Information For the User Ofloxacin (0.3% w/v) + Ketorolac (0.5% w/v) Eye-Ear Drop

Ketorin O Eye/Ear Drop

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Composition (Each ml contains):

- **Ofloxacin IP** ... 0.3% w/v
- **Ketorolac Tromethamine IP** ... 0.5% w/v
- Benzalkonium Chloride Solution IP ... 0.01% w/v (as preservative)
- Excipients ... q.s.

Dosage Form:

Sterile ophthalmic/otic solution (Eye/Ear Drop)

Therapeutic Category:

- Ofloxacin: Fluoroquinolone antibacterial
- **Ketorolac**: Non-steroidal anti-inflammatory drug (NSAID)

Pharmacology & Mechanism of Action:

Ofloxacin is a broad-spectrum fluoroquinolone antibiotic that inhibits bacterial DNA gyrase, preventing DNA replication and leading to bacterial cell death. It is effective against both Grampositive and Gram-negative pathogens.

Ketorolac Tromethamine is an NSAID that inhibits cyclooxygenase (COX) enzymes, thus reducing prostaglandin synthesis. This provides anti-inflammatory and analgesic effects in ocular and otic tissues.

Indications:

- Bacterial conjunctivitis or otitis externa
- Post-operative inflammation and infection in the eye or ear

Dosage & Administration:

Eye Use:

• 1–2 drops in the affected eye(s) every 6 hours or as directed by a physician.

Ear Use:

- 3–4 drops in the affected ear(s) twice daily or as directed.
- Warm the bottle slightly before use.
- Avoid touching the tip to any surface.
- Shake well before use.

Contraindications:

- Hypersensitivity to Ofloxacin, Ketorolac, NSAIDs, or any component of the formulation
- History of NSAID-induced asthma or allergic-type reactions
- Viral or fungal infections of the eye/ear

Warnings & Precautions:

- Use with caution in patients with known bleeding disorders or those on anticoagulants
- Avoid use in patients wearing contact lenses during the course of treatment
- Prolonged use may lead to superinfection with non-susceptible organisms, including fungi
- Use in pediatric patients under supervision only

Adverse Effects:

- Transient burning or stinging sensation
- Eye redness, blurred vision, dry eyes
- Ear irritation, pruritus
- Rare: Hypersensitivity reactions, corneal thinning, or ulceration with prolonged use

Drug Interactions:

- Avoid concurrent use with other topical NSAIDs or steroids in the eye unless prescribed
- Systemic NSAID or anticoagulant use may increase bleeding risk

Storage:

- Store below 25°C in a dry place.
- Protect from light and moisture.
- Do not freeze.
- Use within 30 days after opening the bottle.
- Keep out of reach of children.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I,

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