

Rutix[®]

Ofloxacin USP

COMPOSITION

Rutix[®] 200 Tablet: Each film coated tablet contains Ofloxacin USP 200 mg.

Rutix[®] 400 Tablet: Each film coated tablet contains Ofloxacin USP 400 mg

PHARMACOLOGY

Rutix[®] containing Ofloxacin is a synthetic fluoroquinolone antibacterial agent with bactericidal activity against a wide range of Gram-negative and Gram-positive organisms. Ofloxacin is thought to exert bactericidal effect by inhibiting DNA-gyrase, an essential enzyme that is critical catalyst in the duplication, transcription and repair of bacterial DNA. Following oral administration, Ofloxacin is rapidly and well absorbed from G.I. tract. The bioavailability of Ofloxacin in the tablet formulation is approximately 98%. It is widely distributed into body tissues and fluids. The half-life is about 4.6 to 6.9 hours. Upto 80% of oral dose of Ofloxacin is eliminated in the urine as the parent compound within 48 hours.

INDICATION

Rutix[®] tablet is indicated for the treatment of adults with mild to moderate infections caused by susceptible strains.

Lower Respiratory Tract: Acute Bacterial Exacerbations of Chronic Bronchitis due to Haemophilus influenzae or Streptococcus pneumonia, Community-Acquired Pneumonia due to Haemophilus influenzae or Streptococcus pneumoniae.

Gastrointestinal Tract: Enteric fever due to Salmonella spp. and multi-drug resistant strains of S. typhi.

Skin and skin structure: Uncomplicated skin and skin structure infections due to Staphylococcus aureus, Streptococcus pyogenes or Proteus mirabilis.

Sexually Transmitted Diseases : Acute Uncomplicated urethral and cervical gonorrhoea due to Neisseria gonorrhoeae.

Non gonococcal urethritis and cervicitis due to Chlamydia trachomatis.

Mixed infections of the urethra and cervix due to Chlamydia trachomatis and Neisseria gonorrhoea.

Urinary Tract : Uncomplicated cystitis due to Citrobacter diversus, Enterobacter aerogenes, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, or Pseudomonas aeruginosa.

Complicated urinary tract infections due to Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Citrobacter diversus.

Prostate : Prostatitis due to Escherichia coli.

DOSAGE AND ADMINISTRATION

General dosage recommendation : The dose of Ofloxacin is determined by the type and severity of the infection. The dosage range for adults is 200 mg to 800 mg daily. Upto 400 mg may be given as a single dose, preferably in the morning, larger doses should be given as two divided doses. **Rutix[®]** tablets should be swallowed with liquid; they should not be taken within two hours of magnesium/aluminium containing antacids or iron preparations, since reduction of absorption of Ofloxacin can occur.

Lower urinary tract infection : 200-400 mg daily.

Upper urinary tract infection : 200-400 mg daily, increasing, if necessary to 400 mg twice daily.

Lower respiratory tract infection : 400 mg daily, increasing, if necessary, to 400 mg twice daily.

Enteric fever: 200 mg, every 12 hours/8 hourly in resistant cases. Uncomplicated urethral and cervical gonorrhoea: A single 400 mg dose.

Non-gonococcal urethritis and cervicitis : 400 mg daily in single or divided doses.

Impaired renal function. Following a normal initial dose, dosage should be reduced in patients with impairment of renal function. When creatinine clearance is 20-50 ml/minute, the daily dosage should be reduced to half (100-200 mg daily). If creatinine clearance is less than 20 ml/minute, 100mg should be given in every 24 hours.

In patients undergoing haemodialysis or peritoneal dialysis 100 mg should be given in every 24 hours.

Impaired liver function: The excretion of Ofloxacin may be reduced in patients with severe hepatic dysfunction.

Children : Ofloxacin is not indicated for use in children or growing adolescents.

Elderly : No adjustment of dosage is required in the elderly.

Duration of treatment: Duration of treatment dependent on the severity of the infection and the response to treatment.

The usual treatment period is 6-10 days, except in uncomplicated gonorrhoea, where a single dose is recommended. Treatment should not exceed 2 months duration.

CONTRAINDICATION

Ofloxacin should not be used in patients with known hypersensitivity to fluoroquinolone anti-bacterials. It is contraindicated in patients with a history of epilepsy or with a lowered seizure threshold. Ofloxacin is contraindicated in children or growing adolescents and in pregnant or breast feeding women.

PRECAUTION AND WARNINGS

Patients being treated with Ofloxacin should not expose themselves unnecessarily to strong sunlight and should avoid UV rays. Caution is recommended if the drug is to be used in psychotic patients or in patients with a history of psychiatric disease.

DRUG INTERACTIONS

Cationic antacids and iron.

ADVERSE REACTION

Gastrointestinal and central nervous reactions are more common. Nausea, vomiting, abdominal pain, diarrhoea and gastrointestinal distress are gastrointestinal adverse effects. Common central nervous system reactions are headache, dizziness and insomnia.

STORAGE CONDITION

Keep medicines out of the reach of children. Store at room temperature and protect from light & moisture.

HOW SUPPLIED

Rutix[®] 200 Tablet: Box containing 30 tablets in blister pack.

Rutix[®] 400 Tablet: Box containing 20 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH