

Rocipro[®]

Ciprofloxacin
Film Coated Tablets

Composition

Rocipro[®] 500: Each film coated tablet contains Ciprofloxacin Hydrochloride USP 555 mg equivalent to Ciprofloxacin 500 mg.

Rocipro[®] 750: Each film coated tablet contains Ciprofloxacin Hydrochloride USP 832.50 mg equivalent to Ciprofloxacin 750 mg.

Mechanism of Action

Rocipro[®] containing ciprofloxacin is a synthetic quinolone anti-infective agent. Ciprofloxacin has broad spectrum of activity. It is active against most gram-negative aerobic bacteria including Enterobacteriaceae and *Pseudomonas aeruginosa*. Ciprofloxacin is also active against gram-positive aerobic bacteria including penicillinase producing, non penicillinase producing, and methicillin resistant staphylococci, although many strains of streptococci are relatively resistant to the drug. The bactericidal action of ciprofloxacin results from interference with the enzyme DNA gyrase needed for the synthesis of bacterial DNA.

Following oral administration it is rapidly and well absorbed from the G.I. tract. It is widely distributed into the body tissues and fluids. The half life is about 3.5 hours. About 30% to 50% of an oral dose of ciprofloxacin is excreted in the urine within 24 hours as unchanged drug and biologically active metabolites.

Indications

Ciprofloxacin is indicated for the treatment of single infection or mixed infections caused by two or more susceptible organisms. It can also be used for infections caused by organisms resistant to other antibiotics including Aminoglycosides, Penicillins and Cephalosporins.

As antibacterial concentrations of ciprofloxacin are obtained in serum and body tissues as well as in the urine following administration by mouth, Ciprofloxacin has been suggested for use in the treatment of a wide range of infections caused by susceptible organisms including infections of the urinary, respiratory and gastrointestinal tracts, gonorrhoea and septicæmia. The extensive tissue penetration of ciprofloxacin combined with its enhanced antibacterial activity (including antipseudomonal activity), enables Ciprofloxacin to be used alone (pending sensitivity results) or in combination with an Aminoglycoside or with beta lactam antibiotics for instance when severe neutropenia is present or with an antibiotic active against anaerobes where the presence of bacteroides fragilis is suspected. **Rocipro[®]** is indicated for the treatment of the following infections caused by sensitive bacteria:

Severe systemic infections: e.g. septicæmia, bacteraemia, peritonitis, infections in immunosuppressed patients with haematological or solid tumors and in patients in intensive care unit with specific problems such as infected burns.

Respiratory tract infections: Lobar and bronchopneumonia, acute and chronic bronchitis, acute exacerbation of cystic fibrosis, bronchiectasis, empyema.

Urinary tract infections: Uncomplicated and complicated urethritis, cystitis, pyelonephritis, prostatitis, epididymitis.

Skin and soft tissue infections: e.g. infected ulcers, wound infections, abscesses, cellulitis, otitis externa, erysipelas, infected burns.

Gastro-intestinal infections: e.g. enteric fever, infective diarrhea.

Infection of the biliary tract: e.g. cholangitis, cholecystitis, empyema of the gall bladder.

Intra abdominal infections: e.g. peritonitis, intra abdominal abscesses.

Bone and joint infection: Osteomyelitis, septic arthritis.

Pelvic infections: e.g. salpingitis, endometritis, pelvic inflammatory diseases.

Eye, ear, nose and throat infections: e.g. otitis media, sinusitis, mastoiditis, tonsillitis.

Gonorrhoea: Including urethral, rectal and pharyngeal gonorrhoea caused by beta-lactamase producing organism or organisms moderately sensitive to penicillin.

Dosage And Administration

General dosage recommendations: The dosage of the ciprofloxacin is determined by the severity and type of infection, the sensitivity of the causative organism(s) and the age, weight and renal function of the patient.

Adults: The dosage range for adults is 100-750 mg twice daily.

In infections of the lower and upper urinary tract (depending on severity): 250-500 mg twice daily.

In respiratory tract infections: 250-500mg twice daily for both upper and lower respiratory tract infections, depending on the severity. For the treatment of known Streptococcus pneumonia infection, the recommended dosage is 750 mg twice daily.

In gonorrhoea: A single dose of 250 or 500 mg.

In the majority other infections, 500-750 mg twice daily should be administered.

Cystic fibrosis: In adults with pseudomonal infections of the lower respiratory tract, the normal dose is 750 mg twice daily.

As the pharmacokinetics of Ciprofloxacin remain unchanged in patients with cystic fibrosis, the low body weight of these patients would be fallen into consideration when determining dosage.

Impaired renal function: Dosage adjustment is not usually required except in patients with severe renal impairment, (serum creatinine > 265 micro mol/l or creatinine clearance < 20 ml/minute). If adjustment is necessary, this may be achieved by reducing the total daily dose by half, although monitoring of drug serum levels provide the most reliable basis for dose adjustment.

Elderly: Although higher ciprofloxacin serum levels are found in the elderly, no adjustment of dosage is necessary.

Adolescents and children: As with other drugs in its class, ciprofloxacin has been shown to cause arthropathy in weight bearing joints of immature animals. Although the relevance of this to man is unknown, its use in children, growing children and growing adolescents is not recommended. However, where the benefit of using ciprofloxacin is considered to outweigh the potential risk, the dosage should be 7.5-15 mg/kg/day depending upon the severity of infection, administered in two divided doses.

Duration of treatment: The duration of treatment depends upon the severity of infection, clinical response and bacteriological findings.

For acute infections the usual treatment period is 5 to 10 days with **Rocipro[®]** tablets. Generally treatment should be continued for three days after the signs and symptoms of the infection have disappeared.

Use In Pregnancy And Lactation

Reproduction studies performed in mice, rats and rabbits using parenteral and oral administration did not reveal any evidence of teratogenicity, impairment of fertility or impairment of peri/post natal development. However as with other quinolones, Ciprofloxacin has been shown to cause arthropathy in immature animals and therefore its use during pregnancy is not recommended. Studies in rats have indicated that Ciprofloxacin is secreted in milk, administration to nursing mothers is thus not recommended.

Precaution And Warning

It should be used with caution in patients with suspected or known CNS disorders such as arteriosclerosis or epilepsy or other factors which predispose to seizures and convulsion.

Information For Patients

- Ciprofloxacin may be taken with or without meals and to drink fluids liberally.
- Concurrent administration of ciprofloxacin should be avoided with magnesium/aluminium antacids, or sucralfate or with other products containing calcium, iron and zinc. These products may be taken two hours after or six hours before ciprofloxacin.
- Ciprofloxacin should not be taken concurrently with milk or yogurt alone, since absorption of ciprofloxacin may be significantly reduced. Dietary calcium is a part of a meal, however, does not significantly affect the ciprofloxacin absorption.

Contraindication

Patients with a history of hypersensitivity to ciprofloxacin or to other quinolones.

Adverse Reaction

Adverse effects include nausea and other gastrointestinal disturbance, headache, dizziness and skin rashes. Crystalluria has occurred with high doses.

How Supplied

Rocipro[®] 500: Box containing 3X10's tablets in blister pack.

Rocipro[®] 750: Box containing 2X8's tablets in blister pack.

Storage

Store in a cool and dry place below 30 °C. Protect from light.

Medicine: Keep out of reach of children



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