




### 1.5.3 Patient information leaflet (PIL)

 <h1>Cipro-500</h1> <h2>Ciprofloxacin Tablets BP 500 mg.</h2>	<p><b>Precautions &amp; Warnings :</b> Use with caution in patients of renal impairments, cerebral arteriosclerosis or epilepsy. Keep patient well hydrated to prevent crystalluria. Paediatrics: Safety not established. Pregnancy: Contraindicated. Lactation: Drug passes in to breast milk may affect the infant adversely. Elderly: No special problem.</p> <p><b>Contraindications :</b> Hypersensitivity to ciprofloxacin or any other quinolone derivative. Not recommended for use in children and adolescents.</p> <p><b>Adverse reactions/Side effects :</b> Diarrhoea, vomiting, abdominal pain, headache, restlessness and arthralgia.</p> <p><b>Drug Interactions :</b> Concurrent administrations of Ciprofloxacin with theophylline may lead to elevated serum concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline-related adverse reactions. If concomitant use cannot be avoided, serum levels of theophylline should be monitored and dosage adjustments made as appropriate.</p> <p>Ciprofloxacin, have also been shown to interfere with the metabolism of caffeine. This lead to reduced clearance of caffeine and prolongation of its serum half-life.</p> <p>Concurrent administration of Ciprofloxacin with antacids containing magnesium, aluminum, or calcium; with sucralate or divalent and trivalent cations such as iron may substantially interfere with the absorption of Ciprofloxacin, resulting in serum and urine levels considerably lower than desired. To a lesser extent this effect is demonstrated with zinc-containing multivitamins.</p> <p>Altered serum levels of phenytoin (increased and decreased) have been shown in patient receiving concomitant Ciprofloxacin.</p> <p>Ciprofloxacin, have been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly to enhance the effect of the oral anticoagulant warfarin or its derivatives. When these products are administered concomitantly, prothrombin time or other suitable coagulation tests should be closely monitored.</p> <p>As with other broad spectrum antimicrobial agents, prolonged use of Ciprofloxacin may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patients condition and microbial susceptibility testing is essential. If superinfection occurs during therapy, appropriate measures should be taken.</p> <p><b>Presentation :</b> Bulk pack of 100 / 250 / 500 / 1000 tablets. Blister / Strip pack of 1x 10's / 10 x 10 tablets in a carton.</p> <p><b>STORAGE :</b> Store below 30°C.</p> <p>Manufactured in India by : <b>AGOG PHARMA LTD.</b> Plot No. 33, Sector II, The Vasai Taluka Indi. Co-op. Estate Ltd., Vasai (E), Dist. Thane, INDIA.</p>
<p><b>Appearance :</b> White caplet shaped film coated tablets.</p> <p><b>Label claim :</b> Each film coated tablet contains: Ciprofloxacin HCL BP equivalent to Ciprofloxacin 500 mg.</p> <p>Approved colour used, Warning : Formulation contains Lactose</p> <p><b>Clinical Pharmacology :</b> It is a new fluoroquinolone antimicrobial agent with potent activity against a broad spectrum of gram-positive and gram-negative bacterial including Ps. aeruginosa, Enterobacteriaceae and Staph aureus. Ciprofloxacin does not disturb normal anaerobic intestinal flora and, has significant post-antibiotic effect and thus prevents regrowth of bacteria. Its antibacterial spectrum is wider than that of aminoglycosides, third generation cephalosporins and other fluoroquinolones.</p> <p><b>Indications(s) :</b> Respiratory tract, urinary tract, E.N.T., skin and soft tissue, Gastro intestinal tract, Intra-abdominal Gynaecological. Bone and joint and Server systemic infections, Gonorrhoeas.</p> <p>Ciprofloxacin 400 mg/200 ml IV infusion 12 hourly is indicated for systemic infection, lower respiratory tract infections, skin and skin structure infections, typhoid fever, severe/complicated urinary tract infections, and surgical procedure.</p> <p><b>Dosage and Administration (directions for use) :</b> The dosage of ciprofloxacin is determined on the basis of severity of infection, type of infection organism and age, weight and renal function of the patient. The recommended dosage schedule of oral ciprofloxacin is as follows:</p> <ol style="list-style-type: none"> <li>Uncomplicated UTI: 250 mg every 12 hours.</li> <li>Prostatitis and complicated UTI in patients with server underlying structural abnormalities: 500 mg every 12 hours.</li> <li>Lower respiratory tract infections: mild-250 mg, moderate to server-500 mg, all every 12 hours. Dosage of 750 mg every 12 hours should preferably be used in cases of infection with resistant gram-positive bacteria.</li> <li>ENT infections: 500 to 750 mg every 12 hours.</li> <li>Bone and joint infections: 500 to 750 mg every 12 hours.</li> <li>Gastroenteritis: 250 mg every 12 hours.</li> <li>Enteric fever: 500 mg every 12 hours</li> <li>Gynaecological infection: 500 mg every 12 hours.</li> <li>Gonorrhoea: 250 mg single dose.</li> <li>Septicemia, bacteremia and intra-abdominal infections: Initial IV ciprofloxacin therapy may be followed by oral 500 to 750 mg every 12 hours.</li> </ol>	