

Floxy[®]

Ciprofloxacin

COMPOSITION:

Floxy[®] 500 Tablet: Each film coated tablet contains Ciprofloxacin 500 mg (as Ciprofloxacin Hydrochloride USP).

PHARMACOLOGY:

Ciprofloxacin is one of the most active fluorinated quinolones. Ciprofloxacin is active against both Gram-positive and Gram-negative bacteria. It is particularly active against Gram-negative bacteria, including *Salmonella*, *Shigella*, *Campylobacter*, *Neisseria* and *Pseudomonas*. Ciprofloxacin has moderate activity against Gram-positive bacteria such as *Streptococcus pneumoniae* and *Strep. faecalis*. The principle mode of action is the inhibition of DNA gyrase, which mediates the formation of supercoils of DNA.

INDICATION:

Ciprofloxacin is indicated for the treatment of respiratory tract infections, skin and soft tissue infections, urinary tract infections, typhoid fever, infectious diarrhoea, gonorrhoea and other Sexually transmitted diseases, bacterial gastrointestinal infections, bone and joint infections, osteomyelitis, surgical prophylaxis, acute sinusitis, complicated intra abdominal infection.

DOSE & ADMINISTRATION:

The dosage range for adults is 500-750 mg twice daily.

For urinary tract infections: 500 mg twice daily.

For respiratory tract infections: 500-750 mg twice daily, depending on severity.

For skin, bone and joint infections: 500-750 mg twice daily, depending on severity.

For infectious diarrhoea: 500 mg twice daily.

For acute sinusitis: 500 mg twice daily.

For complicated intra abdominal infection: 500 mg twice daily.

For gonorrhoea: A single dose of 500 mg.

Duration of treatment: The usual treatment period is 7 to 14 days

*** Or as advised by the physician.**

CONTRA-INDICATION:

Patients with a history of hypersensitivity to Ciprofloxacin or to other quinolones.

WARNING AND PRECAUTION:

Ciprofloxacin should be used with caution in patients with epilepsy or a history of epilepsy, in hepatic or renal impairment, in pregnancy, during breast-feeding and in children or adolescents. Avoid excessive alkalinity of urine and ensure adequate fluid intake.

SIDE EFFECTS:

Ciprofloxacin may cause nausea, vomiting, abdominal pain, diarrhea, headache, dizziness, sleeping disorders, rash, pruritus, anaphylaxis, photosensitivity, increase in blood urea and creatinine, transient disturbances in liver enzymes and bilirubin, arthralgia and myalgia, blood disorders.

USE IN PREGNANCY & LACTATION:

The safety and effectiveness of Ciprofloxacin in pregnant and lactating women have not been established.

USE IN CHILDREN & ADOLESCENTS:

The use of fluoroquinolone in a child or adolescent is therefore is restricted to special circumstances after careful assessment of the risks and benefits for the individual patient. Indications in children will include treatment of -

1. Infections caused by multidrug-resistant pathogens for which there is no safe or effective alternative or as second line where first line therapy has failed.
2. Infections where no other effective oral agent is available and parenteral therapy is not feasible.

DRUG INTERACTION:

Antacids and other cations: Early investigational trials with quinolones revealed decreased Ciprofloxacin absorption when co-administered with magnesium-aluminum antacids. Theophylline: Theophylline serum concentrations have been found to be markedly elevated when co-administered with Ciprofloxacin. Others: Rifampicin may induce the metabolism of Ciprofloxacin, leading to lower serum concentrations and failure of therapy. The combination of Ciprofloxacin and chloramphenicol may be antagonistic.

OVERDOSE:

Overdose of Ciprofloxacin may result in reversible renal toxicity. Treatment of overdose includes emptying of the stomach by induced vomiting or gastric lavage, as well as administration of antacids containing magnesium, aluminum or calcium to reduce drug absorption.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Floxy[®] 500 Tablet: Each box contains 3 X 10's tablets in Alu-PVC blister pack.



Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Rajshahi, Bangladesh

IST-0006