Ciprocin®

Ciprofloxacin USP

Ciprocin® contains Ciprofloxacin, which is a synthetic quinolone 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 rapidly and well absorbed from the G.I. tract. 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

Ciprocin® 250: Each film coated tablet contains Ciprofloxacin USP 250 mg as hydrochloride.
Ciprocin® 500: Each film coated tablet contains Ciprofloxacin USP 500 mg as hydrochloride.
Ciprocin® 750: Each film coated tablet contains Ciprofloxacin USP 750 mg as hydrochloride.
Ciprocin® 250 PFS: Each 5 ml contains ciprofloxacin USP 250 mg as hydrochloride.

INDICATION

Ciprocin® is used in adults for the treatment of urinary tract infections, lower respiratory tract infections, skin and soft tissue infections, bone and joint infections and G.I. infections, caused by susceptible gram-negative and gram-positive aerobic bacteria. It is also used for the treatment of uncomplicated gonorrhoea caused by penicillinase producing Neisseria gonorrhoeae. **Ciprocin**® 750 tablet is specially indicated for the treatment of pseudomonal infections of lower respiratory tract; severe infections particularly due to pseudomonas, staphylococcus and streptococci. **Ciprocin**® 750 is also indicated in surgical prophylaxis.

DOSAGE AND ADMINISTRATION

Ciprocin® may be given orally without regard to meals. Patients receiving **Ciprocin**® should be well hydrated and should be instructed to drink fluids liberally. Because of the risk of crystalluria, it is recommended that the usual dosage of the drug should not be exceeded. For the treatment of urinary tract infections, the usual adult oral dosage of **Ciprocin**® for mild to moderate infections is 250 mg every 12 hours and the usual adult dosage for complicated infections, caused by organisms not highly susceptible to drug is 500 mg every 12 hours. The usual adult oral dosage of **Ciprocin**® for infectious diarrhoea is 500 mg every 12 hours. The usual adult dosage for mild to moderate lower respiratory tract, skin and soft tissue, or bone and joint infections is 500 mg every 12 hours; a dosage of 750 mg every 12 hours may be needed, especially in bone and joint infections or when infections are severe or complicated. In severe infections, particularly due to pseudomonas, staphylococcus and streptococci, the higher dosage of **Ciprocin**® 750 tablet twice daily should be used. For surgical prophylaxis, a single dose of **Ciprocin**® 750 is given 60-90 minutes before the procedure. For the treatment of uncomplicated urethral, endocervical or rectal gonorrhoea caused by penicillinase producing strains of Neisseria gonorrhoeae (PPNG) or non-penicillinase producing strains of the organism, adults should receive a single 500 mg oral dose of **Ciprocin**® followed by oral doxycycline therapy for possible coexisting chlamydia infection. In the treatment of chancroid, 500 mg orally twice daily for 3 days is required. The duration of therapy depends on the type and severity of infection and should be determined by the clinical and bacteriologic response of the patients. For most infections, therapy should be continued for at least 48 hours after the patients become asymptomatic. The usual duration is 1-2 weeks but severe or complicated infections may require more prolonged therapy. **Ciprocin**® therapy may need to be continued for 4-6 weeks or longer for the treatment of bone and joint infections. Infectious diarrhoea generally is treated for 3-7 days, although less prolonged therapy may be adequate. Modification of the usual dosage of **Ciprocin**® generally is unnecessary in patients with creatinine clearance greater than 50 ml/minute. In patients with creatinine clearance of 50 ml /minute or less, doses and/or frequency of administration of **Ciprocin**® should be modified in response to the degree of renal impairment and the site and severity of infection. Adults with creatinine clearance of 30-50 ml/minute can receive 250-500 mg of **Ciprocin**® every 12 hours and adults with creatinine clearance of 5-29 ml/minute can receive 250-500 mg every 18 hours. Patients with severe infections and severe renal impairment may be given 750 mg of **Ciprocin**® every 12 or 18 hours. However, these patients should be monitored carefully and serum Ciprofloxacin concentrations determined periodically.

PRECAUTION AND WARNING

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 convulsion.

INFORMATION FOR PATIENTS

Ciprofloxacin may be taken with or without meals and to drink fluids liberally.
Concurrent administration of ciprofloxacin should be avoided with magnesium / aluminium antacids, or sucralfate or with other products containing calcium, iron or zinc. These products may be taken two hours after or six hours before ciprofloxacin.
Ciprofloxacin should not be taken concurrently with milk or yogurt alone, since absorption of ciprofloxacin may be significantly reduced. Dietary calcium is a part of a meal, however, does not significantly affect the ciprofloxacin absorption.

PREGNANCY, LACTATION AND CHILDREN

Not to be used in pregnancy and nursing stage. Though not recommended for the children where benefit out - weighs risk, a dosage of 7.5 - 15 mg/kg/day in two divided doses can be given.

CONTRAINDICATION

Patients with a history of hypersensitivity to Ciprofloxacin or to other quinolones.

ADVERSE DRUG REACTION

Adverse effects include Risk of Retinal detachment, nausea and other gastrointestinal disturbances, headache, dizziness and skin rashes. Crystalluria has occurred with high doses.

STORAGE CONDITION

Store at room temperature, protected from light.

HOW SUPPLIED

Ciprocin® **250** : Box containing 3x10 tablets in blister pack.
Ciprocin® **500** : Box containing 3x10 tablets in Alu-Alu blister pack.
Ciprocin® **750** : Box containing 2x10 tablets in blister pack.0
Ciprocin® **250 PFS**: Box containing two bottles, one HDPE bottle for active ingredient and another PET bottle for diluent.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH