

Dexalev

Dexamethasone 0.1% & Levofloxacin 0.5%

Ophthalmic Solution

Composition:

Dexalev Ophthalmic Solution: Each ml contains Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone 1 mg & Levofloxacin Hemihydrate USP equivalent to Levofloxacin 5 mg.

Preservative:

Benzalkonium Chloride.

Pharmacology:

It is a fixed dose combination of two active substances: Levofloxacin & Dexamethasone.

Levofloxacin is a fluoroquinolone antibacterial agent, that inhibits bacterial type II topoisomerases (DNA gyrase) and topoisomerase IV, enzymes required for DNA replication, transcription, repairing and recombination. Levofloxacin has wide spectrum of activities against different gram-positive microorganisms (e.g. *S. aureus* MSSA, *S. pyogenes*, *S. pneumoniae*, viridans group streptococci), aerobic Gram-negative bacteria (e.g. *E. coli*, *H. influenzae*, *M. catarrhalis*, *P. aeruginosa* community isolates), other organisms (e.g. *Chlamydia trachomatis*).

Dexamethasone inhibits phospholipase A2 enzyme and thus inhibits prostaglandin synthesis and gives anti-inflammatory action.

Indications:

Dexalev ophthalmic solution is indicated in the treatment of eye infections caused by susceptible microorganism and in the prevention of inflammation and bacterial infection that may occur after eye surgery.

Dosage & administration:

One drop instilled into the conjunctival sac after surgery every 6 hours. Duration of treatment is 7 days. If one dose is missed, treatment should continue with the next dose as planned or as directed by physician.

Contraindications:

Contraindicated in patients with hypersensitivity to active substance levofloxacin or to other quinolones, to dexamethasone, or to other steroids, or to any of the excipients.

Adverse effects:

In clinical studies, 438 patients have been treated with Dexamethasone & Levofloxacin fixed dose combination ophthalmic solution. No serious adverse reactions occurred. The most commonly reported non-serious adverse reactions are eye irritation, ocular hypertension and headache.

Precautions:

- For ophthalmic use only.
- Prolonged use may induce antibiotic resistance with result of overgrowth of non-susceptible organisms, including fungi.
- Prolonged use of topical ophthalmic corticosteroids may result in ocular hypertension/glaucoma. In any case, it is advisable that the intraocular pressure be checked frequently.
- Topical ophthalmic corticosteroids may slow corneal wound healing.

Drug Interaction:

No interaction studies have been performed.

Use in special group:

Use in Pregnancy: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Pediatric: Safety and effectiveness in children and adolescents below the age of 18 years have not been established.

Use in Elderly patients: No dosage adjustment in elderly patients is necessary.

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:

Dexalev Ophthalmic Solution: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.