

# Leflox<sup>®</sup> TS

Levofloxacin 1.5%

## Sterile Eye Drops

### Description

**Leflox<sup>®</sup> TS** eye drops is a sterile and preservative free topical ophthalmic solution containing Levofloxacin. Levofloxacin is a fluoroquinolone antibacterial agent active against a broad spectrum of Gram-positive and Gram-negative ocular pathogens.

### Indications

**Leflox<sup>®</sup> TS** eye drops is indicated for the treatment of corneal ulcer caused by susceptible strains of the following bacteria: Gram-positive bacteria: *Corynebacterium species*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumonia*, *Viridans group streptococci*; Gram-negative bacteria: *Pseudomonas aeruginosa*, *Serratia marcescens*.

### Dosage & administration

*Adults and children 6 years and over:*

Days 1 through 3:

Instill 1 to 2 drops in the affected eye(s) every 30 minutes to 2 hours while awake and approximately 4 and 6 hours after retiring.

Days 4 through treatment completion:

Instill 1 to 2 drops in the affected eye(s) every 1 to 4 hours while awake.

### Use in pregnancy and lactation

#### *Pregnancy*

Pregnancy category C. 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.

#### *Lactation*

Levofloxacin has not been measured in human milk. Caution should be exercised when Levofloxacin is administered to a nursing mother.

## Side effects

The most frequent side effects are headache and a taste disturbance following instillation. The other less occurring side effects are decreased or blurred vision, diarrhea, dyspepsia, fever, infection, instillation site irritation or discomfort, ocular infection, nausea, ocular pain or discomfort and throat irritation.

## Contraindications

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

## Precautions

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 corneal ulcer. Avoid contaminating the applicator tip with material from the eye, fingers or other source. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

## Warnings

Levofloxacin should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

## Drug interactions

Specific drug interaction studies have not been conducted.

## Pharmaceutical precautions

- Store in a cool (15°C - 25°C) and dry place protected from light.
- Do not use after one month once the cap is opened.

## Presentation

**Leflox<sup>®</sup> TS** Eye Drops: Each ml contains Levofloxacin 15 mg as Hemihydrate USP.

## Package quantities

**Leflox<sup>®</sup> TS** Eye Drops: Plastic dropper bottle of 5 ml.

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