Toplevo 500

Levofloxacin 500 mg Tablet

COMPOSITION

Each film coated tablet contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 500 mg.

PHARMACOLOGY

Toplevo (Levofloxacin) is a synthetic, broad spectrum, 3rd generation fluoroquinolone antibiotic. It inhibits bacterial DNA synthesis by binding with the bacterial enzyme-DNA gyrase and topoisomerase IV which are responsible for DNA supercoiling.

INDICATION

Toplevo (Levofloxacin) is indicated for the treatment of adults (18 years of age and older) of Nosocomial & Community Acquired Pneumonia, Complicated & Uncomplicated Skin & Skin Structure Infections (SSSI), Chronic Bacterial Prostatitis, Anthrax, Plague, Complicated & Uncomplicated Urinary Tract Infections (UTI), Acute Pyelonephritis, Acute Bacterial Exacerbation of Chronic Bronchitis and Acute Bacterial Sinusitis.

DOSAGE AND ADMINISTRATION

Type of Infection	Dose	Duration
Nosocomial Pneumonia	750 mg Once Daily	7-14 days
Community Acquired Pneumonia	500-750 mg Once Daily	5-14 days
Complicated SSSI	750 mg Once Daily	7-14 days
Uncomplicated SSSI	500 mg Once Daily	5-10 days
Complicated UTI or Acute Pyelonephritis	250-750 mg Once Daily	5-10 days
Uncomplicatd UTI	250 mg Once Daily	3 days
Acute Bacterial Exacerbation of Chronic Bronchitis	500 mg Once Daily	7 days
Acute Bacterial Sinusitis	500-750 mg Once Daily	5-14 days
Anthrax (Adults & Pediatric patients ≥ 50 kg)	500 mg Once Daily	60 days
Anthrax (Pediatric patients > 30 Kg to < 50 kg)	250 mg Twice Daily	60 days
Plague (Adults & Pediatric patients ≥ 50 kg)	500 mg Once Daily	10-14 days
Plague (Pediatric patients > 30 Kg to < 50 kg)	250 mg Twice Daily	10-14 days

CONTRAINDICATIONS

It is contraindicated in patients with a history of hypersensitivity to Levofloxacin and other quinolone antimicrobial agents or any other components of this product.

SIDE EFFECTS

Side effects include- Nausea, Headache, Diarrhea, Insomnia, Constipation, Dizziness, Hepatotoxicity, Prolongation of QT interval, musculoskeletal disorders in pediatric patient, Exacerbation of Myasthenia Gravis, Convulsions, Increased intracranial pressure, Toxic psychosis, Risk of retinal detachment and Increased the risk of tendinitis & tendon rupture etc.

WARNING & PRECAUTIONS

Adequate amount of water should be taken during treatment period to avoid concentrated form of urine. Dose adjustment is required for patients with impaired renal function. Anaphylactic reactions and allergic skin reactions, serious, occasionally fatal, may occur after first dose. Hematologic (agranulocytosis, thrombocytopenia), and renal toxicities may occur after multiple doses. Severe, and sometimes fatal, hepatotoxicity has been reported. Discontinue immediately if signs and symptoms of hepatitis occur. Clostridium difficile associated colitis may occur. Avoid use in patients with known QT prolongation, those with hypokalemia.

USE IN PREGNANCY & LACTATION

Pregnancy category C. There are, however, 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. Levofloxacin is excreted in human Milk.

USE IN CHILDREN & ADOLESCENT

Safety and effectiveness of Levofloxacin in pediatric patients and adolescent less than 18 years of age have not been established.

DRUG INTERACTION

Levofloxacin absorption is decreased when administered with Antacids, Multivalent cations or Didanosine. Concomitant administration of Levofloxacin with Warfarin may enhance the anticoagulation effect. . Blood glucose should be monitored carefully with the concomitant administration of Levofloxacin with Antidiabetic drugs.

OVERDOSE

In the event of overdosage, the stomach should be emptied. The patient should be observed and appropriate hydration maintained. Levofloxacin is not efficiently removed by hemodialysis or peritoneal dialysis.

STORAGE CONDITION

Keep in a cool and dry place below 30°C temperature, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 30 tablets in Alu-PVC blister pack.

02031/00

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.