VEGAFLOX TABLETS

Levofloxacin 250 mg and 500 mg
Oral tablets | Pack size: 10 tablets

COMPOSITION

Each Vegaflox 250 mg tablet contains levofloxacin equivalent to 250 mg. Each Vegaflox 500 mg tablet contains levofloxacin equivalent to 500 mg. Salt/hydrate and excipients must correspond to the approved formulation.

THERAPEUTIC CLASS

Fluoroquinolone antibacterial; systemic anti-infective agent.

PHARMACOLOGY

Levofloxacin inhibits bacterial DNA gyrase (topoisomerase II) and topoisomerase IV, disrupting bacterial DNA replication and repair. It is bactericidal against susceptible organisms.

INDICATIONS

For infections caused by susceptible bacteria, as locally approved: community-acquired pneumonia, complicated urinary tract infection and acute pyelonephritis, chronic bacterial prostatitis, and selected skin and soft-tissue infections. For acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated UTI, reserve use for patients without suitable alternative options because of potentially disabling adverse reactions.

DOSAGE AND ADMINISTRATION

Adults with creatinine clearance at least 50 mL/min: Dose depends on infection and organism. Examples: community-acquired pneumonia 500 mg once daily for 7–14 days; chronic bacterial prostatitis 500 mg once daily for 28 days; complicated UTI/acute pyelonephritis 250 mg once daily for 10 days under applicable labeling; uncomplicated UTI 250 mg once daily for 3 days only when alternatives are unsuitable. Other infections may require 750 mg (not supplied in this pack). Follow culture results, clinical guidance and approved local dosing.

RENAL DOSE ADJUSTMENT

Creatinine clearance below 50 mL/min: Adjust dose/interval. For a usual 500 mg every-24-hour regimen: CrCl 20–49 mL/min, give 500 mg initially then 250 mg every 24 hours; CrCl 10–19 mL/min or dialysis, give 500 mg initially then 250 mg every 48 hours. The 250 mg regimen has different adjustments. Refer to the complete approved renal dosing table.

METHOD OF ADMINISTRATION

Swallow tablets with water, with or without food. Maintain adequate hydration. Separate by at least 2 hours before or after magnesium/aluminium antacids, sucralfate, iron, zinc-containing multivitamins and other metal-cation preparations. Complete the prescribed course unless a serious reaction occurs; do not share antibiotics.

BOXED WARNING: SERIOUS ADVERSE REACTIONS

Fluoroquinolones can cause disabling, potentially irreversible reactions, including tendinitis/tendon rupture, peripheral neuropathy and central nervous system effects. These may occur together. Stop levofloxacin immediately and seek medical advice if tendon pain/swelling, numbness/tingling, weakness, confusion, hallucinations or seizures occur.

MYASTHENIA GRAVIS

Levofloxacin may worsen muscle weakness in patients with myasthenia gravis, potentially causing respiratory failure. Avoid use in patients with a known history of myasthenia gravis.

CONTRAINDICATIONS

Known hypersensitivity to levofloxacin, other quinolone antibiotics or formulation components.

OTHER WARNINGS AND PRECAUTIONS

Risk of QT interval prolongation and arrhythmia, severe allergic or skin reactions, liver injury, dysglycaemia (including severe hypoglycaemia), psychiatric effects, seizures, photosensitivity and Clostridioides difficile-associated diarrhoea. Use caution in patients with known aortic aneurysm or risk factors where alternatives exist. Stop and assess severe diarrhoea, jaundice, rash or palpitations.

DRUG INTERACTIONS

Antacids and mineral supplements reduce absorption. Monitor INR with warfarin; blood glucose with antidiabetic agents; and arrhythmia risk with QT-prolonging medicines. Corticosteroids increase tendon injury risk. NSAIDs may increase central nervous system stimulation/seizure risk.

PREGNANCY, LACTATION AND CHILDREN

Use during pregnancy only if expected benefit justifies potential fetal risk. Levofloxacin may be present in breast milk; assess feeding interruption or alternative treatment according to the indication. Routine paediatric use is restricted because of musculoskeletal safety concerns; use only for specifically approved indications.

ADVERSE REACTIONS

Common effects include nausea, diarrhoea, headache, dizziness, insomnia and constipation. Serious effects include tendon rupture, neuropathy, seizures, severe allergy, arrhythmia, blood glucose disturbances, liver injury and severe antibiotic-associated colitis.

OVERDOSAGE

Seek urgent medical attention. Management is supportive with ECG and clinical monitoring as indicated. Dialysis does not efficiently remove levofloxacin.

STORAGE

Store according to the approved Vegaflox product label, protected from moisture and excessive heat. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Vegaflox Tablets 250 mg: pack of 10 tablets.
Vegaflox Tablets 500 mg: pack of 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.