



Levofloxacin
Eye Drops

Composition:

Ovel Eye Drops: Each ml contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 5 mg.

Ovel TS Eye Drops: Each ml contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 15 mg.

Preservative:

Ovel Eye Drops: Benzalkonium Chloride Solution BP 0.005%

Ovel TS Eye Drops: Preservative free.

Pharmacology:

Levofloxacin is a fluoroquinolone antimicrobial that shows antibacterial activity by inhibiting bacterial topoisomerase II (DNA gyrase) and topoisomerase IV, enzymes required for DNA replication, transcription, repairing and recombination. Levofloxacin has wide spectrum of activities against different Gram-positive bacteria e.g., *Corynebacterium* species, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococci* Group C/F, *Streptococci* Group G, Viridans group streptococci and Gram-negative bacteria e.g., *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, *Haemophilus influenzae*, *Serratia marcescens*.

Indications:

Ovel Eye Drops is indicated for the treatment of bacterial conjunctivitis and other superficial infections caused by susceptible strains of bacteria. It is also effective in post-operative infections. It is also effective as prophylaxis and in the treatment of endophthalmitis.

Ovel TS Eye Drops is indicated for the treatment of corneal ulcer & other severe infections caused by susceptible strains of bacteria.

Dosage & administration:

Ovel Eye Drops: Days 1 & 2: Instill 1 drop in the affected eye(s) every 2 hours while awake, up to 8 times per day. Days from 3 to 7: Instill 1 drop in the affected eye(s) every 4 hours while awake, up to 4 times per day.

Ovel TS Eye Drops: Days from 1 to 3: Instill 1 drop 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 1 drop in the affected eye(s) every 1 to 4 hours while awake.

Contraindications:

Contraindicated in patients who are hypersensitive to Levofloxacin, to other quinolones, or to any of the components in this preparation.

Side effects:

Most frequently reported side effects are transient decreased vision, foreign body sensation, headache, transient ocular burning, ocular pain or discomfort, pharyngitis and photophobia.

Precautions:

Prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, Levofloxacin should be discontinued and alternative therapy should be instituted. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis or corneal ulcer. It should not be injected subconjunctivally or should not be introduced directly into the anterior chamber of the eye.

Drug interactions:

Specific drug interaction studies have not been conducted.

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 lactation:

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

Use in children:

Ovel: Safety and effectiveness in children below the age of 1 year have not been established.

Ovel TS: Safety and effectiveness in children below the age of 6 years have not been established.

Use in elderly patients:

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

Storage:

- Store below 30°C temperature in a dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:

Ovel Eye Drops: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.

Ovel TS Eye Drops: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.

 **ARISTOVISION**

Manufactured by:
 **ARISTOPHARMA LTD.**
GAZIPUR, BANGLADESH

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