# Rutix®

Ofloxacin

***Fluoroquinolone***

## 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 4-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 a 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 almost 100%. It is widely distributed into body tissues and fluid. The half-life is about 4.6 to 6.9 hours. Up to 80% of an oral dose of ofloxacin is eliminated in the urine as the parent compound within 48 hour.



## INDICATION

Rutix® tablets are indicated for the treatment of adults with mild to moderate infections caused by susceptible strains.

*Lower Respiratory Tract:* Acute bacterial exacerbation of chronic bronchitis lung abscess, pneumonia. *Gastrointestinal Tract*: Enteric fever, shigellosis. Multi-drug-resistant Tuberculosis. *Skin and skin structures*: Uncomplicated skin and skin structure infections. *Sexually Transmitted Diseases*: Acute, Uncomplicated urethral and cervical gonorrhoea. Nongonococcal urethritis and cervicitis. Mixed infections of the urethra and cervix. *Urinary tract*: Uncomplicated Urinary Tract Infections, Complicated urinary tract infections.

## DOSAGE AND ADMINISTRATION

General dosage recommendations: 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. Up to 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 intake of magnesium/aluminium containing antacids or iron preparations since reduction of absorption of ofloxacin can occur.

*Enteric fever:* For adults 200 mg, every 12 hours, for 5 days. For children 15 mg/kg/day in 2 divided doses for 3 days.

*Shigellosis*: 400 mg single dose.

*Multi-drug-resistant tuberculosis*: 400 mg twice daily along with conventional anti-tuberculosis drugs.

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

*Uncomplicated Urinary Tract Infections*: A single dose of 200/400 mg.

*Uncomplicated urethral and cervical gonorrhoea*: A single dose of 400 mg.

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

*Complicated Urinary Tract Infection*: 200/400 mg/day for 7 days.

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

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

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

**CONTRAINDICATION AND PRECAUTION**

Ofloxacin should not be used in-patients with known hypersensitivity to 4-fluoroquinolone antibacterials. It is contraindicated in-patients with a history of epilepsy or with a lowered seizure threshold. Ofloxacin is usually contraindicated in children or growing adolescents and in pregnant or breast feeding women.

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.

**SIDE EFFECT**

Ofloxacin is generally well tolerated and clinical side-effects of ofloxacin has been quite low. Among the adverse effects gastrointestinal and central nervous systems' reactions are common. Nausea, rash, vomiting, abdominal pain, diarrhoea and gastrointestinal distress are the gastrointestinal adverse effects. Common central nervous system reactions are headache, dizziness and insomnia.

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## DRUG INTERACTION

Antacids containing magnesium, aluminium or calcium may decrease absorption of ofloxacin. Iron or Zinc may decrease oral absorption of ofloxacin.

## USE IN PREGNANCY AND LACTATION

The safety of ofloxacin during pregnancy has not been established. Ofloxacin may enter breast milk but data are not available.

## HOW SUPPLIED

Rutix® 200 tablet: Box containing 2 x 10 tablets in blister pack.
Rutix® 400 tablet: Box containing 1 x 10 tablets in blister pack.