Only for the use of Medical Professionals

Aciflox®

Presentation:

Aciflox® is a film coated , yellow coloured, caplet shaped tablet with break-line on one side and other side is plain. Each film coated tablet contain Sparfloxacin INN 200 mg.

Uses: Sparfloxacin is a synthetic broad spectrum bactericidal agent from the fluoroquinolone family of antibacterial. It is t6he most active of the currently available fluoroquinolones. It is highly active against Enterobacteriaceae, H. Infulenza, Neisseria spp., Lagionella spp, and C. trachomatis; P. auroginosa is less susceptible. Sparfloxacin is the most active quinolone against Gram positive bacteria with moderate to excellent activity against Staphylococci(both Methicillin resistant and susceptible strains) and streptococci (including Pneumococci and Enterococci).The genital Mycoplasm , M.hominis and U. uredycticum., are susceptible and Sparfloxacin is the most active fluriquinolone against Mycobacterium spp., including MAC strains. It is also moderately active against some anaerobes (including the B. fragilis group); L. monocytogenes is resistant. Aciflox® indicated for the treatment of adults (18 years of age or more with the following infections caused by susceptible strains of microorganisms in the following condition

Upper and lower RTI: Sinusitis, purulent pneumonia, bronchopneumonia, acute bacterial exacerbation of chronic bronchitis, community acquired and hospital acquired pneumonia(especially due to penicillin resistant pneumococci) or bronchiectasis.

Urinary tract Infection (UTI): Sparfloxacin is effective in UTI caused by multidrug resistant garm-negative organisms sensitive to quinolone. These include gonococcal and nongonococcal urethritis, chancroid and other STD's. Aciflox® has been shown effective in the treatment of gonococcal and clamydial genital tract.

Skin and soft tissue Infection (SSTI): Aciflox® is also effective in Skin and soft tissue infection (SSTI).

Urological and ophthalmic operation: Aciflox® has prophylactic use in different urological and ophthalmic operations like cataract removal, virectomy and in the treatment of endophthalmitis.

Bacterial prostitis: Aciflox® is effective in treating bacterial prostatitis because of good penetration into the prostatic tissue.

Tuberculosis and leprosy: Aciflox® can also be used in the treatment of tuberculosis in combination with rifampicin and isoniazid, treatment of leprosy on combination with STD drugs.

Dosage and administration: Aciflox® can be taken with or without food. Depending on the severity of infection , causative pathogen and clinical response, the dosage is to be individualized.

The recommended daily dose of Aciflox® in patient with normal renal function is two 200 mg tablets taken on the first day as a loading dose. Thereafter, take one 200 mg tablet every 24 hours for a total of 10 days of therapy(11 tablets).The recommended daily dose of Aciflox® in patient with renal impairment (creatinine clearance<50 ml/min),is two 200 mg tablets taken on then first day of as a loading dose. Thereafter, take one 200 mg tablet every 48 hours for a total of 9 days of therapy (6 tablets).

Contra-indications, warnings:

Contra-indications: Aciflox® is contraindicated in patient who have known hypersensitivity to any of fluroquinolones; pregnancy and lactation; history of achilis tenditis following the use of fluroquinolones; glucose-6-phasphate dehydrogenese (G6PD) deficiency.

Warnings: Dose adjustment is required in patient with renal impairment (creatinine clearance<50 ml/min).

Side effects: Most common side effects include events related to GIT (nausea,vomiting,diarrhea)and less frequent side effects involve those related to CNS (anxiety,nightmares,hallucanations)and the skin (rash,pruritis,uricaria).The large majority of adverse events resolve without sequelae on stopping the drug. Photosensitivity reactions are most common with Sparfloxacin.

Use in pregnancy and lactation: Since no adequate studies are available. Aciflox® should be administered only if the potential benefits justify the risk of to the foetus/neonates.

Use in children: Safety of Aciflox® in children below 12 years has not established.

Drug Interaction: There is extremely low incidence of increased risk of cardiac arrhythmia (tor sade of des points) on concomitant administration with bretylium diisopyramide, quinidine sotalol, erythromycin ,astemizole, terfenadine,and vinca alkaloids due to prolonged QT interval.

Overdose: Overdose experience is limited. Htdration,gastric lavage, supportive and symptomatic treatment are the mainstay of therapy. Dialysis is not useful due to high tissue uptake.

Storage:

Aciflox®tablets should be stored in a dry place below 30^0 C.

Package quantities:

1×10 coated tablets of 200 mg blister strips.

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