QUINTOR

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

Abbreviated Prescribing information for QUINTOR [Ciprofloxacin hydrochloride 250mg and 500mg Tablets] [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: Quintor Tablet is indicated for Respiratory Tract Infections: Acute bronchitis, acute exacerbation of cystic fibrosis, emphysema, lung abscess, infected bronchiectasis, pneumonia, sinusitis and masiokitis. 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. aoruginosa and resistant staphylococcal infections. Severe Systemic Infections: Septicemia, bacteremia and infections In Imrnunocompromised host. Surgical Infections: Intra-abdominal abscess, peritonitis, cholangitis and cholecystitis. Gynecological Infections: Severe pelvic Infections caused 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.

DOSAGE AND ADMINISTRATION: The dosage is determined by the indication, the severity and the site of the infection. The full dosage and administration section describe in prescribing information which varies from 250 mg to 750 mg twice daily. Tablets are to be swallowed unchewed with fluid. They can be taken independent of mealtimes. If taken on an empty stomach, the active substance is absorbed more rapidly. Ciprofloxacin tablets should not be taken with dairy products (e.g. milk, yoghurt) or mineral-fortified fruit-juice (e.g. calcium-fortified orange juice)

CONTRAINDICATION: Contraindicated in patients with history of hypersensitivity to ciprofloxacin, any member of the quinolone class and concomitant administration with tizanidine.

WARNINGS & PRECAUTIONS: Caution is advised in patient for tendinopathy and tendon rupture, exacerbation of myasthenia gravis, in pregnant women, hypersensitivity reactions, other serious and sometimes 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, syphilis, renal impairment, and photosensitivity/phototoxicity.

DRUG INTERACTION: Tizanidine, theophylline, other xanthine derivatives, chelation complex formation, omeprazole, phenytoin, oral antidiabetic agents, metronidazole, cyclosporine, oral anti-coagulants, probenecid, methotrexate, metoclopramide, duloxetine, nsaids, ropinirole, lidocaine, clozapine, sildenafil and drugs known to prolong QT interval.

ADVERSE REACTIONS: Nausea, diarrhea, liver function tests abnormal, vomiting, rash are most common. Headache, abdominal pain/discomfort, pain, pain in extremities, palpitation, atrial flutter, ventricular ectopy, syncope, hypertension, restlessness, dizziness, lightheadedness, insomnia, nightmares,

hallucinations, manic reaction, irritability, tremor, ataxia, painful oral mucosa, oral candidiasis, dysphagia, intestinal perforation, gastrointestinal bleeding, lymphadenopathy and petechial, amylase increase, lipase increase, arthralgia or back pain, joint stiffness, achiness, interstitial nephritis, nephritis, renal failure, dyspnea, epistaxis, laryngeal or pulmonary edema, allergic reaction, pruritus, urticaria, blurred vision, disturbed vision, agitation, agranulocytosis, albuminuria, anaphylactic reactions (including life-threatening anaphylactic shock) and anosmia.

MARKETED BY:

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IN/QUINTOR/MARCH 2015/01/AbPI
(Additional information is available on request)