ALPHA-CIP TABLETS

(Ciprofloxacin USP)

DESCRIPTION: ALPHA-CIP is a formulation of Ciprofloxacin HCl (USP) in the form of film coated Tablets.

COMPOSITION:

ALPHA-CIP 250mg TABLETS:

Each tablet contains:

Ciprofloxacin HCl equivalent to Ciprofloxacin USP......250mg

ALPHA-CIP 500mg TABLETS:

Each tablet contains:

Ciprofloxacin HCl equivalent to Ciprofloxacin USP......500mg

INTRODUCTION:

PHARMACODYNAMICS:

Inhibits DNA gyrase susceptible organisms. Inhibits relaxation of super coiled DNA and promotes breakage of double stranded DNA.

PHARMACOKINETICS:

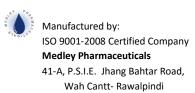
Well absorbed following the oral administration. Bioavailability is 70-80%. The maximum blood concentration is reached within 60-90mins after ingestion. The half life ($t_{1/2}$) is between 3-5hours. Ciprofloxacin is present is high concentration at the sites of infections e.g. in the body fluids and tissues.

INDICATIONS:

Treatment of documented or suspected infections of the lower respiratory tract, sinuses, skin/skin structure, bones/ joints and urinary tract including prostatitis. Due to susceptible bacterial strains, especially indicated for pseudomonal infections and those due to multi drug resistant Gram negative organisms. Chronic bacterial prostatitis, infectious diarrhea, complicated gram negative and anaerobic intra abdominal infections (with metronidazole) due to E.coli (Enteropathic strains), B.fragilis, P.marabilis, K.pneumonia, P. aeruginosa, Campylobacter jejuni or Shigella; approved for acute sinusitis caused by H.influenzae or M.catarrhalis, also used to treat typhoid fever due to Salmonella typhi (although eradication of the chronic thyphoid carrier stage has not been proven), Oeteomyelitis when parentral therapy is not feasible, and sexually transmitted diseases such as uncomplicated cervical and urethral gonorrhea due to Neisseria gonorrhoeae. Used opthalmologically for superficial ocular infections, (Corneal ulcers, and conjunctivitis) due to susceptible strains.

CONTRAINDICATIONS:

Hypersensitivity to Ciprofloxacin and to other Quinolone chemotherapeutics.



DOSAGE:

Oral: 20-30mg/kg/day in 2 divided doses, maximum 1.5g/day.

IV: 15-20mg/kg/day divided every 12 hours.

<u>UTI's</u>: ADULTS: 250mg to 500mg every 12 hrs for 07 -10 Days following oral dose, 250-500mg every 12 hrs for 7-10 days following IV dose, depending on severity of infection and susceptibility.

LOWER RTIs AND SKIN: 500-750mg twice daily for 7-14 days following oral dose and 500mg every 12 hrs

for 7-14 days following IV dose depending on severity and susceptibility.

BONE/ JOINT INFECTIONS: 500-750mg twice daily for 4 to 6 weeks.

INFECTIOUS DIARRHEA: 500mg every 12 hrs for 5-7 days.

TYPHOID FEVER: 500mg every 12 hrs for 10 days.

<u>URETHRAL/ CERVICAL GONOCOCCAL INFECTIONS:</u> 250-500mg as a single dose. (Along with Doxycycline or azithromycin)

DISSEMINATED GONOCOCCAL INFECTIONS: 500mg twice daily to complete 7 days of therapy.

MILD TO MODERATE SINUSITUS: 500mg every 12 hrs for 10 days.

DRUG INTERACTIONS:

Should not be co-administered with iron, sucralfate or antacids containing magnesium, aluminium or calcium. Increased blood levels of theophylline are observed when administered along with Ciprofloxacin and increased creatinine levels are observed when ciprofloxacin is co-administered with Cyclosporin. The concomitant administration of Ciprofloxacin with Warfarin may intensify the action of warfarin. So serum levels should be monitored at regular interval when concomitant use is desirable. Metoclopramide increases the absorption of Ciprofloxacin causing less time to attain peak plasma concentration.

SIDE EFFECTS:

Nausea, Diarrhea, vomiting, dyspepsia, abdominal pain, Flatulence and Anorexia, Dizziness, headache, tiredness, agitation, trembling, peripheral paralgesia, increased in intracranial pressure, confusion, depression, hallucination, skin reaction, pruritus, tachycardia and very rarely hot flashes, migraine, fainting.

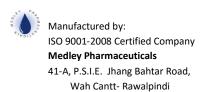
PRECAUTIONS:

Caution in the use of ciprofloxacin should be observed in elderly patients and in patients who have suffered previously from CNS disorders, i.e. previous history of convulsions, reduced cerebral blood flow, in epileptics, caution is necessary in patients having concomitant therapy with theophylline and in patients with impaired renal function .Patient should maintain an adequate fluid intake during treatment with ciprofloxacin.

PACK AND PRESENTATION:

ALPHA-CIP 250mg Tablets: Alu-Alu pack of 1x10's

ALPHA-CIP 500mg Tablets: Alu-Alu pack of 1x10's



STORAGE:

Keep in a cool and dry place. Protect from light. Keep out of the reach of children.