Ciprofloxacin Tablets USP 250/500 mg

Microflox

COMPOSITION:
Each film-coated tablet contains:
Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 250 mg
Each film-coated tablet contains:
Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 500 mg

PROPERTIES:
Microflox is a broad spectrum antibacterial agent for oral administration

INDICATION:
Infections caused by susceptible organisms of lower respiratory tract, skin and soft tissues, bone and joints, urinary tract and infectious diarrhea caused by E.coli, Campylobacter spp. and Shigella spp.

CONTRAINDICATIONS:
Hypersensitivity to Microflox or any member of the quinolone class of antimicrobial agents.

ADVERSE EFFECTS:
The common side effects are diarrhea, vomiting, headache, restlessness and rash. Most of the adverse events reported were described as only mild to moderate in severity, abated soon after the drug was discontinued and required no treatment.
Gastrointestinal: Ileus, jaundice, gastrointestinal bleeding, C. difficile associated diarrhea, pseudomembranous colitis, pancreatitis, hepatic necrosis, intestinal perforation, dyspepsia, epigastric or abdominal pain, vomiting, constipation, oral ulceration, oral candidiasis, mouth dryness, anorexia, dysphagia, flatulence.
Musculoskeletal: Myalgia, possible exacerbation of myasthenia gravis, tendinitis/tendon rupture.
Cardiac disorders: Not known: Ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged.
Nervous system disorders (frequency not known): Peripheral neuropathy (that may be irreversible) and polyneuropathy.

WARNING & PRECAUTIONS:
Microflox should not be used in pregnant women, nursing mothers or children. Should be used with caution in patients with suspected CNS disorders, e.g. cerebral arteriosterosis, epilepsy. Patients receiving Microflox should be well hydrated and wine alkalinity should be avoided. There is a possibility of tendon rupture with use of fluoroquinolones antibiotics. Caution should be exercised during concurrent administration of Antacids, Theophylline and Probenecid and in patients with renal impairment.
Cardiac disorders :Caution should be taken when using Fluoroquinolones, including ciprofloxacin, in patients with known risk factors for prolongation of the QT interval such as: congenital long QT syndrome, concomitant use of drugs that are known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, tricyclic antidepressants, macrolides, antipsychotics), uncorrected electrolyte imbalance (eg. hypokalaemia, hypomagnesaemia), elderly and cardiac disease (e.g. heart failure, myocardial infarction, bradycardia).
Peripheral Neuropathy
Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including Microflox. Symptoms may occur soon after initiation of Microflox and may be irreversible. Microflox should be discontinued immediately if the patient experiences symptoms of peripheral neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.
Vision disorders: If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately
Disabling and potentially irreversible serious adverse reactions
Fluoroquinolones, including Microflox, have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). Patients of any age or without pre-existing risk factors have experienced these adverse reactions.
Discontinue Microflox immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including Ciprofloxacin, in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.
Aortic aneurysm or dissection
Epidemiologic studies report an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones, particularly in the older population. Therefore, fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease, or in patients diagnosed with pre-existing aortic aneurysm and/or aortic dissection, or in presence of other risk factors or conditions predisposing for aortic aneurysm and dissection (e.g. Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, known atherosclerosis). In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department.

Psychiatric Adverse Reactions
Fluoroquinolones, including Microflox, have been associated with an increased risk of psychiatric adverse reactions, including: toxic psychosis, hallucinations, or paranoia; depression or suicidal thoughts or acts; anxiety, agitation, or nervousness; confusion, delirium, disorientation, or disturbances in attention; insomnia or nightmares; memory impairment. These adverse reactions may occur following the first dose. If these reactions occur in patients receiving Microflox, discontinue Microflox immediately and institute appropriate measures.

Blood Glucose Disturbances
As with all fluoroquinolones, disturbances in blood glucose, including both hypoglycaemia and Hyperglycaemia have been reported with Microflox. In Microflox -treated patients, Dysglycaemia occurred predominantly in elderly diabetic patients receiving concomitant treatment with an oral hypoglycaemic agent (for example, sulfonylurea) or with insulin. Severe cases of hypoglycaemia resulting in coma or death have been reported. In diabetic patients, careful monitoring of blood glucose is recommended. If a hypoglycaemic reaction occurs, discontinue Microflox and initiate appropriate therapy immediately.

DRUG INTERACTIONS / INCOMPATIBILITIES:
Concurrent administration of Microflox with Theophylline may lead to elevated serum concentrations of Theophylline and prolongation of its elimination half-life resulting in increased risk of Theophylline-related adverse reactions. If concomitant use cannot be avoided, serum levels of Theophylline should be monitored and dosage adjustments made as appropriate. Microflox also interferes with the metabolism of caffeine. Concurrent administration of Microflox with antacids containing magnesium, aluminium or calcium; with sucralfate or divalent and trivalent cations such as iron may substantially interfere with the absorption of Microflox.
Drugs known to prolong QT interval: Ciprofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics).

PREGNANCY AND LACTATION:
Quinolones cause damage to articular cartilage in the human immature organism / foetus. As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy and during breast-feeding.

DOSAGE AND ADMINISTRATION:
The determination of dosage for any particular patient must take into consideration the severity and nature of the infection, the susceptibility of the causative organism, the integrity of the patient's host defence mechanisms, and the status of renal function and hepatic function.

Mild to moderate RTI	500mg b.i.d
Mild to moderate UTI	250mg b.i.d
Severe UTI	500mg b.i.d
Severe Bone & Joint infection	750mg b.i.d
Mild to moderate infections	500mg b.i.d

Ciprofloxacin is eliminated primarily by renal excretion; however, the drug is also metabolized and partially cleared through the biliary system of the liver and through the intestine. These alternate pathways of drug elimination appear to compensate for the reduced renal excretion in patients with renal impairment. Nonetheless, some modification of dosage is recommended, particularly for patients with severe renal dysfunction. However, monitoring of serum drug levels provides the most reliable basis for dosage adjustment.

OVER DOSAGE:
Symptoms in overdose consist of dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment as well as crystalluria and hematuria. Reversible renal toxicity has been reported. In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

PRESENTATION:
10 x 10's blister pack

STORAGE CONDITIONS:
Store below 25°C.

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Microflox-250: SIN 08940 P
Microflox-500: SIN 12073 P

Manufactured by:
MICRO LABS LIMITED
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