**QUINTOR INFUSION**

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**

Abbreviated Prescribing information for QUINTOR INFUSION [Ciprofloxacin Injection U.S.P. 200 mg/100 ml] [Please refer the complete prescribing information available at www.torrentpharma.com]

**PHARMACOLOGICAL PROPERTIES**: As a fluoroquinolone antibacterial agent, the bactericidal action of ciprofloxacin results from the inhibition of both type II topoisomerase (DNA-gyrase) and topoisomerase IV, required for bacterial DNA replication, transcription, repair and recombination. **INDICATION:** For 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 cholecystilits, severe pelvic infection, acute gastrointestinal tract infections, acute osteomyelitis and severe sexually transmitted disease such as gonorrhea. **DOSAGE AND ADMINISTRATION:** 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. Urinary tract infection: 100mg twice daily, Respiratory tract infection: 200mg twice daily, Gonorrhea: single dose of 100mg I.V., Majority of other infections: 200mg slow I.V. infusion every 12 hours daily. Patients with severe renal impairment: reduce the dose to half of the usual recommended dose. Usual treatment duration for acute infections: 5 to 7 days which may be followed by oral therapy whenever necessary. **CONTRAINDICATION:** Contraindicated in patients with history of hypersensitivity to ciprofloxacin, any member of the quinolone class or to any component of the formulation. Concomitant administration with tizanidine is contraindicated. **WARNINGS & PRECAUTIONS**: Caution is advised in patient for tendinopathy and tendon rupture, exacerbation of myasthenia gravis, in pregnant women, hypersensitivity reactions, other serious and some fatal reactions, severe hepatotoxicity, including hepatic necrosis, life-threatening hepatic failure, use of theophylline, convulsions, increased intracranial pressure (including pseudotumor cerebri), and toxic psychosis, *clostridium difficile*-associated diarrhea, musculoskeletal disorders in pediatric patients, prolongation of the QT interval, co administration of inhibitor of the hepatic CYP1A2 enzyme (e.g., theophylline, methylxanthines, caffeine, tizanidine, ropinirole, clozapine, olanzapine), renal impairment, and photosensitivity/phototoxicity. **DRUG INTERACTION:** Interacts with tizanidine, theophylline, other xanthine derivatives, cyclosporine, omeprazole, phenytoin, oral antidiabetic agents, metronidazole, cyclosporine, oral anti-coagulants, probenecid, methotrexate, metoclopramide, duloxetine, NSAIDs, ropinirole, lidocaine, clozapine, sildenafil, piperacillin sodium and drugs known to prolong QT interval. **ADVERSE REACTIONS:** Nausea, diarrhea, liver function tests abnormal, vomiting, rash are most common. local IV site reactions, eosinophilia, headache, restlessness, abdominal pain/discomfort, pain, pain in extremities, cardiovascular collapse, cardiopulmonary arrest, myocardial infarction, arrhythmia, tachycardia, palpitation, atrial flutter, ventricular ectopy, syncope, hypertension, paranoia, toxic psychosis, depression (potentially culminating in self-injurious behavior, such as suicidal ideations/thoughts and attempted or completed suicide), dysphasia, phobia, depersonalization, manic reaction, unresponsiveness, ataxia, confusion, hallucinations, dizziness, lightheadedness, paresthesia, anxiety, tremor, insomnia, nightmares, drowsiness, irritability, malaise, abnormal gait ileus, jaundice, gastrointestinal bleeding, pseudomembranous colitis, pancreatitis, intestinal perforation, dyspepsia, epigastric pain, constipation, oral ulceration, oral candidiasis, mouth dryness, anorexia, dysphagia, flatulence, hepatitis, painful oral mucosa, aranulocytosis, prolongation of prothrombin time, lymphadenopathy, petechial, amylase increase, lipase increase, hyperglycemia, hypoglycemia, arthralgia, jaw, arm or back pain, joint stiffness, neck and chest pain, achiness, flare up of gout, myasthenia gravis, muscle weakness, renal failure, interstitial nephritis, nephritis, hemorrhagic cystitis, renal calculi, frequent urination, acidosis, urethral bleeding, polyuria, urinary retention, gynecomastia, candiduria, vaginitis, breast pain, crystalluria, cylindruria, hematuria, albuminuria, respiratory arrest, pulmonary embolism, dyspnea, laryngeal or pulmonary edema, respiratory distress, pleural effusion, hemoptysis, epistaxis, hiccough, bronchospasm, anaphylactic reactions including

life-threatening anaphylactic shock, erythema multiforme/Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, vasculitis, angioedema, decreased visual acuity, blurred vision, disturbed vision (flashing lights, change in color perception, over brightness of lights, diplopia), eye pain, anosmia, hearing loss, tinnitus, nystagmus, chromatopsia and a bad taste.

**MARKETED BY:**


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**IN/QUINTOR INFUSION/200mg/MARCH 2015/01/AbPI**
(Additional information is available on request)