

ACER

Nafdac NO. A4-1186

LEVOFLOXACIN 500 MG. TABLETS

Each firm coated tablet contains:

Levofloxacin hemihydrate	
Equivalent to levofloxacin	500 mg.
Excipients	q.s.

It is a third generation fluoroquinolone which is optically active levo-isomer of Ofloxacin. It has excellent activity against gram positive, gram negative, intra cellular, as well as anaerobic bacteria.

Mode of action: It acts by inhibiting bacterial DNA gyrase enzyme which is required for DNA replication and thus causing bacterial lysis.

ANTIBACTERIAL SPECTRUM

Levofloxacin has in vitro activity against a wide range of gram-negative and gram-positive microorganisms as well as against atypical pathogens and certain non-spore forming anaerobes.

Levofloxacin has been shown to be active against most strains of the following microorganisms both in vitro and in clinical infections:

- Aerobic gram positive microorganism:
 - Enterococcus faecalis (heavy strains are only moderately susceptible)
 - Staphylococcus aureus (methicillin-susceptible strains)
 - Staphylococcus saprophyticus
 - Streptococcus pneumoniae (including penicillin-resistant strains)
 - Streptococcus pyogenes
- Aerobic gram-positive microorganisms:
 - Enterobacter cloacae, -Escherichia coli, -Haemophilus influenzae, -Klebsiella pneumoniae, -Legionella pneumophila, -Moraxella catarrhalis, -Proteus mirabilis
 - Pseudomonas aeruginosa.
- Other microorganisms:
 - Chlamydia pneumoniae, -Mycoplasma pneumoniae
- Anaerobic gram-positive (spore forming) Microorganisms: -Clostridium perfringens.
- Anaerobic gram-positive (non spore forming) Microorganisms:
 - Bacteroides fragilis.

THERAPEUTIC INDICATIONS

- Acute sinusitis
- Acute exacerbation of chronic bronchitis
- Community acquired pneumonia
- Complicated urinary tract infections including pyelonephritis
- Skin and soft tissue infections

- Nosocomial pneumonia
- Chronic bacterial prostatitis
- Typhoid Fever
- Complicated skin & skin structure infections

Pharmacokinetics: After oral administration, levofloxacin is nearly 100% bioavailable. A single 500mg oral or intravenous dose achieves plasma levels (against most common pathogens) for 24 hours. It is well distributed to body tissues and fluids, except that penetration into CNS is poor. It is metabolized in liver. 80-86% of the dose is excreted in urine unchanged within 24 hours and 2% is excreted in faeces.

Adverse Effects: It is well tolerated. Most adverse effects are transient in duration and mild to moderate in severity. Nausea, anorexia, abdominal discomfort and diarrhea may be seen after oral administration. After IV infusion, phlebitis and reddening at the infusion site is reported. Allergic reactions like pruritus, rash, urticaria, bronchospasm, dyspnoea, and angio-oedema.

Contraindications: Hypersensitivity to levofloxacin or other fluoroquinolones.

In pregnancy & lactations: Contraindicated.

Dosage and Administration

ACER tablets are administered 500mg once daily for a minimum of 7 days. Administration of ACER should not exceed 14 days without a review by the Physician.

Duration of treatment

The duration of therapy varies according to the cause of the disease. The administration of ACER tablets should be continued for a minimum of 48 to 72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained.

Storage: Do not store above 30°C.

KEEP MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION: Available as Alu-Alu pack of 7 tablets in a pack.