CIPROPYX

CIPROFLOXACIN TABLETS BP 500 MG

COMPOSITION:
Each film coated tablet contains:
Ciprofloxacin Hydrochloride BP eq. to Ciprofloxacin 500 mg
Excipients q.s.
Colour: Titanium Dioxide B.P.

DESCRIPTION:
Cipropyx [Ciprofloxacin] tablets are synthetic broad spectrum antimicrobial agents for oral administration. Cipropyx [Ciprofloxacin hydrochloride], BP, a fluoroquinolone, is the monohydrochloride monohydrate salt of 1-cyclopropy1-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid.

INDICATIONS:
Cipropyx [Ciprofloxacin] is indicated for the treatment of the following infections caused by Cipropyx [Ciprofloxacin] sensitive bacteria:

Lower Respiratory Tract Infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Pseudomonas aeruginosa, Haemophilus influenzae and Haemophilus para-influenzae.

Urinary Tract Infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Serratia marcescens, Proteus mirabilis, Providencia rettgeri, Morganella morganii, Citrobacter diversus, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus epidermidis and Streptococcus faecalis.

Skin and Soft Tissue Infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Morganella morganii, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis and Streptococcus pyogenes.

Gastro-intestinal Infections: Infective diarrhoea caused by E. coli, Campylobacter jejuni, Shigella flexneri and Shigella sonnei.

Bone Infections: Osteomyelitis due to susceptible Gram-negative organisms.

Gonorrhoea: Cipropyx [Ciprofloxacin] is ineffective against Treponema pallidum. In the treatment of infections caused by Pseudomonas aeruginosa, an aminoglycoside must be administered concomitantly.

PHARMACODYNAMICS:
Cipropyx [Ciprofloxacin] is a broad-spectrum anti-infective agent of the fluoroquinolone class. Cipropyx [Ciprofloxacin] has in vitro activity against a wide range of gram-negative and gram-positive microorganisms. The mechanism of action of quinolones, including Cipropyx [Ciprofloxacin], is different from that of other antimicrobial agents such as beta-lactams, macrolides, tetracyclines, or aminoglycosides; therefore, organisms resistant to these drugs may be susceptible to Cipropyx [Ciprofloxacin]. There is no known cross-resistance between Cipropyx [Ciprofloxacin] and other classes of antimicrobials. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian.

The bactericidal action of Cipropyx [Ciprofloxacin] results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair, strand supercoiling repair, and recombination.

PHARMACOKINETICS:
ABSORPTION

Cipropyx [Ciprofloxacin] is well absorbed and peak serum levels are obtained within 1 - 3 hours after oral dosing. The absolute oral bioavailability is approximately 70% with no substantial loss by first pass metabolism.
Food does not impair oral absorption, but may delay the time to peak serum concentrations.
DISTRIBUTION
Distribution of Cipropyx [Ciprofloxacin] is wide and the volume of distribution high, indicating extensive tissue penetration. Cipropyx [Ciprofloxacin] is present in lung, skin, fat, muscle, cartilage and bone. It is also present in active form in the saliva, nasal and bronchial secretions, sputum, skin blister fluid, lymph, peritoneal fluid, prostatic secretions, cerebrospinal fluid and the aqueous humor. High concentrations are achieved in bile.
Protein binding is low and ranges from 20 to 40%.

METABOLISM & EXCRETION
Cipropyx [Ciprofloxacin] is eliminated principally by urinary excretion, but non-renal excretion may account for about a third of elimination and includes hepatic metabolism, biliary excretion and possibly transluminal secretions across the intestinal mucosa. Elimination occurs primarily by the kidneys and mainly during the first 12 hours after dosing. Excretion is virtually complete after 24 hours; about 40% to 50% is excreted in urine as unchanged drug and about 15% as metabolites. Renal clearance is approximately 300 ml/min. The elimination half-life of unchanged Cipropyx [Ciprofloxacin] is 3-5 hours. The elimination kinetics are linear; after repeated dosing at 12 hourly intervals and once steady state has been reached no accumulation occurs.

CONTRAINDICATIONS:
Patients who have shown hypersensitivity to Cipropyx [Ciprofloxacin] or any other quinolones.

PREGNANCY AND LACTATION:
Safety and efficacy in pregnancy and lactation have not been established.
DOSAGE AND DURATION OF TREATMENT:
Cipropyx [Ciprofloxacin] tablets should be swallowed whole with plenty of liquid and may be taken with or without meals.
The dosage range is 250 - 750 mg twice daily. The duration of treatment depends upon the severity and nature of the infection.
For acute uncomplicated cystitis in women, the treatment period is 3 days.
Generally, treatment should be continued for at least 3 days after the signs and symptoms of the infection have disappeared.
For acute infections the usual treatment period is 5 - 10 days. For severe and complicated infections more prolonged therapy may be required.
In streptococcal infections the treatment must last at least 10 days because of the risk of late complications.

Infections of The Lower Respiratory Tract:
Mild to moderate - 250 to 500 mg twice daily; severe or complicated - 750 mg twice daily.
Infections of The Urinary Tract:
Acute uncomplicated cystitis - 250 mg twice daily; severe or complicated -500 mg twice daily.
Infections of The Skin:
Mild to moderate - 500 mg twice daily, severe or complicated -750 mg twice daily.
Infectious Diarrhoea:
500 mg twice daily.
Bone Infections:
Mild to moderate -500 mg twice daily; severe or complicated -750 mg twice daily.
Treatment may be required for 4 - 6 weeks or longer.
Gonorrhoea:
A single dose of 250 mg.
Elderly patients should receive a dose as low as possible; this will depend on the severity of the illness and on the creatinine clearance.
If the patient is unable to take Cipropyx [Ciprofloxacin] tablets, because of the severity of his illness or for other reasons, it is recommended to commence the therapy with intravenous ciprofloxacin. After intravenous administration the treatment can be continued orally or as directed by Physician.

SIDE EFFECTS:
Skin reactions e.g. rashes, pruritus, drug fever.
Nausea, diarrhoea, vomiting, dyspepsia, abdominal pain, flatulence, anorexia in the event of severe and persistent diarrhoea during or after treatment.
DRUG INTERACTIONS:
Concurrent administration of Cipropyx [Ciprofloxacin] with theophylline may lead to elevated plasma 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, plasma levels of theophylline should be monitored and dosage adjustments made as appropriate.
The simultaneous administration of Cipropyx [Ciprofloxacin] and warfarin may intensify the action of warfarin.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In the event of acute, excessive oral overdosage, reversible renal toxicity has been reported. Therefore, apart from routine emergency measures, it is recommended to monitor renal function and to administer Mg or Ca containing antacids which reduce the absorption of Cipropyx [Ciprofloxacin].Only a small amount of Cipropyx [Ciprofloxacin] (<10%) is removed from the body after haemodialysis or peritoneal dialysis. Treatment should be symptomatic and supportive.

STORAGE INSTRUCTIONS:
Store in cool and dry place. Protect from light and moisture.
Keep medicine out of reach of children.

PRESENTATION: 10 Tablets ALU ALU BLISTER PACK

Marketed by:

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