

# Cipronil®

Ciprofloxacin

**Cipronil®**, containing Ciprofloxacin is a synthetic quinolones anti-infective agent. Ciprofloxacin has broad spectrum of activity. It 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 of Ciprofloxacin results from interference with the enzyme DNA gyrase needed for the synthesis of bacterial DNA.

Following oral administration it is absorbed from the G.I tract rapidly and well. 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 active metabolites.

#### Composition

**Cipronil® 500:** Each film-coated tablet contains Ciprofloxacin 500 mg as Ciprofloxacin Hydrochloride USP.

**Cipronil® PFS :** when reconstitute each 5 ml contains ciprofloxacin 250mg.

#### Description

**Cipronil®** is used in the treatment of infections caused by sensitive organisms.

**Respiratory tract infections:** lobar and bronchopneumonia, acute & chronic bronchitis, cystic fibrosis, bronchiectasis.

**Ear, nose and throat infections:** otitis media, sinusitis, mastoiditis, and tonsillitis.

**Skin and soft tissue infection:** infection of wound, abscess, cellulitis, furunculosis, impetigo, and infected burn.

**Acute systemic infections:** septicemia, peritonitis.

**Gastrointestinal tract infections:** enteric fever, diarrhoea due to infection, bacillary dysentery, enteritis, peritonitis.

**Eye infections:** bacterial conjunctivitis.

**Infections of bone joints:** osteomyelitis, septic arthritis.

**Gonorrhoea:** urethral, rectal and pharyngeal gonorrhoea caused by beta lactamase producing organisms.

#### Dosage and administration

The dose of **Cipronil®** is determined according to the type of infection, severity of the pathogen and age, weight and effectiveness of the kidney of the patient.

**General dosage for adults:** 250-750 mg 12 hourly.

**For the treatment of gonorrhoea:** 500 mg as a single dose.

**Depending on the severity of urinary tract infection:** 250-500 mg 12 hourly.

**Depending on the severity of respiratory tract infection:** 250-500 mg 12 hourly according to the direction of the physician.

**Serious skin and soft tissue infections and osteomyelitis:** Caused by Gram-negative bacteria recommended dose 500-750 mg twice daily. For serious skin and soft tissue infections, the duration of treatment is 5 to 10 days. For osteomyelitis, the usual duration of treatment is 4 to 6 weeks or longer.

**Impaired renal function:** Dosage adjustments are required with severe renal impairment (serum creatinine > 265 micromole/l or creatinine < 20 ml/minute). Adjustment is achieved by reducing the total daily dose by half, although monitoring of drug serum levels provides the most reliable basis for dose adjustment.

**Elderly:** Although higher Ciprofloxacin serum levels are found in the elderly, no adjustment in dosage is necessary.

#### Pediatric (Patients from 1-17 years of age):

Infection	Dose	Duration	Frequency
Complicated Urinary Tract or Pyelonephritis	10 mg/kg to 20 mg/kg (maximum 750 mg per dose; not to be exceeded even in patients weighing > 51 kg)	10 to 21 days	Twice daily
Typhoid fever	12 mg/kg	10 days	Twice daily
Invasive diarrhea	10 mg/kg	3 days	Twice daily
Shigellosis	10 mg/kg	5 days	Twice daily
Inhalational anthrax (post exposure)	15 mg/kg (maximum 500 mg per dose)	60 days	Twice daily

#### Contraindication

Ciprofloxacin should not be given to patients with a history of hypersensitivity to Ciprofloxacin and to other quinolones.

#### Precaution

It should be used with caution in patients with suspected or known CNS disorders such as arteriosclerosis or epilepsy or other factors which predispose to seizures and convulsions. It is

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excreted in human milk and because of the potential for serious adverse reaction to Ciprofloxacin in infants, it may be used after taking into account the importance of the drug to the mother. Patients taking Ciprofloxacin should drink a large amount of water or other liquids to prevent excessive alkalinity in urine.

#### Drug interaction

Magnesium hydroxide or aluminium hydroxide containing antacids decreases the absorption of Ciprofloxacin. The use of Ciprofloxacin with theophylline may increase the plasma concentration of theophylline.

#### Pregnancy and lactating mother

Ciprofloxacin cannot be used during pregnancy or for lactating mothers.

#### Side effects

Nausea, vomiting, abdominal pain, diarrhoea, headache, dizziness, rash, itching, fatigue, joint pain, mild light sensitivity, crystalluria, temporary disturbance of liver enzymes, myalgia etc.

#### Direction of preparation of suspension (সাস্পেনশন তৈরীর নিয়মাবলী)

1. The small bottle contains the pellets, the large bottle contains the diluent.

(ছোট বোতলে রয়েছে পিলেট এবং বড় বোতলে রয়েছে ডাইলুয়েন্ট।)



2. Pour the pellets (components of small bottle) completely into the large bottle of diluent. Do not add water to the suspension.

(ছোট বোতলের পিলেট বড় বোতলের ডাইলুয়েন্ট এ ঢালুন। সাস্পেনশনে পানি ঢালবেন না।)



3. Close the large bottle tightly. Shake vigorously for about 1 min.

(বড় বোতলের মুখ ভালভাবে বন্ধ করে কমপক্ষে ১ মিনিট ভালভাবে ঝাঁকান।)



4. The suspension is ready for use.

(সাস্পেনশন এখন সেবনের জন্য তৈরী।)



5. Shake the bottle at least 15 seconds each time before use.

(প্রতিবার সেবনের পূর্বে বোতলটি কমপক্ষে ১৫ সেকেন্ড ভালভাবে ঝাঁকিয়ে নিন।)

6. Do not chew the pellets.

(পিলেট চিবিয়ে খাবেন না।)

#### Commercial Pack

**Cipronil® 500 :** Each box containing 30 tablets in alu-alu pack.

**Cipronil® PFS :** Bottle containing pellets to make 60 ml suspension when reconstituted.

Manufactured by :  

**Silva**  
 Pharmaceuticals Limited  
 Maijdee, Noakhali, Bangladesh

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