

CIPROQUIN

Ciprofloxacin 750 TABLETS

DESCRIPTION

Ciprofloxacin is a fluoroquinolone, a synthetic broad spectrum antimicrobial agent for oral administration. CIPROQUIN film-coated tablets are available in 750 mg (ciprofloxacin equivalent) strength.

CLINICAL PHARMACOLOGY

Absorption

Ciprofloxacin given as an oral tablet is rapidly and well absorbed from the gastrointestinal tract after oral administration. The absolute bioavailability is approximately 70 – 80 %.

Maximum serum concentrations are attained 1 to 2 hours after oral dosing. Serum concentrations increase proportionately with doses up to 1000 mg. A 750 mg oral dose given every 12 hours has been shown to produce an AUC at steady-state equivalent to that produced by an intravenous infusion of 400 mg given over 60 minutes every 8 hours. A 750 mg oral dose results in a C_{max} similar to that observed with a 400 mg I.V. dose.

Distribution

After oral administration, ciprofloxacin is widely distributed throughout the body. Ciprofloxacin is present in active form in the saliva, lung, nasal and bronchial secretions, mucosa of the sinuses, sputum, skin, fat, muscle, cartilage and bone, blister fluid, lymph, peritoneal fluid, bile and prostatic secretions..

Metabolism

Four metabolites have been identified in human urine which together account for approximately 15% of an oral dose. The metabolites have antimicrobial activity, but are less active than unchanged ciprofloxacin.

Excretion

The serum elimination half-life in subjects with normal renal function is approximately 4 hours. Approximately 40 to 50% of an orally administered dose is excreted in the urine as unchanged drug.

SPECIAL POPULATIONS

In patients with reduced renal function, the half-life of ciprofloxacin is slightly prolonged. Dosage adjustments may be required.

In preliminary studies in patients with stable chronic liver cirrhosis, no significant changes in ciprofloxacin pharmacokinetics have been observed.

MICROBIOLOGY

CIPROQUIN (ciprofloxacin) has in vitro activity against a wide range of gram-negative and gram-positive micro-organisms. The bactericidal action of ciprofloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair, and recombination. The mechanism of action of ciprofloxacin is different from that of penicillins, cephalosporins, aminoglycosides, macrolides, and tetracyclines; therefore, micro-organisms resistant to these classes of drugs may be susceptible to ciprofloxacin. There is no known cross-resistance between ciprofloxacin and other classes of antimicrobials.

Ciprofloxacin has been shown to be active against most strains of the following micro organisms:

Aerobic gram-positive micro-organism

Staphylococcus aureus (methicillin-susceptible strains only), Streptococcus pneumoniae (penicillin-susceptible strains only), Streptococcus pyogenes, Enterococcus faecalis (Many strains are only moderately susceptible.), Staphylococcus epidermidis (methicillin-susceptible strains only), Staphylococcus saprophyticus.

Aerobic gram-negative micro-organisms

Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Salmonella typhi, Serratia marcescens, Neisseria gonorrhoeae, Morganella morganii, Shigella boydii, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Enterobacter cloacae, Campylobacter jejuni, Citrobacter diversus, Citrobacter freundii, Proteus mirabilis, Proteus vulgaris, Providencia rettgeri, Providencia stuartii, Bacillus anthracis.

Miscellaneous micro-organisms

Acinetobacter Iwoffii, Pasteurella multocida, Aeromonas hydrophila, Salmonella enteritidis, Edwardsiella tarda, Vibrio cholerae, Vibrio parahaemolyticus, Vibrio vulnificus, Enterobacter aerogenes, Klebsiella oxytoca, Legionella pneumophila, Yersinia enterocolitica.

INDICATIONS AND USAGE

- *Lower Respiratory Tract Infections* caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, or Streptococcus pneumoniae. Also, Moraxella catarrhalis for the treatment of acute exacerbations of chronic bronchitis.
- *Bone and Joint Infections* caused by Enterobacter cloacae, Serratia marcescens, or Pseudomonas aeruginosa.
- *Skin and Skin Structure Infections* caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Morganella morganii, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus aureus (methicillin-susceptible), Staphylococcus epidermidis, or Streptococcus pyogenes.
- *Typhoid Fever (Enteric Fever)* caused by Salmonella typhi.
- *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, Staphylococcus saprophyticus, or Enterococcus faecalis.
- *Acute Uncomplicated Cystitis* in females caused by Escherichia coli or Staphylococcus saprophyticus.
- *Chronic Bacterial Prostatitis* caused by Escherichia coli or Proteus mirabilis.
- *Acute Sinusitis* caused by Haemophilus influenzae, Streptococcus pneumoniae, or Moraxella catarrhalis.
- *Complicated Intra-Abdominal Infections* (used in combination with metronidazole) caused by Escherichia coli, Pseudomonas aeruginosa, Proteus mirabilis, Klebsiella pneumoniae, or Bacteroides fragilis.
- *Infectious Diarrhoea* caused by Escherichia coli (enterotoxigenic strains), Campylobacter jejuni, Shigella boydii, Shigella dysenteriae, Shigella flexneri or Shigella sonnei when antibacterial therapy is indicated.
- *Uncomplicated cervical and urethral gonorrhoea* due to Neisseria gonorrhoeae.

CONTRAINDICATIONS

CIPROQUIN is contraindicated in persons with a history of hypersensitivity to ciprofloxacin or any member of the quinolone class of antimicrobial agents.

DRUG INTERACTION

- As with some other quinolones, concurrent administration of ciprofloxacin with theophylline may lead to elevated serum concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline-related adverse reactions.
- Concurrent administration of a quinolone, including ciprofloxacin, with magnesium / aluminium antacids, sucralfate or products containing calcium, iron, or zinc may substantially decrease its absorption, resulting in serum and urine levels considerably lower than desired.
- Quinolones, including ciprofloxacin, have been reported to enhance the effects of the oral anticoagulant warfarin or its derivatives.
- Renal tubular transport of methotrexate may be inhibited by concomitant administration of ciprofloxacin potentially leading to increased plasma levels of methotrexate. This might increase the risk of methotrexate associated toxic reactions. Therefore, patients under methotrexate therapy should be carefully monitored when concomitant ciprofloxacin therapy is indicated.
- Metoclopramide significantly accelerates the absorption of oral ciprofloxacin resulting in shorter time to reach maximum plasma concentrations. No significant effect was observed on the bioavailability of ciprofloxacin.

DOSAGE AND ADMINISTRATION:

One tablet every 12 hours for 7-14 days

PACKING

A box of 10 tablets (1 strip).

Produced by:

Unipharma, El-Obour City, EGYPT