

Genolev

Levofloxacin
Sterile Eye Drops

Presentation

Genolev: Each ml sterile eye drops contains Levofloxacin 5 mg (as Levofloxacin Hemihydrate USP).

Preservative: Preservative Free

Pharmacological Action

Levofloxacin has in vitro activity against a wide range of Gram-negative and Gram-positive microorganisms and is often bactericidal at concentrations equal to or slightly greater than inhibitory concentrations. Levofloxacin interferes with bacterial DNA related processes like replication, transcription, DNA repair, recombination, transposition, supercoiling and relaxation of DNA. The target molecule for quinolones is the A subunit of bacterial enzyme gyrase (topoisomerase II). The forming of a stable complex between the quinolone and the whole gyrase tetramer A2B2 leads to impaired enzyme functions, resulting in a rapid killing of sensitive bacteria.

Indications

Genolev eye drops are indicated for the treatment of bacterial conjunctivitis caused by susceptible organisms.

In some studies it has been found that Levofloxacin is indicated in post-operative ocular infections and endophthalmitis.

Dosage and Application

Days 1 and 2: Instill 1 drop in the affected eye(s) every 2 hours while awake, up to 8 times per day.

Days 3 through 7: Instill 1 drop in the affected eye(s) every 4 hours while awake, up to 4 times per day.

Contraindications

Levofloxacin is contraindicated in persons with a known hypersensitivity to any component of this product.

Side Effects

Frequently: Transient decreased vision, fever, foreign body sensation, headache, transient ocular burning, ocular pain or discomfort, pharyngitis and photophobia. Occurred in approximately 1-3% of patients. *Rare:* Allergic reactions, lid edema, ocular dryness, and ocular itching. Occurred in approximately 1% of patients.

Precautions

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Drug Interactions

Specific drug interaction studies have not been conducted.

Use in Pregnancy and Lactation

There are, however, no adequate and well-controlled studies in pregnant women. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Levofloxacin has not been measured in human milk. Based upon data from Ofloxacin it can be presumed that Levofloxacin is excreted in human milk. Caution should be exercised when Levofloxacin is administered to a nursing mother.

Overdose

There is no risk of adverse effects due to accidental oral ingestion since a bottle of 5 ml eye drops solution contains only 25 mg Levofloxacin. This corresponds to < 5% of the recommended oral daily dose for adults.

Storage Conditions

Store in a cool and dry place away from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of the opening do not use the medicine of dropper.

Commercial Pack

Genolev: Each plastic dropper bottle containing 5 ml sterile eye drops.

Manufactured by :

 **GENERAL**
Pharmaceuticals Ltd.

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