Ciprol

Ciprofloxacin

COMPOSITION:

Ciprol 500 Tablet: Each coated tablet contains Ciprofloxacin USP 500 mg as hydrochloride.
Ciprol DS Powder for suspension: Each 5 ml contains Clprofloxacin USP 250 mg as hydrocholoride.

PHARMACOLOGY:

Ciprol 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.

INDICATION:

Ciprol 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*.

DOSAGE AND ADMINISTRATION:

Adult Dose:
For oral dosage &suspension:
Urinary Tract infection: Acute uncomplicated: 250 mg twice daily for 3 days; Mild/Moderate: 250 mg twice daily for 7 to 14 days; Severe/Complicated: 500 mg twice daily for 7 to 14 days; *Chronic Bacterial Prostitis* : 500 mg twice daily for 28 days; *Lower Respiratory Tract infection:* Mild/Moderate: 500 mg twice daily for 7 to 14 days, Severe/Complicated : 750 mg twice daily for 7 to 14 days; Acute Sinusitis : 500 mg twice daily for 10 days; *Skin and Skin Structure infection:* Mild/Moderate : 500 mg twice daily for 7 to 14 days, Severe/Complicated : 750 mg twice daily for 7 to 14 days, *Bone and joint infection*: Mild/Moderate 500 mg twice daily for 4 to 6 weeks, Severe/Complicated : 750 mg twice daily for 4 to 6 weeks, *Intra Abdominal Infection:* 500 mg twice daily for 7 to 14 days, *Infectious Diarrhea:* Mild/Moderate/Severe: 500 mg twice daily for 5 to 7 days, *Typhoid Fever :* 500 mg twice daily for 10 days, *Urethral & Cervical Gonococcal Infections*: Uncomplicated: 250 mg Single dose.

Children and adolescents:

RTI & GI infections: Neonate-15mg/kg twice daily, Child (1 month -18 years)-20mg/kg (max 750 mg) twice daily; UTI: Neonate-10 mg/kg twice daily, Child (1 month -18 years)-10mg/kg (max 750 mg) twice daily; *Pseudomonal lower respiratory tract infection in cystic fibrosis:* Child (1 month -18 years) - 20mg/kg (max 750 mg) twice daily; Anthrax (treatment & post exposure prophylaxis): Child (1 month -18 years) - 20mg/kg (max 750 mg) twice daily.

CONTRAINDICATION:

Ciprofloxacin is contraindicated in patients who have hypersensitivity to Ciprofloxacin or other quinolones.

SIDE EFFECTS:

Ciprofloxacin is generally well tolerated. Frequent adverse reactions are- Gastrointestinal disturbance: e.g. nausea diarrhea, vomiting, dyspepsia, abdominal pain. Disturbance of the CNS: e.g. dizziness, headache, tiredness, confusion, convulsions. Hypersensitivity reactions: e.g. skin rashes, pruritus, and possible systemic reactions. Other

possible side effects are - joint pain, light sensitivity, transient increase in liver enzyme (especially in patients with history of liver damage), serum bilirubin, urea or serum creatinine. Arthralgia and myalgia may also occur.

PRECAUTIONS:

Ciprofloxacin should be used with caution in patients with a history of convulsive disorders. Crystalluria related to the use of Ciprofloxacin has been observed only rarely. Patients receiving Ciprofloxacin should be well hydrated to avoid excessive alkalinity of the urine.

USE IN PREGNANCY AND LACTATION:

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.

DRUG INTERACTIONS:

Concurrent administration of Ciprofloxacin with theophylline may lead to elevated plasma concentrations of theophylline. Plasma level of theophylline should be monitored and dosage adjustments made as appropriate. Antacid containing magnesium hydroxide or aluminium hydroxide may interfere with the absorption of Ciprofloxacin & concurrent administration of these agents with Ciprofloxacin should be avoided. Probenecid interferes with renal tubular secretion of Ciprofloxacin and produces an increase in the level of Ciprofloxacin in the serum. As with other broad spectrum antibiotics prolonged use of Ciprofloxacin may result in over growth of non-susceptible organisms. Repeated evaluation of patient\\\\\\\'s conditions and microbial susceptibility testing is essential. If superinfections occur during therapy, appropriate measure should be taken.

OVERDOSAGE:

In case of acute overdose, the patient should be carefully observed and given supporative treatment, including monitoring of renal function. Adequate hydration must be maintained.

PHARMACEUTICAL PRECAUTION:

It should be stored at a cool and dry place, protected from light and moisture.

HOW SUPPLIED:

Ciprol 500 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Ciprol DS Powder for suspension: Each box contains two bottles, one HDPE bottle for active ingredient and another PET bottle for diluent.

Manufactured by:

MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh