

# Lequin

Levofloxacin 0.5%

## Sterile Eye Drops

### Composition

Each ml contains Levofloxacin Hemihydrate INN equivalent to Levofloxacin 5 mg.

### Pharmacology

Lequin eye drops is a sterile topical ophthalmic solution containing Levofloxacin, a fluoroquinolone antibacterial active against a broad spectrum of Gram-positive and Gram-negative ocular pathogens. Levofloxacin is the pure (-)-(S)-enantiomer of the racemic drug substance, ofloxacin. It is more soluble in water at neutral pH than ofloxacin. Levofloxacin is a fluorinated 4-quinolone containing a six-member (pyridobenzoxazine) ring from positions 1 to 8 of the basic ring structure.

### Indications & Usage

It is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

#### **Aerobic Gram-positive Microorganisms**

*Corynebacterium species*  
*Staphylococcus aureus*  
*Staphylococcus epidermidis*  
*Streptococcus pneumoniae*  
*Viridans group streptococci*

#### **Aerobic Gram-negative Microorganisms**

*Acinetobacter lwoffii*  
*Haemophilus influenzae*  
*Serratia marcescens*

### Dosage & Administration

Days 1 and 2 : Instill one to two drops in the affected eye(s) every 2 hours while awake, up to 8 times per day.  
Days 3 through 7: Instill one to two drops in the affected eye(s) every 4 hours while awake, up to 4 times per day.

### Precautions

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis. Avoid contaminating the applicator tip with material from the eye, fingers or other source. Systemic quinolones have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction. Do not touch dropper tip to any surface to avoid contamination.

### Adverse Reaction

The most frequently reported adverse events in the overall study population were transient decreased vision, fever, foreign body sensation, headache, transient ocular burning, ocular pain or discomfort, pharyngitis and photophobia. These events occurred in approximately 1-3% of patients. Other reported reactions occurring in less than 1% of patients included allergic reactions, lid edema, ocular dryness, and ocular itching.

### Drug Interactions

Specific drug interaction studies have not been conducted with levofloxacin. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives, and has been associated with transient elevations in serum creatinine in patients receiving systemic cyclosporine concomitantly.

### Contraindications

It is contraindicated in patients with a history of hypersensitivity to levofloxacin, to other quinolones, or to any of the components in this medication.

### Use in Pregnancy & Lactation

Teratogenic Effects: Pregnancy Category C. Levofloxacin at oral doses of 810 mg/kg/day in rats, which corresponds to approximately 7,000 times the highest recommended human ophthalmic dose, caused decreased fetal body weight and increased fetal mortality. No teratogenic effect was observed when rabbits were dosed orally as high as 50 mg/kg/day, which corresponds to approximately 400 times the highest recommended maximum human ophthalmic dose, or when dosed intravenously as high as 25 mg/kg/day, corresponding to approximately 200 times the highest recommended human ophthalmic dose. 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.

### Pediatric Use

Safety and effectiveness in infants below the age of one year have not been established.

### Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

### 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 is administered to a nursing mother.

### Storage

Store in cool, dry place & away from light. Keep out of the reach of children. Use within one month after the first opening.

### Packaging

Each plastic dropper bottle contains 5 ml sterile Eye Drops.