

# Isofloxin®

Tablet

## Description

Isofloxin is a film coated tablet containing Pefloxacin Mesylate BP.

## Indications

Isofloxin is indicated for the treatment of single or mixed infections caused by two or more susceptible organisms. It can also be used for infections caused by organisms resistant to other antibiotics including aminoglycoside, penicillin and cephalosporin.

Isofloxin is indicated for the treatment of the following infections caused by sensitive bacteria.

*Severe systemic infection* : Septicaemia, bacteraemia, peritonitis, infections in immunosuppressed patients with haematological or solid tumors and in patients in intensive care unit with specific problems such as infected burns.

*Urinary tract infection* : Uncomplicated and complicated urethritis, cystitis, pyelonephritis, prostatitis, epididymitis.

*Respiratory tract infection* : Lobar and bronchopneumonia, acute and chronic bronchitis, acute exacerbation of cystic fibrosis, bronchiectasis, empyema.

*Gastrointestinal infection* : Enteric fever, infective diarrhoea.

*Infections of the biliary system* : Cholangitis, cholecystitis, empyema of the gall bladder.

*Skin and soft tissue infection* : Infected ulcers, wound infections, abscesses, cellulitis, otitis externa, erysipelas, infected burns.

*Eye, ear, nose and throat infection* : Otitis media, sinusitis, mastoiditis, tonsillitis.

*Intra abdominal infection* : Peritonitis, intra abdominal abscesses.

*Bone and joint infection* : Osteomyelitis, septic arthritis.

*Pelvic infection* : Salpingitis, endometritis, pelvic inflammatory diseases.

*Gonorrhoea* : Including urethral, rectal and pharyngeal gonorrhoea caused by  $\beta$  lactamase producing organisms or organisms moderately sensitive to penicillin.

### **Dosage and Administration**

The usual dose is 400 mg twice daily (morning and evening) by mouth in most infections. Dosage should be adjusted for adults with hepatic insufficiency. Patients should take the drug with meals to avoid gastrointestinal disturbances.

### **Contraindications**

Pefloxacin is contraindicated in patients who have known hypersensitivity to Pefloxacin or other quinolones. Pefloxacin is also contraindicated in children and growing adolescents except where the benefits of treatment exceed the risks, in pregnant women, nursing mothers and in patients with glucose-6-phosphate dehydrogenase deficiency.

### **Precautions**

Avoid exposure to sunlight and ultraviolet radiation during treatment with Pefloxacin because of the risk of photosensitivity reactions. Dosage readjustment is required in severe hepatic insufficiency.

### **Drug Interactions**

Antacids may interfere with absorption of Pefloxacin resulting in serum and urine levels lower than desired, so concurrent administration of these agents with Pefloxacin should be avoided.

### **Side Effects**

Gastrointestinal system : Nausea, diarrhoea, vomiting, dyspepsia, abdominal pain. Central nervous system (CNS) : Dizziness, headache, tiredness, confusion, convulsions. Hypersensitivity reactions : skin rashes, pruritus. The other reactions have also been reported are joint pain, mild photosensitivity and thrombocytopenia (at doses of 1600 mg daily).

### **Commercial Pack**

Isofloxin<sup>®</sup> Tablet : Box containing 5 aluminium strips of 10 film coated tablets. Each tablet contains Pefloxacin Mesylate BP equivalent to Pefloxacin 400 mg.