LEVOSINA TS

LEVOFLOXACIN INN

Compositions:
Levosina TS Eye Drops : Each ml contains Levofloxacin Hemihydrate INN equivalent to Levofloxacin 15 mg.

Pharmacology:
Levofloxacin ophthalmic solution is a synthetic, broad-spectrum, third generation fluoroquinolone antimicrobial agent. It acts by the inhibition of bacterial topoisomerase IV and DNA gyrase enzymes require for DNA replication, transcription, repair and recombination. It is more soluble in water at neutral pH than Ofloxacin.

Dosage And Administration:
1.5% eye drop: Adults and children 6 years of age and older:Days 1 through 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.Day 4 through treatment completion: Instill one to two drops in the affected eye(s) every 1 to 4 hours while awake.Children <1 year: Safety and effectiveness of Levofloxacin below 1 year of age have not been established.

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

Warning And Precaution:
Avoid contaminating the applicator tip with material from the eye, fingers or other source. If hypersensitivity reaction occurs, discontinue use immediately and contact your physician at the first sign of rash or allergic reaction.

Side Effects:
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.

Use in Pregnancy and Lactation:
Pregnancy Category C. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Drug Interaction:
Specific drug interaction studies have not been conducted with Levofloxacin eye drops. However, the systemic administration of some quinolones has been shown to elevate plasma concentration of theophylline, interfere with the metabolism of caffeine and has been associated with transient elevation in serum creatinine level in patients receiving systemic cyclosporine concomitantly.

Overdosage:
No information provided.

Storage:
Store at room temperature (15°-25°C) and dry place protected from light. Do not use more than 30 days after first opening of the bottle. Keep out of the reach of children.

Packing:
Levosina TS Eye Drops : Each plastic dropper bottle contains 5 ml sterile eye drops.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.