OFLOXACIN

Indications/Uses

Listed in Dosage.

Dosage/Direction for Use

Adult: PO Non-gonococcal cervicitis/urethritis due to Chlamydia trachomatis 400 mg/day as single dose or in divided doses. Alternatively, 300 mg 12 hourly. Treatment duration: 7 days. Uncomplicated gonorrhoea 400 mg as a single dose. Acute exacerbations of chronic bronchitis; Community-acquired pneumonia; Uncomplicated skin and skin structure infections 400 mg 12 hourly for 10 days. Complicated UTI 200 mg 12 hourly for 10 days. Alternatively, 200 mg bid, may be increased to 400 mg bid according to severity for 7-21 days. Skin and soft tissue infections 400 mg bid. Uncomplicated cystitis; Uncomplicated UTI 200 mg 12 hourly for 3-7 days. Acute pelvic inflammatory disease 400 mg 12 hourly for 10-14 days. Prostatitis 200 mg bid, may be increased to 400 mg bid according to severity. Treatment duration: 2-4 weeks (acute); 4-8 weeks (chronic). Alternatively, 300 mg 12 hourly for 6 weeks. Lower respiratory tract infections 400 mg/day, increased to 400 mg bid if necessary. IV Acute exacerbations of chronic bronchitis; Community-acquired pneumonia 200 mg bid. Complicated skin and soft tissue infections 400 mg bid. Complicated UTI 200 mg bid, may be increased to 400 mg bid according to severity. Treatment duration: 7-21 days. Lower respiratory tract infections 200 mg bid, may be increased to 400 mg bid according to severity. Pyelonephritis 200 mg bid, may be increased to 400 mg bid according to severity. Treatment duration: 7-10 days, up to 14 days as necessary. Prostatitis 200 mg bid, may be increased to 400 mg bid according to severity. Treatment duration: 2-4 weeks (acute); 4-8 weeks (chronic). Epididymo-orchitis 200 mg bid, may be increased to 400 mg bid according to severity. Treatment duration: 14 days. Pelvic inflammatory disease 400 mg bid for 14 days. Administer via slow infusion over at least 30 minutes for each 200 mg dose. Ophth Bacterial conjunctivitis As 0.3% eye drop solution: Instill 1-2 drops into the affected eye(s) 2-4 hourly for days 1 and 2, then 1-2 drops 4 times/day for days 3-7. Max treatment duration: 10 days. Bacterial corneal ulcer As 0.3% eye drop solution: Instill 1-2 drops into the affected eye(s) every 30 minutes while awake and 4-6 hourly after retiring for days 1-2. Starting on day 3, instill 1-2 drops hourly while awake for 4-6 additional days; thereafter, 1-2 drops 4 times/day until clinical cure is achieved. Otic Otitis externa As 0.3% otic solution: Instill 10 drops (1.5 mg) into the affected ear(s) once daily for 7 days. Otitis media Chronic suppurative cases with perforated tympanic membranes: As 0.3% otic solution: Instill 10 drops (1.5 mg) into the affected ear(s) bid for 14 days.

Administration

May be taken with or without food. Avoid antacids or supplements containing Fe or Zn w/in 2 hr before or after ofloxacin. Ensure adequate hydration.

Contraindications

Hypersensitivity to ofloxacin or to other quinolone antibacterials. History of tendon disorders associated with quinolone use, epilepsy or lowered seizure threshold.

Special Precautions

Patient with known/suspected CNS disorders (e.g. epilepsy, severe cerebral arteriosclerosis) or risk factors that may predispose to seizures or lower the seizure threshold; myasthenia gravis, rheumatoid arthritis, latent or diagnosed G6PD deficiency, risk factors for QT interval prolongation

(e.g. congenital long QT syndrome, uncorrected hypokalaemia or hypomagnesaemia, heart failure, MI, bradycardia), history of aneurysm disease, pre-existing aortic aneurysm/dissection or its predisposing conditions (e.g. Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu/giant cell arteritis, Behcet's disease); psychiatric disease, history of psychotic disorder or risk factor for depression; diabetes. Organ transplant recipients. Not indicated for the treatment of syphilis as it may mask symptoms (oral). Renal and hepatic impairment. Children and elderly. Pregnancy and lactation. Patient Counselling This drug may cause drowsiness, dizziness and visual disturbances; if affected, do not drive or operate machinery. Avoid excessive exposure to sunlight or artificial UV light. Do not wear contact lenses during treatment of ophthalmic infections. Monitoring Parameters Monitor CBC, hepatic and renal function periodically (prolonged therapy). Perform culture and sensitivity tests and consult local recommendations before treatment initiation due to antibiotic resistance risks; test for syphilis at the time of gonorrheal diagnosis and 3 months later. Assess for signs and symptoms of glucose disturbances, CNS effects, and tendon problems. Monitor ofloxacin serum concentration for patient with severe renal impairment and on dialysis (IV).

Adverse Reactions

Significant: Tendon rupture or tendinitis, aortic aneurysm ruptures or dissection, CNS effects (e.g. seizures, tremors, dizziness, lightheadedness, increased intracranial pressure), hyperglycaemia, psychiatric reactions (e.g. hallucinations, toxic psychosis), phototoxicity. Rarely, peripheral neuropathy, QT interval prolongation, torsades de pointes, haemolytic reactions (G6PD deficient patients). Cardiac disorders: Chest pain. Ear and labyrinth disorders: Vertigo. Otic: Earache, application site reactions. Eye disorders: Visual disturbance. Ophthalmic: Blurred vision, ocular burning or discomfort (transient), lacrimation, photophobia, foreign body sensation in eyes, chemical conjunctivitis, keratitis; eye discomfort, dryness, pain, pruritus or redness. Gastrointestinal disorders: Nausea, vomiting, diarrhoea, constipation, dysgeusia, abdominal pain or cramps, flatulence, gastrointestinal distress, dry mouth. General disorders and administration site conditions: Fever, infusion site reaction (IV). Infections and infestations: Pathogen resistance, fungal infection. Metabolism and nutrition disorders: Decreased appetite. Nervous system disorders: Headache, dizziness, drowsiness. Psychiatric disorders: Insomnia, agitation, sleep disorder, nervousness, somnolence. Reproductive system and breast disorders: Vaginitis, genital pruritus. Respiratory, thoracic and mediastinal disorders: Nasopharyngitis, cough. Skin and subcutaneous tissue disorders: Pruritus, rash. Vascular disorders: Phlebitis (IV).

Potentially Fatal: Fungal or bacterial superinfection including C. difficile-associated diarrhoea (CDAD) and pseudomembranous colitis (prolonged use); liver failure, myasthenia gravis exacerbation, severe hypoglycaemia. Rarely, severe bullous skin reactions (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome), hypersensitivity reactions (e.g. anaphylaxis, anaphylactic shock).

Pregnancy Category (US FDA)

ROUTE(S) : Ophth / Otic: C

ROUTE(S) : PO: C Caution esp in 1st trimester.

Drug Interactions

Increased risk of tendon rupture or inflammation with concomitant use of corticosteroids. Increased risk of QT interval prolongation with Class IA and III anti-arrhythmics, TCAs, macrolides, antipsychotics. May increase the risk of bleeding when given with vitamin K antagonists (e.g. warfarin). Reduced absorption with Mg-, Ca- or Al-containing antacids, Zn or Fe preparations,

sucralfate and didanosine chewable or buffered tab. Decreased clearance with drugs that affect the renal tubular secretion (e.g. probenecid, furosemide, cimetidine, methotrexate). May slightly increase plasma levels of glibenclamide. Theophylline and NSAIDs may cause pronounced lowering of cerebral seizure threshold.

CIMS Class

Ear Anti-Infectives & Antiseptics / Eye Anti-Infectives & Antiseptics / Quinolones

ATC Classification

S02AA16 - ofloxacin ; Belongs to the class of antiinfectives used in the treatment of ear infections.

J01MA01 - ofloxacin ; Belongs to the class of fluoroquinolones. Used in the systemic treatment of infections.

S01AE01 - ofloxacin ; Belongs to the class of quinolone antiinfectives. Used in the treatment of eye infections.