

Cipro®

Ciprofloxacin

Description: Ciprofloxacin (Cipro®) is a fluorinated 4-quinolone antimicrobial agent. Ciprofloxacin has been suggested for use in the treatment of a wide range of infections caused by susceptible organisms including infections of the urinary, respiratory, gastrointestinal tract, gonorrhoea and septicæmia.

Mode of action: The mode of action of ciprofloxacin involves the inhibition of DNA gyrase (Topoisomerase II), which mediates the formation of supercoils of DNA.

Pharmacokinetics: Ciprofloxacin is rapidly and well absorbed after oral administration. The absolute bioavailability is approximately 70%. Maximum serum concentrations are attained 1 to 2 hours after oral dosing. The serum elimination half-life is approximately 4 hours. Serum concentrations increase proportionately with doses upto 1000 mg. The binding of ciprofloxacin to serum proteins is 20 to 40%. The serum elimination half-life is approximately 4 hours. Approximately 40 to 50% of an orally administered dose is excreted in the urine as unchanged drug.

Composition: Cipro® 250 mg Tablet: Each film-coated tablet contains Ciprofloxacin Hydrochloride Monohydrate USP 291.125 mg equivalent to Ciprofloxacin 250 mg.

Cipro® 500 mg Tablet: Each film-coated tablet contains Ciprofloxacin Hydrochloride Monohydrate USP 582.250 mg equivalent to Ciprofloxacin 500 mg.

Cipro® 750 mg Tablet: Each film-coated tablet contains Ciprofloxacin Hydrochloride Monohydrate USP 873.375 mg equivalent to Ciprofloxacin 750 mg.

Cipro® XR 1000 mg Tablet: Each Extended Release tablet contains Ciprofloxacin Hydrochloride Monohydrate USP 1164.5 mg equivalent to Ciprofloxacin 1000 mg.

Cipro® DS Granules for Suspension: After reconstitution each 5 ml contains Ciprofloxacin Hydrochloride Granules 625 mg equivalent to Ciprofloxacin USP 250 mg.

Cipro® 100 ml IV Infusion: Each 100 ml contains Ciprofloxacin lactate BP 254.36 mg equivalent to Ciprofloxacin 200 mg.

Cipro® Eye/Ear Drops: Each ml sterile eye & ear drops contains Ciprofloxacin Hydrochloride Monohydrate USP 3.49 mg equivalent to Ciprofloxacin 3 mg.

Indications: Urinary tract infections, Respiratory tract infections, Gastrointestinal tract infections, Uro-genital tract infections, Bone and joint infections, Skin and skin structure infections, Systemic infections.

Dosage & administration: **By mouth:** lower respiratory-tract infections: 500–750 mg 12 hourly for 7 to 14 days.

Urinary-tract infections: 250–750 mg 12 hourly for 3 to 14 days.

Acute Sinusitis: 500 mg 12 hourly for 10 days.

Chronic Bacterial prostatitis: 500 mg 12 hourly for 28 days.

Skin and skin structure infections: 500–750 mg 12 hourly for 7 to 14 days.

Bone and Joint infections: 500–750 mg 12 hourly for 4 to 6 Weeks.

Gonorrhoea: 500 mg as a single dose, Infectious Diarrhoea: 500 mg 12 hourly for 5 to 7 days.

Typhoid Fever: 500 mg 12 hourly for 10 days.

Most other infections: 500mg twice daily (increased to 750 mg 12 hourly in severe or deep-seated infection)

By Intravenous Infusion: Urinary-tract infections: 200-400 mg 12 hourly for 7 to 14 days

Lower respiratory-tract infections: 400 mg 8-12 hourly for 7 to 14 days

Nosocomical Pneumonia: 400 mg 8 hourly for 10 to 14 days

Skin and skin structure infections: 400 mg 8 to 12 hourly for 7 to 14 days

Bone and Joint infections: 400 mg 12 hourly for 4 to 6 Weeks (If complicated, 400 mg 8 hourly for more than 6 Weeks)

Acute Sinusitis: 400 mg 12 hourly for 10 days.

Chronic Bacterial prostatitis: 400 mg 12 hourly for 28 days.

Children and adolescents:

Urinary-tract infections: Neonate-10 mg/kg twice daily, Child (1 month–18 years) 10 mg/kg twice daily, dose doubled in severe infection (max. 750mg twice daily).

Severe respiratory-tract infections, gastro-intestinal Infections: Neonate 15 mg/kg twice daily Child (1 month–18 years) 20 mg/kg (max. 750 mg) twice daily.

Anthrax: Child (1 month–18 years) 15 mg/kg (max. 500 mg) twice daily.

Cipro® Eye drops:

For Corneal Ulcers: Instill 2 drops into the affected eye every 15 minutes for the first six hours and then 2 drops into the affected eye every 30 minutes for the remainder of the first day. On the second day, instill 2 drops into the affected eye hourly. On the third through the fourteenth day, place 2 drops into the affected eye every four hours. Treatment may be continued after 14 days if corneal re-epithelialization has not occurred.

Bacterial Conjunctivitis/Blepharitis:

Instill 1 drop to the conjunctival sac(s) every two hours for two days and 1 drop every four hours for the next five days.

Cipro® Ear drops: The ear drops are typically applied in the affected ear twice a day, about 12 hours apart for 7 days.

Dosage guideline for ciprofloxacin XR 1000 mg tablet:

Indication	Dose	Usual Duration
Complicated urinary tract infections	1000 mg	7 ~ 14 days
Acute uncomplicated pyelonephritis	1000 mg	7 ~ 14 days

Contraindications: Ciprofloxacin is contraindicated in case of known hypersensitivity to it, quinolone antibiotics, or any other components of this product.

Side effects: Ciprofloxacin is generally well tolerated. The most frequently reported adverse reactions are nausea, abdominal pain, dyspepsia, diarrhoea, vomiting and rash.

Use in pregnancy & lactation: The safety and effectiveness of ciprofloxacin in pregnant and lactating women have not been established.

Precautions: Ciprofloxacin should be used with caution in epileptics and patients with a history of CNS disorders. Adequate amount of water should be taken with ciprofloxacin. Caution should be taken in renal impairment patients. **Cipro® XR** Should be swallowed whole; do not split, crush, or chew the tablet.

Drug interactions: Increased plasma levels of theophylline have been observed following concurrent administration with ciprofloxacin. Phenytoin level may be altered when ciprofloxacin is used concomitantly. Ciprofloxacin should not be administered within 4 hours of medications containing magnesium, aluminium, calcium or iron salts, as interference with absorption may occur.

Overdosage: In the event of acute overdosage, reversible renal toxicity has been reported in some cases. The stomach should be emptied by inducing vomiting or by gastric lavage. Calcium or magnesium containing antacid may be administered as soon as possible after ingestion of ciprofloxacin in order to reduce the absorption of ciprofloxacin.

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging: **Cipro® 250 mg Tablet:** Each carton contains 10X3 tablets in blister pack.

Cipro® 500 mg Tablet: Each carton contains 10X4 tablets in blister pack.

Cipro® 750 mg Tablet: Each carton contains 6X3 tablets in blister pack.

Cipro® XR 1000 mg Tablet: 6X1 tablets in Alu-Alu blister.

Cipro® DS Granules for Suspension: Each carton containing two bottles; one bottle for granules and another bottle for diluent.

Cipro® 100 ml IV Infusion: Each vial contains 100 ml infusion for intravenous use.

Cipro® Eye & Ear drops: Each plastic dropper bottle contains 5 ml sterile eye & ear drops.

