For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory. xxxxxxxx-8883

QUINTOR

(Ciprofloxacin 250 mg & 500 mg Tablets)

Quintor is a synthetic, fluoroquinolone derivative with bactericidal activity against a wide range of Gram-negative and Gram-positive organisms. It is indicated in infections by a number of Gram-negative and Gram-positive microbes, such as, respiratory tract infections, urinary tract infections, skin and soft tissue infections, osteomyelitis and sexually transmitted diseases caused by susceptible microorganisms.

MODE OF ACTION :

In-vitro studies have shown that the antibacterial action of Quintor results from the inhibition of bacterial DNA gyrase. Quintor does not cross-react with penicillins, cephalosporins, aminoglycosides or tetracyclines and organisms resistant to these antibiotics are generally sensitive to Quintor.

ANTIBACTERIAL EFFECTS :

Quintor is active against the following Gram-negative and Gram-positive organisms in vitro : E. coli. Shigella, Salmonella, Citrobacter, Klebsiella, Enterobacter, Serratia, Proteus (indole-positive and indole-negative), Providencia, Vibrio, Aeromonas, Pasteurella, Haemophilus, Gardnerella, Campylobacter, Pseudomonas, Legionella, Neisseria, Acinetobacter, Brucella, Streptococcus (including S. faecalis), Staphylococcus, Corynebacterium, Fusobacterium, Actinomyces, Mycoplasma, Yersinia, Clostridium and Chlamydia. In-vitro studies have shown that additive activity often results when Quintor is combined with other antibacterial agents. Synergism is observed occasionally but antagonism is rarely seen.

CLINICAL PHARMACOLOGY :

After oral administration of single doses of Quintor, peak serum concentrations of 0.28 to 5.92mg/L were reached within 0.5 to 2 hours. Mean peak concentrations increased in proportion to the dose within the normal therapeutic range of 250mg to 750mg twice a day. Multiple dose administration for upto 8 days in healthy volunteers did not produce significant drug accumulation. Food delays the absorption of Quintor however, simultaneous administration of antacids containing magnesium hydroxide/aluminium hydroxide with Quintor reduces its bioavailability. The absolute bioavailability of oral Quintor averages between 69 and 85%. The tissue concentrations achieved are atleast as high as the serum concentrations for most tissues. Quintor was approximately 16 to 40% bound to plasma proteins. The elimination half-life of Quintor after single and multiple doses ranges from 3.4 to 6.9 hours following oral administration. Pharmacokinetics of Quintor are altered in patients with renal dysfunction and dosage adjustment may be required in such subjects. Unchanged Quintor is the major moiety in both urine (45%) and feces (25%). Small amounts of 4 metabolites are present in urine and feces and all of them possess some antibacterial activity. However, this is less than that of Quintor.

INDICATIONS :

Respiratory Tract Infections : Acute bronchitis, acute exacerbation of cystic fibrosis, empyema, lung abscess, infected bronchiectasis, pneumonia, sinusitis and mastoiditis. Urinary Tract Infections : Acute pyelonephritis, complicated urinary tract infections, recurrent UTI and infections caused by multi-drug resistant organisms. Skin and Soft Tissue Infections : Infected wounds and postoperative infections caused by Gram-negative organisms e.g., Enterobacteriaceae, Ps. aeruginosa and resistant staphylococcal infections. Severe Systemic Infections : Septicemia, bacteremia and infections in immunocompromised host. Surgical Infections : Intra-abdominal abscess, peritonitis, cholangitis and cholecystitis. Gynaecological Infections : Severe pelvic infections casued by susceptible organisms. Gastrointestinal Tract Infections : Typhoid fever, including carrier stage and resistant Salmonella typhi infections. Bone and Joint Infections : Since adequate levels of ciprofloxacin are achieved in bone it is useful for treatment of acute and chronic osteomyelitis. Sexually Transmitted Disease : Uncomplicated Gonococcal infections including those caused by beta-lactamase resistant strains and chancroid caused by H. ducreyi.

CONTRAINDICATIONS :

Quintor is contraindicated in patients who have shown hypersensitivity to quinolones and in children, except where the benefits of treatment exceed risks.

WARNINGS AND PRECAUTIONS :

Quintor should be used with caution in patients with convulsive disorders. Increased serum levels of theophylline have been observed following concurrent administration with Quintor. Caution is therefore advised and an appropriate reduction in the dosage of theophylline may be needed. Crystalluria has rarely been observed. However, in order to avoid this, the patient should be well hydrated and excessive alkalinity of the urine should be avoided.

USE IN PREGNANCY, LACTATION AND CHILDREN :

Use of Quintor during pregnancy is not recommended. As Quintor is secreted in milk, its administration to nursing mothers is also not recommended. Quintor has been shown to cause arthropathy in weight bearing joints of immature animals and so, its use in children and growing adolescence is not recommended. However, where the benefit of using Quintor is considered to out-weigh this potential risk, the dosage should be 7.5 to 15mg/kg/day administered in two divided doses/day depending upon the severity of infections.

ADVERSE EFFECTS :

The following adverse effects have occasionally been observed: Gastrointestinal disturbances like nausea, diarrhoea, vomiting, dyspepsia, abdominal pain; disturbances of the central nervous system such as insomnia, headache and giddiness; hypersensitivity reactions e.g. skin rashes, pruritus, transient increases in liver enzyme values may occur particularly in patients with previous liver damage.

DRUG INTERACTIONS :

1. Probenecid delays excretion of Quintor.
2. Antacids containing magnesium hydroxide and or aluminium hydroxide may interfere with the absorption of Quintor resulting in lower serum and urine levels.

DOSAGE AND ADMINISTRATION :

The dosage of Quintor is determined by the severity and type of infections, the sensitivity of the causative organisms and the age, weight and renal function of the patient. Quintor should be swallowed whole with liquid and the dosage range for adult patient is 250mg-750mg twice daily. In infections of the lower and upper urinary tract, 250mg-750mg twice daily is recommended depending on severity of infection. However, for uncomplicated urinary tract infections, 250mg b.i.d. may suffice. In respiratory tract infections, about 500mg-750mg twice daily for both upper and lower respiratory tract infections, depending on severity are recommended. For the treatment of known Streptococcus pneumoniae infection, the recommneded dosage is 750mg twice daily; in gonorrhoea, a single dose of 250mg is sufficinent for complete cure. In the majority of other infections, 500mg-750mg twice daily should be administered. In patients of cystic fibrosis with Pseudomonal infections of lower respiratory tract, the usual dose is 750mg twice daily. For pelvic inflammatory disease and septicemia, 500mg to 750mg every 12 hours are recommended. In impaired renal function, the daily dose of Quintor is recommended to be reduced to half the usual recommended dose (creatinine clearance less than 20ml/minute). In elderly patients the same doses of Quintor which are recommended for adult patients may be administered. The duration of treatment with Quintor depends upon the severity of infection, clinical response and bacteriological findings. For acute infections the usual treatment period is 5 to 10 days with Quintor tablets. Generally, treatment should be continued for atleast 3 days after the signs and symptoms of the infection have disappeared.

OVERDOSAGE :

Routine measures such as gastric lavage should be performed as soon as possible after ingestion of a overdose of Quintor.

PRESENTATION :

Quintor is available as film coated tablets of 250 mg in blister strip of 10 tablets and 500 mg in blister strip 4 & 10 tablets.

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