# Florocin

Ciprofloxacin

## COMPOSITION

**Florocin 500 Tablet :** Each film coated tablet contains Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 500 mg.
**Florocin Pellets For Suspension :** After reconstitution, each 5 ml suspension contains Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 250 mg.

## PHARMACOLOGY

**Florocin** (Ciprofloxacin) 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.

## INDICATION

It is indicated for the treatment of Respiratory Tract Infections,Urinary tract infections, Pelvic Inflammatory Diseases, Infectious Diarrhea (*Shigella dysenteriae, Vibrio cholera*), Typhoid fever, Intra-abdominal infections, Prostatitis, Skin and Soft Tissue Infections, Bone and Joint Infections, Gonorrhea, Neutropenic patients with fever due to bacterial infection, Meningitis, Surgical prophylaxis.

## DOSAGE AND ADMINISTRATION

**Adult:**
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)
Gonorrhea: 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 procedure.
**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 infection.

### Dosage Guideline according to Body Weight

| Body Weight (kg) | Recommended Dose in mg/kg Body Weight (Twice Daily) | |
|---|---|---|
| | 10 mg/kg | 20 mg/kg |
| 9-10 kg | 125 mg (2.5 ml) | 250 mg (5 ml) |
| 11-15 kg | 125 mg (2.5 ml) | 250 mg (5 ml) |
| 16-20 kg | 250 mg (5 ml) | 375 mg (7.5 ml) |
| 21-25 kg | 250 mg (5 ml) | 500 mg (10 ml) |
| 26-28 kg | 250 mg (5 ml) | 625 mg (12.5 ml) |
| 29-31 kg | 375 mg (7.5 ml) | 625 mg (12.5 ml) |
| 32-40 kg | 375 mg (7.5 ml) | 750 mg (15 ml) |

## RECONSTITUTION PROCEDURE OF SUSPENSION

Pour all the pellets of sachet into the diluent bottle. Shake the bottle until pellets are completely mixed with diluent and use as per prescription.

## CONTRAINDICATION

It is contraindicated in patients who have known hypersensitivity to Ciprofloxacin or other quinolones.

## WARNING AND PRECAUTION

Patients receiving Ciprofloxacin should be instructed to drink fluids liberally. 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 EFFECT

Side effects include-nausea and other gastrointestinal disturbances, headache, dizziness, joint pain, skin rashes, risk of retinal detachment and increased the risk of tendinitis & tendon rupture.

## USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant women. Ciprofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus and mother. Ciprofloxacin is excreted in human milk. Due to the potential risk of articular damage, Ciprofloxacin should not be used during lactation.

## USE IN CHILDREN

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

## DRUG INTERACTION

Concurrent administration of Ciprofloxacin should be avoided with Magnesium or Aluminum containing antacids or sucralfate or with other products containing Calcium, Iron or Zinc. These products may be taken two hours after or six hours before Ciprofloxacin. Ciprofloxacin should not be taken concurrently with milk or other dairy products, since absorption of Ciprofloxacin may be significantly reduced. Dietary calcium is a part of a meal, however, does not significantly affect the absorption of Ciprofloxacin.

## OVERDOSE

Overdose following Ciprofloxacin administration may lead to seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment as well as crystalluria, haematuria, & reversible renal toxicity.

## STORAGE CONDITION

Keep below 30°C temperature, protected from light & moisture. Keep out of the reach of children.

## HOW SUPPLIED

**Florocin 500 Tablet :** Each box contains 30 tablets in Alu-Alu blister pack.
**Florocin Pellets For Suspension :** Each box contains one amber bottle and one sachet. Sachet contains Ciprofloxacin pellets and amber bottle contains diluent for reconstitution of 60 ml suspension.

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NIPRO JMI Pharma

Manufactured by:
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