

Prescribing Information

Ultraflox[®]-500

COMPOSITION:

Each film coated tablet contains:
Ciprofloxacin Hydrochloride USP
Equivalent to Ciprofloxacin USP 500 mg.

PHARMACOLOGICAL CLASSIFICATION:

Ciprofloxacin is a DNA gyrase inhibitor used as an antibacterial agent.

CHEMISTRY:

1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid.

PHARMACOLOGY:

Ciprofloxacin is a new fluoroquinolone antimicrobial agent with potent activity against a broad spectrum of gram-positive and Gram-negative bacteria, including *Pseudomonas aeruginosa*, Enterobacteriaceae and *Neisseria* spp.

In the gastrointestinal tract Ciprofloxacin markedly reduces or eradicates Enterobacteriaceae, with a less dramatic effect against Staphylococci and enterococci and little effect on the anaerobic microflora. There is little evidence of overgrowth or super infection.

Predclinical toxicology studies, including ophthalmological examination, in various animal species reveal, no significant evidence of toxicity. In young rats and dogs Ciprofloxacin does cause articular damage, but the clinical implications, if any are unknown.

INDICATIONS:

Ciprofloxacin has been effective, but not necessarily the drug of first choice in the treatment of the following infections.

1. Urinary tract infections
2. Gonorrhoea and certain other sexually transmitted diseases
3. Bacterial gastrointestinal infections
4. Osteomyelitis
5. Infection of respiratory tract
6. Skin structure infections
7. Prophylaxis in granulocytopenic patients and other possible uses
8. Other infections like types of hospital acquired infections caused by multiple-resistant organisms.

CONTRA INDICATIONS:

Ciprofloxacin should not be given in patients with known hypersensitivity to Ciprofloxacin or other quinolone antibiotics.

ADVERSE REACTIONS:

In patients treated with Ciprofloxacin, the most frequent reactions were from the gastrointestinal system (nausea, diarrhea, vomiting, dyspepsia), central nervous system (dizziness, headache, nervousness) and skin rash, (photosensitivity). Eosinophilia, leucopenia and thrombocytopenia have also been related to Ciprofloxacin.

WARNING & PRECAUTIONS:

Ciprofloxacin should be used with caution in patients with epilepsy or a history of CNS disorders. Since Ciprofloxacin and related fluoroquinolones have, like nalidixic acid, been shown to cause degenerative changes in weight bearing joints of young animals, it is been suggested that these compounds should not be used in children, adolescents, pregnant women or breast feeding mothers. Exposure to strong sunlight or sunlamps should also be avoided. The manufacturers recommend that Ciprofloxacin should not be administered by mouth within 4 hours of taking preparations containing magnesium, aluminium or iron salts.

DOSAGE:

Ciprofloxacin is given by mouth as the hydrochloride or in severe infections, by intravenous infusion over 30 to 60 minutes as the lactate.

The adult oral dose of Ciprofloxacin ranges from 250 to 750 mg twice daily depending on the severity and nature of the infection.

The usual intravenous dose is 100 to 400 mg twice daily. A single oral dose of 500 mg is suggested for the treatment of gonorrhoea (by WHO) and also for meningococcal meningitis prophylaxis. Ciprofloxacin is not recommended in children and adolescents. Doses of 7.5 to 15 mg per kg of body-weight daily by mouth or 5 to 10 mg per kg daily intravenously have been suggested.

INSTRUCTIONS FOR THE PATIENTS:

Ciprofloxacin should not be used for children and adolescents upto 18 years since all quinolone derivatives cause arthropathy in experimental animals.

OVERDOSAGE:

In the event of acute overdosage, the patient should be carefully observed and given supportive treatment. Adequate hydration must be maintained. Only a small amount of Ciprofloxacin (10%) is removed from the body after hemodialysis or peritoneal dialysis.

PRESENTATION:

ULTRAFLOX - 500 Tablets are packed in a blister of 10's.

STORAGE:

Store in a cool, dry place.

® Registered Trade Mark

Lit-1066/A

Manufactured by:

BAL PHARMA LIMITED

21 & 22, Bommasandra Industrial

Area, Bangalore - 560 059, INDIA.

Front

80 X 130 mm

Back