**Ketorolac Tromethamine + Ofloxacin Ophthalmic Solution**

**DESCRIPTION**
- Ketorolac Tromethamine USP: 5 mg
- Ofloxacin IP: 3 mg
- Bromanilum Chloride (Ph USNF): 0.04 mg
- Purified Water IP: q.s.

**CLINICAL PHARMACOLOGY**
- **Description**: Ketorolac tromethamine is a member of the pyrrolidine group of nonsteroidal anti-inflammatory drugs (NSAIDs) for opthalmic use. Ketorolac tromethamine's chemical name is (1S,5R)-4-(3-tert-butyl-4-hydroxybenzyl)-5-(4-hydroxy-3-methylphenoxy) 1,3,4,5-tetrahydropyrimidine-2-carboxylic acid with 2-(aminomethyl)-pyridine. Ketorolac tromethamine is a non-steroidal anti-inflammatory drug (NSAID) that acts by inhibiting the production of cyclooxygenase, an enzyme involved in the synthesis of prostaglandins.
- **Microbiology**: Ofloxacin is a quinolone antibiotic that acts by inhibiting DNA gyrase, an essential bacterial enzyme, which is a critical step in DNA replication, transcription, and repair. Ofloxacin is effective against the majority of Gram-negative and Gram-positive bacteria.

**Aerobic Gram-Positive Bacteria**
- *Staphylococcus aureus*
- *Streptococcus pneumoniae*

**Aerobic Gram-Negative Bacteria**
- *Escherichia coli*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*

**Indications and Usage**
- It is indicated for the reduction of post-operative inflammatory condition of the eye.

**CONTRAINDICATIONS**
- Ketorolac tromethamine should not be used in patients with a history of hypersensitivity to ketorolac, ofloxacin, or to any of the components in this medication.

**WARNINGS**
- **NOC FOR INJECTION**: Ketorolac tromethamine should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye. In patients receiving systemic quinolones, including ofloxacin, serious and occasionally fatal drug interactions (anticholinergic) may be observed if the eyes have been treated. Ofloxacin can cause a decrease in intraocular pressure and may be associated with adverse effects such as conjunctivitis and iritis.

**DOSAGE AND ADMINISTRATION**

**Special Instructions**: Topical instillation studies have not been conducted with Ketorolac tromethamine. However, the systemic administration of ofloxacin has been shown to elevate plasma concentrations of ofloxacin in urine. If the eye is involved in the disease, it should be treated with a systemic antibiotic, such as ciprofloxacin or ofloxacin.

**Pregnancy**: Teratogenic Effects, Pregnancy Category C:
- These are no adequate and well-controlled studies in pregnant women. Ketorolac tromethamine should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.

**Nursing Mothers**: It is not known whether ketorolac tromethamine is excreted in human milk. Breastfeeding mothers should not use ketorolac tromethamine.

**ADVERSE REACTIONS**
- In controlled clinical trials, the most frequent adverse events reported were conjunctival irritation and burning on instillation. These events were reported in up to 40% of patients treated with ketorolac tromethamine. In clinical studies conducted in patients with keratitis, 1% of patients experienced conjunctival irritation and burning. Other reported adverse reactions included ocular discomfort, conjunctival hyperemia, and foreign body sensation. Other reported reactions include burning, redness, itching, injection, conjunctival hyperemia, lacrimation, ocular discomfort, foreign body sensation, pain, and tearing.

**DOSAGE AND ADMINISTRATION**
- For the use only of a registered medical practitioner, a hospital or a laboratory.

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