

QUINTOR

(Ciprofloxacin Injection USP 200 mg/100 ml)

DESCRIPTION

Quintor is a synthetic fluoroquinolone derivative with bactericidal activity against a wide range of organisms. It is indicated in acute infections by a number of Gram-negative and Gram-positive microbes. Quintor infusion is a drug of choice in life threatening infections due to susceptible organisms in immunocompromised patients.

CLINICAL PHARMACOLOGY

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.

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, Gardenerella, 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. The mean peak serum concentration following single I.V. doses of 100, 150, and 200mg Quintor Infusion were 1.4, 2.0 and 3.2mg/litre respectively. The mean terminal elimination half-life was about 180 minutes after 50mg dose and 185 minutes after 100mg dose. Quintor has a high volume of distribution suggesting effective diffusion into the extravascular space. The tissue concentrations achieved are at least as high as the serum concentrations for most tissues. Quintor is 16 to 40% bound to plasma proteins. Pharmacokinetics of Quintor are altered in patients with renal dysfunction. Unchanged Quintor is the major moiety in both urine and faeces.

INDICATIONS

Quintor infusion is indicated in the treatment of acute respiratory tract infections, acute urinary tract infections, acute skin and soft tissue infections, severe systemic infections such as septicemia, bacteremia and acute infections in immunocompromised host. Severe surgical infections such as intra-abdominal abscess, acute peritonitis, cholangitis and acute cholecystitis, severe pelvic infection, acute gastrointestinal tract infections, acute osteomyelitis and severe sexually transmitted disease such as gonorrhoea.

CONTRAINDICATIONS

Quintor infusion is contraindicated in patients who have shown hypersensitivity to quinolones and in children and adolescents, during pregnancy and breast feeding mothers.

PRECAUTIONS

Quintor should be used with caution in epileptics and patients with a history of CNS disorders and only if benefit of treatment are considered to outweigh the risk of possible CNS side effects. Quintor could result in an impairment of patient's ability to drive or operate machinery particularly in conjunction with alcohol. Crystalluria has rarely been observed and to avoid this the patients should be well hydrated and excessive alkalinity of the urine should be avoided. Probenecid delays excretion of Quintor.

ADVERSE REACTIONS

Quintor is well tolerated. However, gastrointestinal disturbances and CNS disturbances such as insomnia, headache and giddiness have occasionally been observed. Transient increase in liver enzyme values may occur.

DRUG INTERACTIONS

Increased plasma levels of theophylline have been observed following concurrent administration with Quintor. It is recommended that the dose of theophylline be reduced and plasma levels of theophylline monitored. Prolongation of bleeding time has been reported during concomitant administration of Quintor and anticoagulants. Transient increases in serum creatinine have been seen following concomitant administration of Quintor and cyclosporin. Therefore monitoring of serum creatinine levels is advisable. It is recommended that opiate premedicants or regional anaesthetic agents are not administered concomitantly with Quintor when used for surgical prophylaxis.

DOSAGE AND ADMINISTRATION

The dosage of Quintor Infusion is determined by the severity and type of infections, the sensitivity of the causative organisms and the age, and renal function of the patient. Quintor is compatible with all i.v. fluids. Quintor may be administered by short term infusion over a period of 30-60 minutes. The solution should not be used if it is found discoloured or if it contains any suspended particles. The usual recommended dosage of Quintor in acute urinary tract infections is 100mg twice daily by slow i.v. infusion. In acute respiratory tract infections, Quintor Infusion is given in dose of 200mg twice daily by slow i.v. infusion. In gonorrhoea, single dose of 100mg i.v. is sufficient. In majority of other infections, 200mg Quintor should be administered by slow i.v. infusion every 12 hours daily. In patients with severe renal impairment (Creatinine clearance less than 20ml/min) the total daily dose of Quintor Infusion should be reduced to half of the usual recommended dose.

The usual treatment period of acute infections is 5 to 7 days with Quintor Infusion. Initial i.v. administration may be followed by treatment with oral Quintor whenever necessary.

PHARMACEUTICAL PRECAUTIONS:

As Quintor is light-sensitive, the bottles should be protected from light on removal from the cardboard container. Quintor Infusion should be used within 24 hours of removal from container.

The recommended pH of the infusion is to be 3.9-4.5 as otherwise the preparation shall be incompatible with injection chemically or physically unstable at this pH it is suggested that drug products with higher pH should not be added to ciprofloxacin injection.

INCOMPATIBILITY :

Quintor is incompatible with aminophylline and with clindamycin.

STORAGE :

Store below 30°C, Protect from light.

Do not freeze

PRESENTATION

Quintor Infusion is supplied in bottle of 100ml, each 100ml containing ciprofloxacin lactate equivalent to ciprofloxacin 200mg.



Manufactured by :
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