GATIFLOXACIN PLUS KETOROLAC OPHTHALMIC SOLUTION

DESCRIPTION
Gatifloxacin: Gatifloxacin is an 8-methoxy fluoroquinolone with a 3'-methylpiperazine substituent at C7. The antibacterial action of gatifloxacin results from inhibition of DNA gyrase and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division. The mechanism of action of gatifloxacin includes inhibition of DNA gyrase, DNA topoisomerase IV, and tetracycline antibiotics. Therefore, gatifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to gatifloxacin. There is no cross-resistance between gatifloxacin and the aforementioned classes of antibiotics. Cross-resistance has been observed between gatifloxacin and some other fluoroquinolones.

Ketorolac: Ketorolac is a nonsteroidal, anti-inflammatory agent demonstrating analgesic and anti-inflammatory activity. It inhibits the cyclic-eicosanoid enzyme essential for prostaglandin biosynthesis. Oral administration of ketorolac reduces prostaglandin E2 levels in the aqueous humor. Ketorolac drops systemically does not cause pupil constriction. Results from clinical studies indicate that ketorolac eye drops have no significant effect upon intraocular pressure.

INDICATIONS AND USAGE: Gatifloxacin Plus Ketorolac Ophthalmic Solution is indicated for the treatment of perioperative inflammatory conditions of the eye.

CONTRAINDICATIONS: Contraindicated in patients with a history of hypersensitivity to gatifloxacin. Ketorolac or any of the components of this medication, and also in patients with a history of hypersensitivity to other nonsteroidal anti-inflammatory medicines.

WARNINGS: NOT FOR INJECTION.

If an allergic reaction to Gatifloxacin occurs, discontinue use of the drug. There have been reports that acutely applied non-steroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunctival with ocular surgery.

PRECAUTIONS:
- General: As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superficial infection occurs, discontinue and institute alternative therapy. Patients with bleeding tendencies: Ketorolac + Gatifloxacin should be used with care in patients with known bleeding tendencies, or in patients who are receiving other medications, which may prolong bleeding time. Ability to drive: As Ketorolac + Gatifloxacin eye drops may cause transient blurring on instillation, caution is required with the use of hazardous machinery or driving, which are not recommended unless vision is clear. Pregnancy: Since there are no adequate and well-controlled studies in pregnant women, Gatifloxacin and ketorolac combination ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Lactation: Caution should be exercised when Gatifloxacin and ketorolac combination ophthalmic solution is administered to a nursing woman.

Pediatric Use: Safety and efficacy in pediatric patients below the age of 3 have not been established.

Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

ADVERSE EFFECTS: The most frequently reported undesirable effects in the overall study population were conjunctival irritation, increased lacrimation, keratitis, conjunctival hyperemia, corneal infiltrates, headache, ocular edema, ocular pain and papillary conjunctivitis.

DOSAGE AND ADMINISTRATION: The general recommended dose of Ketorolac + Gatifloxacin is one drop installed into the affected eye(s) four times daily.

Storage: Store in a cool and dark place

PRESENTATION: Available in 5ml vial.

Marketed by: ALLERGAN INDIA PRIVATE LIMITED

Manufactured in India by: Piramal Healthcare Limited

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