

CIPROLAB[®]

Ciprofloxacin Tablets

COMPOSITION:

Ciprolab[®] 250

Each film coated tablet contains: Ciprofloxacin HCl BP equivalent to Ciprofloxacin 250 mg.

Ciprolab[®] 500

Each film coated tablet contains: Ciprofloxacin HCl BP equivalent to Ciprofloxacin 500 mg.

INDICATIONS:

Ciprolab[®] tablets are used in the treatment of uncomplicated and complicated, acute and chronic conditions /infections caused by or associated with pathogens sensitive to ciprofloxacin. These infections/conditions include, biliary-tract infections, bone and joint infections, brucellosis, animal bites, cat scratch disease, chancroid, gastro-enteritis (including travellers' diarrhoea and cholera, Salmonella enteritis and shigellosis) gonorrhoea, meningitis, peritonitis, otitis externa, Q fever, lower respiratory tract infections, urinary tract infections, spotted fevers, typhoid and paratyphoid fever.

DOSAGE AND ADMINISTRATION:

Ciprolab[®] tablets are administered by the oral route.

TREATMENT REGIMEN:

The duration of treatment depends on the severity of illness and on the clinical and bacteriological course. The therapy should in principle be continued systematically for at least 3 days after disappearance of the clinical symptoms. In streptococcal infections, the treatment must be continued for at least 10 days because of the risk of late complications.

| Diagnosis | Dosage | Duration of Therapy |
|--|------------------------|---------------------|
| Acute gonorrhoea and acute uncomplicated cystitis | 250 - 500 mg | Single dose |
| Uncomplicated upper and lower urinary tract infections | 250 mg twice daily | 7 days |
| Complicated urinary tract infections | 250-500 mg twice daily | 7 days |
| Respiratory tract infections (e.g bronchitis) | 250-500 mg twice daily | 7 days |
| Prophylaxis of meningococcal meningitis | 500 mg | Single dose |
| Other infections/conditions (see the indications) | 500 mg twice daily. | 7 - 14 days |

PRECAUTIONS, WARNINGS AND ADVERSE EFFECTS:

- Ciprolab[®]** is contraindicated in patients with known hypersensitivity to ciprofloxacin or other quinolone chemotherapeutics.
- Ciprolab[®]** is not generally recommended for use in children and adolescents and during pregnancy and in breast feeding mothers.
- The preparation should be used with caution in elderly patients, those with a history of stroke, convulsions, damage to the CNS and in epileptic patients.

- Prolonged use of the preparation may result in overgrowth of non-susceptible pathogens, including fungi and in such cases appropriate medication should be instituted immediately.
- The most frequent side effects occasionally associated with the preparation include, nausea, diarrhoea, vomiting, digestive disturbances, abdominal pain, flatulence, anorexia, dizziness, headache, tiredness, tremor and skin reactions such as pruritus.
- Other rare toxic effects that have been reported with the use of ciprofloxacin are arthropathy, allergic interstitial nephritis, allergic nephropathy, acute renal failure especially in overdose and possible fulminant hepatic failure. Convulsions could also occur both in patients with epilepsy and in those with no previous history of convulsions.
- Fluroquinolones including Ciprofloxacin are associated with increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients over 60 years of age, in patients taking corticosteroid drugs and in patients with kidney, heart or lung transplants.

PHARMACOLOGY:

Ciprolab[®] tablets contain ciprofloxacin, a fluorinated 4-quinolone or fluoroquinolone antibacterial agent with a wide spectrum of activity. Ciprofloxacin is bactericidal and acts by inhibiting the A subunit of DNA gyrase (topoisomerase) which is essential in the reproduction of bacterial DNA. DNA gyrase is responsible for the continuous introduction of negative supercoils into DNA. This is an ATP-dependent reaction that requires that both strands of the DNA be cut to permit passage of a segment of DNA through the break; the break is then resealed. Inhibition of this enzyme causes DNA tangling during replication hence terminates the process. Ciprofloxacin does not generally exhibit parallel resistance to any other antibiotic outside the gyrase inhibitor group, thus is highly effective against bacteria which are resistant to aminoglycosides, penicillins, cephalosporins and tetracyclines.

On oral administration, Ciprofloxacin is rapidly and well absorbed from the gastrointestinal tract and attains peak plasma concentration in 1 to 2 hours after a dose of 500 mg. Bioavailability after an oral dose is approximately 70 % and the plasma half-life is about 3.5 to 4.5 hours and this may be prolonged in severe renal failure to about 8 hours. Ciprofloxacin is eliminated principally by urinary excretion, but non-renal clearance may account for an about a third of elimination and includes hepatic metabolism, biliary excretion, and possibly transluminal secretion across the intestinal mucosa.

ANTIMICROBIAL SPECTRUM AND RESISTANCE:

Ciprolab[®] tablets are active against the following bacteria, *Escherichia coli*, *Citrobacter spp*, *Enterobacter aerogenes*, *Klebsiella pneumoniae*, *Proteus spp*, *Providencia spp*, *Salmonella spp*, *Serratia spp*, *Shigella spp*, *Yersinia spp*, *Pseudomonas aeruginosa*, *Haemophilus ducreyi*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Neisseria gonorrhoeae*, *Acinetobacter spp*, *Campylobacterium spp*, *Pasteurella multocida*, *Vibrio spp*, *Corynebacterium spp*, *Listeria monocytogenes* and *Brucella melitensis*.

Ciprolab[®] tablets are also active against staphylococci including penicillinase-producing strains and against some methicillin resistant strains. Resistance has emerged during treatment with ciprofloxacin mostly with the following organisms, *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

There is complete cross-resistance between ciprofloxacin and other fluoroquinolones and nalidixic acid.

LEGAL CATEGORY: Prescription Only medicines (POM).

STORAGE CONDITIONS: Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

PRESENTATION:

Ciprolab[®] 500mg available in packs of 1 x 10's, 5 x 10's, 10 x 10's & bulk pack of 500's & 1000's.

Ciprolab[®] 250mg available in packs of 1 x 10's, 5 x 10's, 10 x 10's & bulk pack of 500's & 1000's

SHELF LIFE: As per the product label

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LICENCE HOLDER: LABORATORY & ALLIED LTD.

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