Brand Name : CIPRO-250 TABLETS **Generic Name :** Ciprofloxacin Tablets BP 250 mg		2021
Module 1 **1.5**	Administrative Information and Product Information Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

CIPRO-250 TABLETS (Ciprofloxacin Tablets BP 250 mg)

2. Qualitative and Quantitative Composition:

Each film coated tablet contains: Ciprofloxacin Hydrochloride BP ≡ to Ciprofloxacin 250 mg

3. Pharmaceutical form:

White elongated, film coated tablet having a breakline on one side and other side plain of each tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

Urinary tract infections

The antimicrobial spectrum of ciprofloxacin encompasses the usual bacterial causes of urinary tract infection (UTI) including Pseudomonas species and Staphylococcus saprophyticus. After oral administration ciprofloxacin reaches serum, kidney, prostrate, and urine, in concentrations well above the MICs for most urinary pathogens. Furthermore, ciprofloxacin inhibits the growth of aerobic Gram-negative fecal, vaginal, and periurethral flora which is The reservoir of pathogenic bacteria for reinfection and emergence of resistance during treatment.

Although there have been no large controlled trials available evidence suggests that ciprofloxacin is at least as effective as other agents at eradicating infection from the urinary tract. This is particularly true in patients with structural abnormalities of the urinary tract and many authors feel that fluoroquinolones are the treatment of choice

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for complicated urinary tract infections caused by susceptible bacteria. The role of ciprofloxacin as prophylaxis against urinary infection is not fully established but it is effective in various high risk group including patients with urinary catheters and renal transplant recipients.

Reports of resistance of urinary bacterial isolates to fluoroquinilones have been increasing. In spain in 1992, 8.4 % of urinary isolates of Escherichia coli were resistant to norfloxacin and 7.1 % were resistant to ciprofloxacin. The rise in quinolone resistance followed a dramatic increase in the use of fluoroquinolones, highlighting the need for restraint in the use of these as first-line agents in uncomplicated urinary tract infection.

A ciprofloxacin dosage of 250 mg appears to be as effective as 500 and 750 mg given twice a day for 7 days, for the treatment of complicated UTIs a single dose of ciprofloxacin (100 or 250 mg by mouth) is effective curing more than 84 % of patients with uncomplicated cystitis.

Gonorrhea and other sexually transmitted disease

The very low MIC values of Ciprofloxacin for Neisseria gonorrhoea both penicillinase producing and non-penicillnase producing strains, make Ciprofloxacin a potentially useful agent for the treatment of gonorrhea. In two open studies the administration of a single dose of Ciprofloxacin, 250 or 500 mg cured all the patient including 12 patient with rectal and three with pharyngeal infections. In a double bind comparative trial of a single dose of 250 mg of Ciprofloxacin or 3.5 g of ampicillin plus 1.0 g probenecid gonococcal urethritis was cured in all 49 patients treated with ciprofloxacin and in 47 of 51 patient treated with ampicillin plus probenecid. The efficacy of Ciprofloxacin in disseminated gonococcal infection remains to be proven. For pharyngeal and rectal gonococcal infections more experience is required to determine the efficacy of ciprofloxacin compared to procaine penicillin. Neither of the test regimens above eradicated co- infection with C. trachomatis. Ciprofloxacin is ineffective against treponemal infections.

In larger doses for longer periods of time ciprofloxacin can clear non-gonococcal urethritis, but its activity against C. trachomatis appears to be less than that of the tetracyclines.

A blinded randomized clinical trial comparing ciprofloxacin and co-trimoxazole for the treatment of chancroid showed that a single daily dose of 500 mg ciprofloxacin was as effective as 160/800 mg co-trimoxazole twice daily for 3 days.

Bacterial gastrointestinal infections

The lack of plasmid mediated mediated resistance in Ciprofloxacin, the very low MIC of pathogenic enteric bacteria, the drug concentration achieved in the feces and the preservation of the anaerobic bowel flora during treatment are properties that make Ciprofloxacin highly effective in the treatment of enteric infections.

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Numerous studies have shown that ciprofloxacin (500-750 mg twice daily) is effective in the treatment of typhoid fever, shigellosis, enterotoxigenic Escherichia coli, Campylobacter jejuni and both as prophylaxis and therapy for traveler's diarrhea. However, the superiority of quinolone treatment over previous regimens ahs not been fully established, with the exception of enteric fever where quinolones are the treatment of choice. Quinolone-resistant strains of Salmonella spp. And shigella spp. Have been reported from both Africa and India and, although quinolones remain first-line therapy for enteric fever, the possibility of resistance should be considered. In patients with AIDS, recurrent salmonella infection may require continuous prophylaxis with quinolones.

Osteomyelitis

Ciprofloxacin bone levels exceed 50 % of the simultaneous serum levels, resulting in sufficient drug concentrations to kill most Enterobacteriaceae, Staphylococci and Pseudomonas aeruginosa. Penetration into neutrophils and macrophages, interaction with bacterial adherence and bactericidal action on micro organisms in the stationary phase of growth are additional properties that make ciprofloxacin a promising oral antimicrobial agent for the treatment of osteomyelitis.

Thus far, several open trials have appeared in the literature indicating the efficacy of ciprofloxacin in the treatment of osteromyelitis. The majority of patients in those trials were given ciprofloxacin 750 mg orally twice a day for 1-6 months. The follow-up period was than 6 months and in most of the cases exceeded 1 year. The predominant pathogens were Enterobacteriaceae, pseudomonas aeruginosa and staphylococci. Amongst 219 patients, 75 % has no recurrence during the follow-up period. Approximately one third of treatment failures were caused by ciprofloxacin-resistant strains.

Infection of the respiratory tract

Relatively poor efficacy against Streptococcus pneumoniae precludes the use of quinolones as single-agent empiric therapy for community acquired pneumonia. Ciprofloxacin has an important role in the treatment of lower respiratory tract infection caused by susceptible Gram-negative pathogens making it particularly suitable for use in nosocomial infections. the activity of ciprofloxacin against Legionella spp. Make it a suitable second line therapy for atypical pneumonia. Ciprofloxacin is as effective as other agents in the treatment of exacerbations of chronic bronchitis, but there are many other therapies available.

Oral ciprofloxacin in doses of 750 mg two or three times a day has been shown to be at least as effective as the combination of a β-lactam agent with an aminoglycoside for the treatment of acute episodes of infection associated with Pseudomonas aeruginosa in adult patients with cystic fibrosis. There was a significant improvement in symptoms, sputum production, and lung-function tests. Drug-resistant organisms were isolated no more frequently after ciprofloxacin than after conventional therapy. Discontinuation of treatment was followed by repopulation with a flora susceptible to ciprofloxacin.

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Skin structure infections

In several double-blind comparison studies of a variety of infections of skin structures it was shown that oral ciprofloxacin in doses of 750 mg twice daily was as effective as cefotaxime given intravenously in doses of 2 g every 8 h. the efficacy of ciprofloxacin in patients with poor blood supply to the sites of infection (diabetics, sickle cell anemia, elderly) requires further study.

Prophylaxis in immunocopromised patients

Ciprofloxacin can eliminate the aerobic Gram-negative bacteria from the bowel while maintaining colonization resistance from the resident anaerobic bacterial flora. Therefore, prophylaxis with ciprofloxacin, and other quinolones, in patients with neutropenia has been the subject of much study and many authors now feel that ciprofloxacin 250 mg twice daily should be given to all patients with severe neutropenia (absolute count<500 x $10^{-9}.1^{-1}$). Randomized trials have shown a clear reduction in Gram-negative bacteremia in treated patients although quinolone-resistatn Gram-positive and Gram-negative pathogens may emerge during treatment. Ciprofloxacin has also been shown to be effective as part of combination therapy for neutropenic fever and may allow for oral therapy at home in selected patients. However it is not appropriate to use ciprofloxacin as treatment for febrile episodes in patients already using quinolone prophylaxis because of the likelihood of superinfection with resistant bacteria. The role of quinolones as prophylaxis in other immunocompromised hosts is not as ewll established exept in the context of recurrent salmonella bacteremia in patients with AIDS.

Other infections

Ciprofloxacin is useful for the treatment of a variety of hospital-acquired infection caused by multiple resistant bacteria. Other potential uses include meningitis caused by Gram-negative bacilli, elimination of the carrier state of neisseria meningitides and Staphylococcus aureus and as prophylaxis against spontaneous bacterial peritonitis in patients with cirrhosis.

4.2 Posology and Method of Administration:

The adult oral dose of Ciprofloxacin ranges from 500 to 750 mg twice daily depending on the severity and nature of the infection. A single oral dose of 500 mg is suggested for the treatment of gonorrhoea (by WHO) and also for meningococcal meningitis prophylaxis. Ciprofloxacin is not generally recommended in children and adolescents but if considered essential, doses of 7.5 to 15 mg per kg of body-weight daily by mouth or 5 to 10 mg per kg daily intravenously have been suggested.

Doses should be reduced inpatients with severe renal impairment. Halving the dose has been suggested when the creatinine clearance is less than 20 ml per minute or alternatively the dosage interval may be increased; ideally plasma concentrations of Ciprofloxacin should be monitored.

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Method of administration : Oral.

4.3 Contraindications:

Ciprofloxacin should not be given with known hypersensitivity to Ciprofloxacin or other quinolone antibiotics.

4.4 Special Warnings and Precautions for Use :

Ciprofloxacin should be used with caution in patients with epilepsy or a history of CNS disorders. Since Ciprofloxacin have been shown to cause degenerative changes in weight-bearing joints of young animals, it has been suggested that these compounds should not be used in children adolescents, pregnant women, or breast-feeding mothers.

Care is necessary in patients with impaired hepatic or renal function, glucose-6-phosphate dehydrogenase deficiency, or myasthenia gravis. An adequate fluid intake should be maintained during treatment with Ciprofloxacin and excessive alkalinity of the urine avoided because of the risk of crystalluria. Exposure to strong sunlight or sunlamps should also be avoided. The ability to drive or operate machinery may be impaired by Ciprofloxacin, especially when alcohol is also taken.

Ciprofloxacin may interact with various compounds including antacids, iron preparations, opioids, theophylline, and warfarin.

4.5 Interaction with other medicinal products, and other forms of interaction:

Potentially hazardous interactions

Several important ciprofaloxacin drug interaction have been recognized.

Antacids and other cations

Early investigational trials with quinolones revealed decreased ciprofloxacin absorption when co-administered with magnesium-aluminum antacids. Other cations, such as calcium, iron, and probably zinc, appear to interact in a similar manner. The proposed mechanism of the interaction is chelation between metal and the 4-oxo and adjacent carboxyl groups of quinolones.

Theophylline

Theophylline serum concentration haven been found to be markedly elevated when co-administered with ciprofloxacin. At dose used fro systemic infection, ciprofloxacin decreases theophylline clearance by approximately 30 %. It appears that quinolones inhibit specific cytochrome P450 isozymes responsible for metabolism of methylxanthlines.

Anticoagulants

Ciprofloxacin may increase the prothrombin time in patients receiving warfarin and monitoring should be performed during concomitant treatment.

Others

A decreased ciprofloxacin absorption has been observed with concurrent sucralfate administration. It is possible that rifampin may induce the metabolism of ciprofloxacin, leading to lower serum concentration and failure of therapy. The combination of ciprofloxacin and chloramphenicol may be antagonistic. Increased creatinine may occur if patients receiving cyclosporine are given ciprofloxacin. Ciprofloxacin may potentiate the effect of glyburide if the drugs are taken simultaneously.

Potentially useful interactions

The combination of ciprofloxacin with an antipseudomal penicillin has been reported to be synergistic for 20 -50 % of isolates of Pseudomonas aeruginosa.

4.6 Pregnancy and Lactation:

Pregnancy

In animal studies ciprofloxacin does not appear to be teratogenic but it may damage developing cartilage. There are insufficient data to recommend the use of ciprofloxacin in pregnancy.

Lactation

Ciprofloxacin does cross into breast milk and its use during lactation is not advised.

4.7 Effects on ability to drive and use machines:

Patients experiencing visual disturbances, dizziness, vertigo, somnolence, or other central nervous system disturbances while taking Ciprofloxacin Tablets should refrain from driving or using machines.

4.8 Undesirable effects:

A series of 15 cases of anaphylactoid reactions has been reported associated with ciprofloxacin Stevens-Johnson syndrome, toxic epidermal necrolysis, fluminant hepatic failure and acute renal failure have been reported rarely.

Severe of irreversible adverse effects

As with all quinolones seizures may occur and this effects may be potentiated by concurrent use of non-steroidal anti-inflammatory drugs. Pseudomembranous colitis

has occurred with ciprofloxacin therapy. Transient disturbance of hearing has been reported, particularly during high-dose therapy.

Symptomatic adverse effects

Probable or possible drug-related related reaction were reported in 9.3 % of 9473 patients treated with ciprofloxacin worldwide. The incidence of severe reaction was 0.6 %. The most frequent reaction were from the gastrointestinal system (nausea, diarrhea, vomiting, dyspepsia), central nervous system (dizziness, headache, nervousness, tremors, seizures, confusion) and skin (rash, pruritus, urticaria, photo sensitivity).

Other effects

Elevation of AST (SGOT) and ALT (SGPT), blood creatinine and blood urea have been observed. Eosinophilia, leucopenia and thrombocytopenia have also been related to ciprofloxacin use.

4.9 Overdose:

No case of this kind appears to have been reported.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Ciprofloxacin is one of the most active fluorinated quinolones. It is absorbed by mouth with the production of serum and tissue levels that enable the effective treatment of local and systemic infections.

The antimicrobial activity is retained the presence if pus but is diminished by acidic PH, high concentration of mg^{2+} in the medium an a high inoculum size,> 10 CFU ml^{-1} at concentration <0.5 $mg.1^{-1}$ciprofloxacin inhibits more than 90 % of strains (MIC_{90}) among the species of Entero bacteriaceae haemophilus and Neisseria; at concentration of 1 $mg.1^{-1}$ non-fementative Gram-negative bacteria are inhibited with the exception of Pseudomonas maltophilia and Pseudomonas cepacia, which are relatively resistant. The MIC_{90} for staphylococci including methicillin-resistant strains Is <1.0 $mg.1^{-1}$ sreptococci are less susceptible with an MIC_{90} for streptococcus pneumoniae of 2.0 $mg.1^{-1}$ the MIC_{90} for streptococcus pyogenes is 0.8 $mg.1^{-1}$ obligate anaerobes are generally not susceptible to ciprofloxacin at concentration below 1 mg but strains of Bacteroides fragilis are inhibited at 2 mg and other species of Bacteroides at 8 mg legionella pneumophila, Mycoplasma Pneumoniae and Chlamydia trachomatis have been reported to be sensitive at concentration of 1 mg. species of Brucella and Mycobacterium (tuberculosis, kansasii, xenopi, fortuitum) are inhibited at a concentration of <1 mg M. avium complex is more resistant.

Ciprofloxacin penetrates neutrophils and other inflammatory cells increasing intracellular killing of bacteria.

Plasmid-mediated resistance to ciprofloxacin has not been convincingly demonstrated. Resistance seems to be mediated by infrequent mutations (rate <10) in DNA gyrase or alterations in outer membrane proteins. Ciprofloxacin resistance in staphylococcus epidermidis has been associated with a ser-84- Phe mutation in the DNA gyrase A protein and in staphylococcus aureus a ser 84- Leu mutation is important. In Escherichia coli a mutation at ser-83 is sufficient to generate a high level of resistance to malidixic acid, whereas a second mutation at Asp -87 in the A subunit of DNA gyrase seems to play a role in developing a high level of ciprofloxacin resistance. In Pseudomonas aeruginosa DNA gyrase gyra gene mutations of Asp-87 to Asn, Asp-87 to tyr, and Thr-83 to Ile were associated with resistance to quinoloes but a number of resistant strains did not show mutations suggesting that other mechanisms are also important. Resistance to ciprofloxacin may be induced by other fluoroquinolones and exposure to quinolones may induce resistance to unrelated antibiotics, probably by altering a common pathway of transport across the bacterial membrane interestingly there is some evidence that ciprofloxacin may be able to eliminate some plasmids but the clinical significance of this observation for patterns of antimicrobial resistance is unknown.

The impact of unrestricted ciprofloxacin use on the incidence of quinolone resistance has not been fully studied. However, the emergence of resistance has been clearly documented in areas of high use or where fluoroquinolones have been used as long term prophylactic therapy. Poor vascularization of the infected site and instrumentation appear to be additional risk factors with Pseudomonas aeruginosa and staphylococci the most common resistance isolates.

5.2 Pharmacokinetic Properties:

The concentration of ciprofloxacin in body fluids can be determined by high pressure liquid chromatography (HPLC) and bioassay, Both method have proven satisfactory with regard to sensitivity and precision. The limits of detection are 0.006mg.1^{-1} and 0.03 mg.1^{-1} for HPLC and bioassay, respectively. Ciprofloxacin administered orally is sufficiently absorbed and the bioavailability reported by different investigators varied from 50 to 84 %. Mean peak serum concentration from oral administration of 500 and 750 mg are 1.5 ± 0.36 mg.1^{-1} and 2.0±0.5 mg.1^{-1} respectively, 60-75 min after the dose. another study using twice daily administration of 500 or 750 mg reported peak concentration of 2.5 and 3.5 mg.1^{-1} respectively. Intravenous infusion of 200 mg produced a mean serum concentration of 4.0±1.2 mg.1^{-1}. the volume of distribution is 177-2171 per 70 kg indicating tissue penetration and intracellular concentration of the drug. There has been interest in the degree to which lipid solubility of quinolones determines their entry into microorganisms and their efficacy. The evidence suggests that lipid solubility is of minor importance compared with the underlying efficacy as a DNA gyrase inhibitor. Approximately 30 % of ciprofloxacin in the blood is protein bound. The concentration of drug achieved in urine and feces is several hundred times greater than the MIC of most pathogenic bacteria that cause urinary tract infection and the majority of the aerobic bacterial fecal flora. At recommended doses the

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concentration of ciprofloxacin in nasal secretions, bronchial secretions, sputum, bile, prostate, kidney, female organs, skin and bone is several times above the MIC of pathogenic organisms. The drug penetrates relatively poorly into normal CSF with CSF/plasma ratios ranging from 0.02 to 0.19. However, in patients with meningitis penetration is good and CSF concentration exceed the MIC for most enterobacteria. Ciprofloxacin penetrates the placenta and is excreted in the breast milk. The half-life is 3-4 h and is moderately prolonged in renal failure. The total clearance in different reports varies between 400 and 700 ml. min per 70 kg body weight. Renal clearance accounts for approximately 70 % of the total clearance and far exceeds the glomerular filtration rate. Clearance is reduced by the administration of probenecid indicating net tubular secretion in renal elimination of the drug. Urinary recovery of parent compound during the first 24 h varies from 25 to 45 % of the administered oral dose and 53 to 75 % of the intravenous dose. Active metabolites comprise 15 % of the drug in the urine; 15-30 % is recovered from the stool as unchanged drug. Enterohepatic recirculation of ciprofloxacin has been suggested by some studies.

Oral absorption	50-84 %
Presystemic metabolism	little, if any
Plasma half-life	
Range	3-4 h
Volume of distribution	177-217 I
Plasma protein binding	30 %

Concentration- effect relationship

Ciprofloxacin is bactericidal for the majority of pathogenic bacteria at 1-4 x MIC. It continues to produce an antibacterial effect after removal of the drug (post antibiotic effect) on most Gram-negative bacteria and Staphylococcus aureus. The effect of subinhibitory concentration of ciprofloxacin on ultrastructure and virulent factors of different pathogens has not been studied. Examples of MIC values are given in the clinical pharmacology section. An attempt has been made to predict trough concentration of ciprofloxacin In routine therapy. For patients with creatinine clearance 30 ml.min or above age is an important predictor of ciprofloxacin trough concentration the coefficients are not high enough for this to be of great value in adjusting dosage.

Metabolism

Preliminary studies of drug metabolism in human indicate that there are four metabolites if ciprofloxacin desethyl-ciprofloxacin (M_1) sulfociprofloxacin (M_2), oxociprofloxacin (M_3), and formylcirprofloxacin (M_4),. the main metabolites are sulfociprofloxacin and oxociprofloxacin (oxidation at the C3 position of the piperazine ring). Both of which account for about 5 % of an oral dose. All of the metabolites are microbiologically active within the range of the parent compound except M_1 which is substantially less active. The serum concentration of the metabolites are less than 10 % of the ciprofloxacin levels. Even in renal failure. The

total renal elimination of the parent compound and is metabolites is approximately 60% over the first 48 h after a dose. Ciprofloxacin is an inhibitors of cytochrome P 450IA2 activity in vitro and in vivo. A concentration of 500 µM caused a 70 % reduction in the 3-demethylation rate if caffeine.

5.3 Pre-clinical safety data:

Damage to the weight bearing joints of juvenile animal has been observed in studies with Ciprofloxacin and other quinolones. Ciprofloxacin is not a primary nephrotoxic substance but in high doses with restricted urine volume and alkaline urine crystalluria occurs. In eukaryotic cells there was a decrease in scheduled DNA synthesis by ciprofloxacin with MICs of 270, 100, 1000, and 850 $mg.1^{-1}$ in chicken embryo brain and liver clls and in rat thymic and splenic cells, respectively. Comparable values for inhibition of RNA synthesis gave MIC values of 82, 82, 12.5, and 48 $mg.1^{-1}$ ciprofloxacin It causes mechanical damage and elicits a foreign body reaction in the renal tubules.

With the exception of two in vitro tests (unscheduled DNA synthesis and mouse lymphoma cell assay) all in vitro and vivo mutagenicity studies have been negative. In addition, chronic toxicity studies in rats lasting several months failed to produce any evidence that Ciprofloxacin was tumorigenic. No teratogenic or embryolethal effects were observed in cytomegalus monkeys. In mice doses of 0.6, 6 and 20 $mg.kg^{-1}$ body weight intra peritomeally caused a dose dependent clastogenic effect although the effect were not specific for phases of the cell cycle. Central nervous system interaction toxicity between Ciprofloxacin and non-steroidal anti-inflammatory drugs was observed in rats only at therapeutically irrelevant high dose levels.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Maize starch	BP
Sodium methyl paraben	BP
Sodium propyl paraben	BP
Purified talc	BP
Colloidal silicon dioxide	BP
Sodium starch glycolate	BP
Magnesium stearate	BP
Crospovidone	USP
COATING	
Colour instacoat sol white 010	Inhouse
Isopropyl alcohol	BP
Dichloromethane	BP

6.2 Incompatibilities:

None Reported

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6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:
10 tablets packed in one blister. Such blisters packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

6.6 Special precautions for disposal:
None reported.

7. Registrant:

AGOG PHARMA LTD.
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Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane,
India.

8. Manufacturer:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane,
India.

9. Date of revision of the text :