Floxacin

Composition:

Floxacin 250 mg Tablet: Each tablet contains Ciprofloxacin

Hydrochloride USP equivalent to 250 mg Ciprofloxacin.

Floxacin 500 mg Tablet : Each tablet contains Ciprofloxacin

Hydrochloride USP equivalent to 500 mg Ciprofloxacin.

Floxacin Pellets for Suspension: Each 5 ml suspension contains Ciprofloxacin Hydrochloride USP equivalent to 250 mg Ciprofloxacin.

Indications:

Ilnfectious diarrhoea IUrinary tract infection ITyphoid fever ILower respiratory tract infection IAcute sinusitis IBone and joint infection IChronic bacterial prostitis I Pyelonephritis I Gonococcal infection I Inhalational anthrax.

Dosage and Administration:

| | ADULT DOSAGE (| ADULT DOSAGE GUIDELINES | | | |
|--|---------------------------|-------------------------|----------------|--------------------|--|
| Infection | Severity | Dose | Frequency | Usual Durations | |
| Urinary Tract | Acute Uncomplicated | 250 mg | q 12 h | 3 days | |
| | Mild/Moderate | 250 mg | q 12 h | 7 to 14 days | |
| | Severe/ Complicated | 500 mg | q 12 h | 7 to 14 days | |
| Chronic Bacterial Prostatitis | Mild/ Moderate | 500 mg | q 12 h | 28 days | |
| Lower Respiratory Tract | Mild/ Moderate | 500 mg | q 12 h | 7 to 14 days | |
| | Severe/ Complicated | 750 mg | q 12 h | 7 to 14 days | |
| Acute Sinusitis | Mild/ Moderate | 500 mg | q 12 h | 10 days | |
| SSTIs | Mild/ Moderate | 500 mg | q 12 h | 7 to 14 days | |
| | Severe/ Complicated | 750 mg | q 12 h | 7 to 14 days | |
| Bone and Joint | Mild/ Moderate | 500 mg | q 12 h | 4 to 6 weeks | |
| | Severe/ Complicated | 750 mg | q 12 h | 4 to 6 weeks | |
| Intra - Abdominal | Complicated | 500 mg | q 12 h | 7 to 14 days | |
| Infectious Diarrhoea | Mild/ Moderate/ Severe | 500 mg | q 12 h | 5 to 7 days | |
| Typhoid Fever | Mild/ Moderate | 500 mg | q 12 h | 10 days | |
| Urethral and Cervical Gonococcal Infections | Uncomplicated | 250 mg | single dose | single dose | |
| Inhalational anthrax (post- exposure) | - | 500 mg | q h 12 | 60 days | |

Paediatric Dosage Guideline:

Complicated urinary tract infections: Neonate-10mg /kg twice daily, Child 1 month to18 years-10mg/kg twice daily; dose should be double in severe infection(max. 750 mg twice daily).

Severe respiratory-tract infections & Gastro-intestinal infections: Neonate 10mg /kg twice daily, Child 1 month to18 years-10mg/kg twice daily; dose should be double in severe infection (max. 750 mg twice daily).

Pseudomonal lower respiratory tract infection in cystic fibrosis: Child 1 month to 18 years-20mg/kg (max.750 mg) twice daily.

Recommended Starting and Maintenance Doses:

For patients with impaired renal function

| Creatinine Clearance (mL/min) | Dose | |
|--|---|--|
| > 50 | See Usual Dosage. | |
| 30 - 50 | 250 - 500 mg q 12 h | |
| 5 - 29 | 250 - 500 mg q 18 h | |
| Patients on hemodialysis or Peritoneal dialysis | 250 - 500 mg q 24 h (after dialysis) | |

Or as directed by the physician.

Contraindications

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

Warnings & Precautions

Ciprofloxacin should not be given to patients with known hypersensitivity to it, or to other quinolones. Ciprofloxacin is contra-indicated in children and growing adolescents except where the benefit of treatment exceeds the risk. Ciprofloxacin should not be used in patients with CNS disorders. Crystalluria related to the use of Ciprofloxacin has been reported. Therefore, patients should be well hydrated. It is not recommended during pregnancy and nursing mother.

Side Effects

Ciprofloxacin is usually well tolerated. Sometime may cause nausea, diarrhoea, vomiting, dyspepsia, abdominal pain, headache, dizziness, pruritus, rarely pseudomembranous colitis, confusion, Retinal detachment etc.

Use in Pregnancy & Lactation

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

Drug Interactions

Concurrent administration of antacids containing magnesium hydroxide or aluminum hydroxide may reduce the bioavailability of ciprofloxacin by as much as 90%. The serum concentrations of ciprofloxacin and metronidazole were not altered when these two drugs were given concomitantly. Concomitant administration with tizanidine is contraindicated. Concomitant administration of ciprofloxacin with theophylline decreases the clearance of theophylline resulting in elevated serum theophylline levels and increased risk of a patient developing CNS or other adverse reactions. Ciprofloxacin also decreases caffeine clearance and inhibits the formation of paraxanthine after caffeine administration.

Overdosage

In case of acute over dose, the patients should be carefully observed and given supportive treatment, including monitoring of renal function. Adequate hydration must be maintained.

Storage

Store below 30° C, protected from light & in a dry place. Keep all medicine out of the reach of children.

Packing

Floxacin 250 Tablet: Each box contains 5 x 10 tablets in Blister pack.
Floxacin 500 Tablet: Each box contains 3 x 10 tablets in Blister pack.
Floxacin 60 ml Pellets for Suspension: Each box contains two bottles, one bottle for pellets and another bottle for diluents.

Manufactured by:

Navana Pharmaceuticals Ltd.

Rupshi, Rupganj, Narayanganj, Bangladesh NCLT0506_04-21_01

