Levoxcin

Levofloxacin Hemihydrate Tablets

Composition:
Each coated tablet contains:
Levofloxacin (as Hemihydrate) USP 750 mg
Levofloxacin (as Hemihydrate) USP 500 mg
Excipients: Monocrystalline cellulose pH 102, Maize Starch, Polyvinylpyrrolidone K 30, Purified Talc, Sodium Starch glycollate, Aerosil, Croscarmellose Sodium, Magnesium Stearate, Hypromellose 6CPS, Titanium dioxide and Red Iron Oxide
Pharmacological Properties: Quinolone antibacterial, fluoroquinolone
Levofloxacin is a synthetic antibacterial agent of the fluoroquinolone class and is the S (-) enantiomer of the racemic drug substance ofloxacin.
Mechanism of action: As a fluoroquinolone antibacterial agent, levofloxacin acts on the DNA-DNA-gyrase complex and topoisomerase IV.
PK/PD relationship: The degree of the bactericidal activity of levofloxacin depends on the ratio of the maximum concentration in serum (Cmax) or the area under the curve (AUC) and the minimal inhibitory concentration (MIC).
Pharmacokinetic Properties:
Absorption: Orally administered levofloxacin is rapidly and almost completely absorbed with peak plasma concentrations being obtained within 1h. The absolute bioavailability is approximately 100%.Food has little effect on the absorption of levofloxacin.
Distribution: Approximately 30 - 40% of levofloxacin is bound to serum protein.
Biotransformation: Levofloxacin is metabolized to a very small extent, the metabolites being desmethyllevofloxacin and levofloxacin N-oxide. These metabolites account for < 5% of the dose excreted in urine. Levofloxacin is stereochemically stable and does not undergo chiral inversion.
Elimination: Following oral administration of levofloxacin, it is eliminated relatively slowly from the plasma (t½: 6 - 8 h). Excretion is primarily by the renal route (> 85% of the administered dose).
Therapeutic indications: In adults with infections of mild or moderate severity, Levoxcin tablets are indicated for the treatment of the following infections when due to levofloxacin-susceptible microorganisms:

- Acute bacterial sinusitis
- Acute bacterial exacerbations of chronic bronchitis
- Community-acquired pneumonia
- Uncomplicated urinary tract infections
- Complicated urinary tract infections including pyelonephritis
- Chronic bacterial prostatitis.
- Skin and soft tissue infections.

Posology and Method of Administration:
Route of administration: Oral.
Levoxcin tablets are administered once or twice daily depending on severity of infection.
Posology
The following dose recommendations can be given for Levoxcin: Dosage in patients with normal renal function (creatinine clearance > 50 ml/min). Once daily for 5 days for acute sinusitis, community urinary tract infections including pyelonephritis and community-acquired pneumonia. Once daily for 7 -10 days for nosocomial pneumonia and once daily for 7 – 14 days for Skin and soft tissue infections.
Special populations
Impaired renal function (creatinine clearance ≤50ml/min)
No additional doses are required after haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).
Impaired liver function: No adjustment of dosage is required since levofloxacin is not metabolized to any relevant extent by the liver and is mainly excreted by the kidneys.
In the elderly: No adjustment of dosage is required in the elderly, other than that imposed by consideration of renal function.
In children: Levoxcin is contraindicated in children and growing adolescents.
Contraindications:
Levoxcin tablets must not be used:

- In patients hypersensitive to levofloxacin or other quinolones or any of the excipients,
- In patients with epilepsy,
- In patients with history of tendon disorders related to fluoroquinolone administration,
- In children or growing adolescents,
- During pregnancy,
- In breast-feeding women.

Interaction with other medicinal products and other forms of interactions:
Effect of other medicinal products on Levoxcin: Iron salts, magnesium- or aluminium-containing antacids: Levofloxacin absorption is significantly reduced when iron salts, or magnesium- or aluminium containing antacids are administered concomitantly with Levoxcin tablets
Sucralfate: The bioavailability of Levoxcin tablets is significantly reduced when administered together with sucralfate it is best administer sucralfate 2 hours after.
Probenecid and cimetidine: Probenecid and cimetidine had a statistically significant effect on the elimination of levofloxacin. Caution should be exercised when levofloxacin is coadministered with probenecid and cimetidine, especially in renally impaired patients.
Effect of Levoxcin on other medicinal products
Ciclosporin: The half-life of ciclosporin was increased by 33% when coadministered with levofloxacin.
Vitamin K antagonists: Increased coagulation tests (PT/INR) and/or bleeding, which may be severe, have been reported in patients treated with levofloxacin in combination with a vitamin K antagonist (e.g. warfarin).
Drugs known to prolong QT interval: Levofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval.
Other forms of interactions
Meals: There is no clinically relevant interaction with food. Levoxcin tablets may therefore be administered regardless of food intake.
Pregnancy and Lactation:
Pregnancy: Levoxcin tablets must not be used in pregnant women.
Lactation: Levoxcin tablets must not be used in breast-feeding women.
Undesirable effects:
Leukopenia, eosinophilia, Anaphylactic and anaphylactoid reactions may sometimes occur even after the first dose, Hypoglycemia, particularly in diabetic patients, Insomnia, nervousness, Psychotic disorder, depression, confusional state, agitation, anxiety, Psychotic reactions with self-endangering behaviour including suicidal ideation or acts, hallucination, Dizziness, headache, somnolence, Convulsion, tremor, paraesthesia, sensory or sensorimotor peripheral neuropathy, dysgeusia including ageusia, parosmia including anosmia, Visual disturbance, Ear and Labyrinth disorders, Vertigo, Hearing impaired, Tinnitus, Tachycardia, Hypotension, Bronchospasm, dyspnea, Pneumonitis allergic, Diarrhoea, nausea, Vomiting, abdominal pain, dyspepsia, flatulence, constipation, Hepatic enzyme increased (ALT/AST, alkaline phosphatase, GGT), Rash, pruritus
Overdose: Signs to be expected following acute overdosage are central nervous system symptoms such as confusion, dizziness, impairment of consciousness, and convulsive seizures, increase
in QT interval as well as gastro-intestinal reactions such as nausea and mucosal erosions.
In the event of overdose, symptomatic treatment should be implemented. Antacids may be used for protection of gastric mucosa. Haemodialysis, including peritoneal dialysis and CAPD, are not effective in removing levofloxacin from the body. No specific antidote exists.
Presentation: 1 X 10 Tablets in Alu-Alu Blister Pack, packed in printed unit carton along with package insert
Shelf life: 3 years
Special precautions for storage: Do not store above 30^{0}C. Protect from direct sunlight. Keep all medicines out of reach of children.
Manufactured By:

Dawa Limited Plot No. 7879/8 Baba Dogo Road, Ruaraka. P. O. Box 16633-00620, Nairobi, Kenya.

Ref: 201161/08/25

PRODUCT:	201161 Levoxcin Leaflet
SIZE:	A6 105 x 148
COLOUR(S):	Black
LAST UPDATE:	Rebrand | 05/09/2025