

Levomax[®] TS

Levofloxacin Hemihydrate USP
Sterile Ophthalmic Solution

DESCRIPTION

Levomax[®] TS is a preparation of Levofloxacin ophthalmic solution. Levofloxacin is a fluoroquinolone antibacterial agent active against a broad spectrum of Gram-positive and Gram-negative ocular pathogens. The mechanism of action of Levofloxacin and other fluoroquinolone antimicrobials involve the inhibition of bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerases), enzymes required for DNA replication, transcription, repair, and recombination.

INDICATIONS

Levofloxacin ophthalmic solution is indicated for the treatment of bacterial conjunctivitis.

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.

CONTRAINDICATIONS

Levofloxacin ophthalmic solution is contraindicated in patients with a history of hypersensitivity to Levofloxacin.

SIDE EFFECTS

The most frequently reported adverse events were transient decreased vision, foreign body sensation, headache, transient ocular burning and ocular discomfort. 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.

PRECAUTION & WARNING

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 slitlamp biomicroscopy and where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

USE IN PREGNANCY & LACTATION

Pregnancy Category C. 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.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children. To prevent contamination of the dropper tip and solution, care should be taken. Don't touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Levomax[®] TS Ophthalmic Solution: Plastic dropper bottle containing 5 ml sterile ophthalmic solution. Each ml contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 15 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

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