AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

1.5.3 Patient information leaflet (PIL)

Cipro-250

Ciprofloxacin Tablets BP 250 mg

COMPOSITION :
Each film coated tablet contains:
Ciprofloxacin Hydrochloride BP
Equivalent to Ciprofloxacin ...250 mg
Excipients .....q.s.

Clinical Pharmacology : It is a new fluroquinolone antimicrobial agent with potent activity against a broad spectrum of gam-positive and gram-negative bacterial including Ps. acruginosa, Enterobacteriacease and Staph aureus. Ciprofloxacin doses 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 fluroquinolones.

Indications(s) : Respiratory tract, urinary tract, E.N.T., skin and soft tissue, Gastro intestinal tract, Intra-abodminal Gynaecological. Bone and joint and Server systemic infections, Gonorrhoes.

Dosage and Administration (directions for use) : 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:

i) Uncomplicated UTI: 250 mg every 12hours.
ii) Prostatitis and complicated UTI in patients with server underlying structural abnormalities: 500 mg every 12 hours.
iii) 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.
iv) ENT infections: 500 to 750 mg every 12 hours.
v) Bone and joint infections: 500 to 750 mg every 12 hours.
vi) Gastroenteritis: 250 mg every 12 hours.
vii) Enteric fever: 500 mg every 12 hours
viii) Gynacecological infection: 500 mg every 12 hours.
ix) Gonorrbhoea: 250 mg single dose.
x) Septicemia, bacteremia and intra-abdominal infections: Initial IV ciprofloxacin therapy may be followed by oral 500 to 750 mg every 12 hours.

Precautions & Warnings : Use with caution in patients of renal impairments, cerebal 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.

Contraindications : Hypersensitivity to ciprofloxacin or any other quinolone derivative. Not recommended for use in children and adolescents.

Adverse reactions/Side effects : Diarrhoea, vomiting, abdominal pain, headache, restlessness and arthralgia.

Drug Interactions : 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 l events of theophylline should be monitored and dosage adjustments made as appropriate.

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.

Concurrent administration of Ciprofloxacin with antacids containing magnesium, aluminum, or calcium; with sucralfate or divalent and trivalent cautions 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.

Altered serum levels of phenyhtoin (increased and decreased) have been shown in patient receiving concomitant Ciprofloxacin.

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.

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.

STORAGE : Store under normal storage conditions (15°C to 30°C)

Protect from light.

Keep all medicines out of reach of children.

PRESENTATION: Blister pack of 10 x 10 Tablets.

Jar pack of 1000 Tablets.

Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl.
Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.