

Levox®

Levofloxacin

Description: Levox® is a broad spectrum antibiotic of the fluoroquinolone class which has activity against a wide range of Gram-negative and Gram-positive microorganisms.

Mode of action: Levox® inhibits bacterial topoisomerase IV and DNA gyrase enzymes required for DNA replication, transcription, repair and recombination.

Pharmacokinetics: Levofloxacin is rapidly and completely absorbed after oral administration. Peak plasma concentrations are usually attained 1-2 hours after oral dosing. Bioavailability is approximately 99%. The mean volume of distribution of levofloxacin generally ranges from 74 to 112 L. Levofloxacin undergoes limited metabolism and is primarily excreted as unchanged drug in the urine.

Composition:

Levox® 250 mg Tablet: Each film-coated tablet contains Levofloxacin Hemihydrate USP 256.225 mg equivalent to Levofloxacin 250 mg.

Levox® 500 mg Tablet: Each film-coated tablet contains Levofloxacin Hemihydrate USP 512.450 mg equivalent to Levofloxacin 500 mg.

Levox® 750 mg Tablet: Each film-coated tablet contains Levofloxacin Hemihydrate USP 768.68 mg equivalent to Levofloxacin 750 mg.

Levox® Oral Solution: Each 5 ml contains Levofloxacin Hemihydrate USP 128.11 mg equivalent to Levofloxacin 125 mg.

Levox® IV Infusion: Each 100 ml contains Levofloxacin Hemihydrate USP 512.45 mg equivalent to Levofloxacin 500 mg.

Levox® Eye Drops: Each ml sterile eye drop contains Levofloxacin Hemihydrate USP 5.125 mg equivalent to Levofloxacin 5 mg.

Levox® TS Eye Drops: Each ml sterile eye drop contains Levofloxacin Hemihydrate USP 15.38 mg equivalent to Levofloxacin 15 mg.

Indications: Levofloxacin is indicated for the treatment of acute sinusitis, acute exacerbation of chronic bronchitis, community-acquired pneumonia, Urinary-tract infections, complicated skin and soft tissue infections, chronic prostatitis, inhalation anthrax, bacterial conjunctivitis, endophthalmitis & corneal ulcer.

Dosage & administration:

By mouth, acute sinusitis, acute exacerbation of chronic bronchitis, community-acquired pneumonia, urinary-tract infections & complicated skin and soft tissue infections, 500 mg once or twice daily for 7–14 days.

Chronic prostatitis, 500 mg once daily for 28 days.

Inhalation anthrax, 500 mg once daily for 8 weeks.

Levox® Oral Solution for Pediatric patients:

● 6 months to <5 years: 10 mg/kg twice daily.

● > 5 years: 10 mg/kg once daily.

By intravenous infusion (over at least 60 minutes for 500 mg), community-acquired pneumonia, complicated urinary-tract infections, chronic prostatitis, complicated skin

and soft tissue infections & Inhalation anthrax, 500 mg once or twice daily.

As eye drops, bacterial conjunctivitis, endophthalmitis & corneal ulcer, 1-2 drops every 2 hours (maximum 8 times daily) for the first 2 days, then 4 times daily for 3 days.

Contraindications: Levofloxacin is contraindicated in patients with a history of hypersensitivity to Levofloxacin, quinolone antimicrobial agents or any other components of Levofloxacin.

Side effects: Levofloxacin is generally well tolerated. However, a few side effects can usually be seen. Side effects include; nausea, vomiting, diarrhea, abdominal pain, flatulence and rare occurrence of phototoxicity (0.1%). Side effects that may be seen very rarely include tremors, depression, anxiety, confusion etc.

Use in pregnancy & lactation: US FDA Pregnancy Category C. During lactation a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Precautions: The following measures should be taken during administration of Levofloxacin:

- While taking Levofloxacin, adequate amount of water should be taken to avoid concentrated form of urine.
- Dose adjustment should be exercised during Levofloxacin ingestion in presence of renal insufficiency.

Drug interactions: Antacids, Iron and Adsorbents-reduce absorption of Levofloxacin. NSAID- may increase the risk of CNS stimulation. Warfarin- may increase the risk of bleeding.

Storage: Store in a cool and dry place, protected from light.

For eye drops: Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after 1 month of first opening.

Packaging

Levox® 250 mg Tablet: Each carton contains 10X3 tablets in blister pack.

Levox® 500 mg Tablet: Each carton contains 10X2 tablets in blister pack.

Levox® 750 mg Tablet: Each carton contains 6X2 tablets in blister pack.

Levox® Oral Solution: Each bottle contains 100 ml oral solution.

Levox® IV Infusion: Each vial contains 100 ml solution.

Levox® Eye Drops: Each plastic dropper bottle containing 5 ml sterile eye drops.

Levox® TS Eye Drops: Each plastic dropper bottle containing 5 ml sterile eye drops.



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