

### Composition

**Lox 500 mg Tablet:** Each film coated tablet contains Ciprofloxacin 500 mg as Ciprofloxacin Hydrochloride USP.

### Pharmacology

Lox is a synthetic fluoroquinolone. It has bactericidal activity against a wide range of gram-positive and gram-negative organisms. It inhibits bacterial DNA synthesis by binding with the bacterial enzyme DNA gyrase and topoisomerase IV which are responsible for DNA supercoiling.

Lox is active against most gram-negative aerobic bacteria including *Enterobacteriaceae* and *Pseudomonas aeruginosa*. Ciprofloxacin is also active against gram-positive aerobic bacteria including penicillinase producing, non-penicillinase producing, and methicillin resistant staphylococci, although many strains of streptococci are relatively resistant to the drug. The bactericidal action results from interference with the enzyme DNA gyrase needed for the synthesis of bacterial DNA. Following oral administration, it is rapidly and well absorbed from the G.I tract. It is widely distributed into body tissues and fluids. The half-life is about 3.5 hours. About 30% to 50% of an oral dose of Ciprofloxacin is excreted in the urine within 24 hours as unchanged drug and biologically.

### Indications

Lox is indicated for the treatment of single or mixed infections caused by two or more susceptible organisms. It may be used for infections caused by organisms resistant to other antibiotics including aminoglycosides, penicillins and cephalosporins.

Lox is widely used in adults for the treatment of urinary tract infections, lower respiratory tract infections, skin and soft tissue infections, bone and joint infections and G.I. infections, caused by susceptible gram-negative and gram-positive aerobic bacteria. It is also used for the treatment of uncomplicated gonorrhoea caused by penicillinase producing *Neisseria gonorrhoea*. Lox 750 tablet is specially indicated for the treatment of pseudomonal infections of lower respiratory tract; severe infections particularly due to pseudomonas, staphylococcus and streptococci. Lox 750 is also indicated in surgical prophylaxis.

### Dosage & Administration

**Route of Administration:** Should be taken orally.

**Dosage:** The dosage of Lox is determined by the severity and type of infection, the sensitivity of the causative organisms and the age, weight and renal function of patient. The dosage ranges for adults is 250-750 mg twice daily.

### Tablet:

- **Respiratory Tract Infections:** 500 to 750 mg twice daily (7 to 14 days)
- **Urinary tract infections:** 250 to 750 mg twice daily (3 to 10 days)
- **Pelvic Inflammatory Diseases:** 500 to 750 mg twice daily (14 days)
- **Infectious Diarrhea (*Shigella dysenteriae*, *Vibrio cholera*):** 500 mg twice daily (1 to 5 days)
- **Typhoid fever:** 500 mg twice daily (7 days)
- **Intra-abdominal infections:** 500 to 750 mg twice daily (5 to 14 days)
- **Prostatitis:** 500 to 750 mg twice daily (2 to 6 weeks)
- **Skin and Soft Tissue Infections:** 500 to 750 mg twice daily (7 to 14 days)
- **Bone and Joint Infections:** 500 to 750 mg twice daily (max. 3 months)
- **Gonorrhoea:** 500 mg as a single dose
- **Neutropenic patients with fever due to bacterial infection:** 500 to 750 mg twice daily co-administered with appropriate antibacterials.
- **Meningitis:** 500 mg as a single dose
- **Surgical prophylaxis:** 500 mg as a single dose, 60 minutes before the procedure.

### Suspension:

**Pediatric:** 10-20 mg/kg (max. 750 mg) twice daily (10 to 21 days). The duration of therapy depends on the type and severity of the infection.

### Contraindication

Patients who have known hypersensitivity to Ciprofloxacin or other quinolones.

### Warnings & Precautions

It should be used with caution in patients with suspected or known CNS disorders such as epilepsy or other factors which predispose to seizures and convulsion. Avoid in patients with known QT prolongation, hypokalemia.

### Side-Effects

**Common:** Nausea, vomiting, stomach pain, heartburn, diarrhea, vaginal itching and/or discharge, pale skin, unusual tiredness, sleepiness.

**Rare:** Severe diarrhea (watery or bloody stools) that may occur with or without fever and stomach cramps, rash, hives, itching, peeling or blistering of the skin, fever, swelling of the eyes, face, mouth, lips, tongue, throat, hands, feet, ankles or lower legs, hoarseness or throat tightness, difficulty breathing or swallowing.

### Use in Pregnancy & Lactation

**Pregnancy:** Pregnancy category C (USA) & B3 (UK). Ciprofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus and mother.

**Lactation:** Ciprofloxacin is excreted in human milk. Due to the potential risk of articular damage, Ciprofloxacin should not be used during lactation.

### Use in Children & Adolescents

Although effective in clinical trials, Ciprofloxacin is not a drug of first choice in pediatric population.

### Drug Interactions

**With medicines:** Concurrent administration of Ciprofloxacin should be avoided with Magnesium or Aluminium containing antacids or sucralfate or with other products containing Calcium, Iron or Zinc.

**With food and others:** Milk or other dairy products.

### Overdose

No information on overdose is available. Routine measures such as gastric lavage should be performed as soon as possible after ingestion of ciprofloxacin. Serum levels of ciprofloxacin are reduced by dialysis.

### Storage

Store in a cool and dry place, protected from light & moisture. Keep all medicines out of reach of children.

### Packing

**Lox 500 mg Tablet:** Each box contains 3 x 10's tablets in blister packs.