: asthenia, chills, facial edema, headache, vomiting, rhinitis, and viral infection.

Precautions

General
It is recommended that Diclofenac sodium ophthalmic be used with caution in surgical patients with known bleeding tendencies or who are receiving other medications that may prolong bleeding time. Diclofenac sodium may slow or delay healing.

Pregnancy
Category B (1st and 2nd trimesters)
Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Category D (If used in 3rd trimester)
There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Uses in children
There is no specific investigations have been carried out on the use of Diclofenac sodium ophthalmic solution in children.

Dosage and Administration

Cataract Surgery
One drop of Rufenal ophthalmic should be applied to the affected eye four times daily beginning 24 hours after cataract surgery and continuing throughout the first 2 weeks of the postoperative period.

Incisional Refractive Surgery
Within the hour prior to incisional refractive surgery, one drop of Rufenal ophthalmic should be applied to the operative eye(s). Within 15 minutes after surgery, a second drop should be applied to the operative eye(s). One drop of Rufenal ophthalmic should be applied to the operative eye(s) four times daily beginning 4 to 6 hours after surgery and continuing for up to 3 days as needed.

Patient Information
Diclofenac sodium is a nonsteroidal anti-inflammatory medication. The ophthalmic solution is used for the treatment of inflammation following cataract surgery.

Notify your physician if you are pregnant or nursing. Do not take Diclofenac sodium if you are allergic to aspirin. This medication may cause dizziness or lightheadedness; use caution while driving or operating hazardous machinery. Do not drink alcohol or take aspirin while taking Diclofenac sodium.

Diclofenac sodium may cause increased sensitivity to sunlight. Use sunscreens and wear protective clothing until degree of sensitivity is determined. Do not wear contact lenses while using Diclofenac sodium eye drops.

Over Dosage

Over Dosage will not ordinarily cause acute problems. If accidentally ingested, fluids should be taken to dilute the medication.

Presentation

Dropper bottle of 5 ml.