Lifcin

Levofloxacin 1.5%

Sterile and Pyrogen free Eye Drops

Composition

Each ml contains: Levofloxacin Hemihydrate USP equivalent to Levofloxacin 15 mg. Preservative: Benzalkonium chloride BP 0.05 mg.

Description

Levofloxacin 1.5 % Eye drops is a sterile and pyrogen free ophthalmic solution containing Levofloxacin - a fluorinated quinolone derivative for topical administration into the eyes.

Clinical Pharmacology

Levofloxacin is a fluorinated quinolone. 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 eradicates targeted pathogens by inhibiting both topoisomerase IV and DNA gyrase enzymes and sequentially interferes with DNA replication, transcription, repair and recombination.

Levofloxacin concentration in tears was measured in 100 healthy adult volunteers at various time points following instillation of 2 drops of levofloxacin 1.5% solution. Mean Levofloxacin concentration in tear measured 15 minutes after instillation was 757 µg /ml.

Indications

Levofloxacin 1.5% Eye Drops is indicated for the treatment of corneal ulcer caused by susceptible strains of bacteria.

Dosage & Administration

Days from 1 to 3:

Instill one to two drops in the affected eye(s) every 30 minutes to 2 hours while awake and approximately 4 and 6 hours after retiring.

Days from 4 up to completion:

Instill one drops in the affected eye(s) every 1 to 4 hours while awake.

Contraindications

Levofloxacin 1.5% Eye Drops is contraindicated in persons with a known hypersensitivity to levofloxacin, to other quinolones, or to any component of this product.

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 conjunctivitis.

Side-Effects

The most frequently reported adverse events in the overall study population were headache and a taste disturbance following instillation. These events occurred in approximately 8-10% of patients. Adverse events occurring in approximately 1-2% of patients included decreased / blurred vision, diarrhea, dyspepsia, nausea, ocular pain / discomfort and throat irritation. Other reported ocular reactions occurring in less than 1% of patients including chemosis, corneal erosion, corneal ulcer, diplopia, floaters , hyperemia, lid edema and lid erythema.

Use in Pregnancy

There are 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.

Use in Nursing Mothers

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 1.5% Eye Drops is administered to a nursing mother.

Pediatric Use

Safety and efficacy in children below the age of 6 years have not been established.

Overdosage

There is no risk of adverse effects due to accidental oral ingestion since a bottle of 5 ml eye drops solution contains only 75 mg Levofloxacin. This corresponds to <15% of the recommended oral daily dose for adults.

Drug Interactions

Specific drug interaction studies have not been conducted.

Pharmaceutical Precautions

Store at room temperature, protect from light. It is desirable that the contents should not be used more than one month after first opening of the bottle.

Commercial Pack

Plastic dropper bottle of 5 ml.

Manufactured by

Popular Pharmaceuticals Ltd. for

BIOPHARMA LIMITED

A-116, BSCIC Industrial Estate

Tongi, Gazipur, Bangladesh

For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.