Ofloxacin Tablets USP 200 mg

Oflomac 200

Each film coated tablet contains:
Ofloxacin USP 200 mg

Product Description
Yellow colored, oval shaped biconvex film coated tablets with plain surface on both the sides.

Pharmacodynamics
Ofloxacin exerts its effect by inhibiting the bacterial DNA gyrase, which is responsible for coiling the genetic material as a prerequisite for bacterial multiplication. This fights infection by preventing bacteria cells from reproducing.

Pharmacokinetics
The tolerability and pharmacokinetics have been investigated for the dose range from 100 mg to 2 X 600 mg. The substances has to be proved well tolerated; investigation of the effects in renal enzymes after multiple dosing with 300 mg b.i.d, showed that the risk of nephrotoxicity is negligible. Ofloxacin is rapidly and completely absorbed. Cmax and AUC are dose dependant. The favorable half life between 6 and 7 hr, irrespective of the dose results in prolonged serum concentrations. Food interaction is slight and of no clinical relevance .The penetration into tissue and body secretion is rapid, and high levels are reached. The main route of elimination is the kidneys. The urinary concentration are dose dependant ;but the proportion of dose excreted via the kidneys remains approximately constant ,80 % or more of the dose being recovered as unchanged ofloxacin. The degree of metabolism in human s is small and is of no clinical relevance. The glucuronide of ofloxacin found in the bile together with metabolites detected in the urine account for at most 5 % of the dose given. The favorable kinetic profile of ofloxacin means that the daily regimen required is two doses at the most.

Indication
Ofloxacin is a synthetic 4-fluoroquinolone antibacterial agent with bactericidal activity against a wide range of Gram-negative and Gram-positive organisms. It is indicated for the treatment of the following infections when caused by sensitive organisms: Upper and lower urinary tract infections; lower respiratory tract infections; uncomplicated urethral and cervical gonorrhoea; non-gonococcal urethritis and cervicitis, skin and soft tissue infections.

Recommanded Dose
General dosage recommendations: The dose of ofloxacin is determined by the type and severity of the infection. The dosage range for adults is 200mg to 800mg daily. Up to 400mg may be given as a single dose, preferably in the morning, larger doses should be given as two divided doses.
Generally, individual doses are to be given at approximately equal intervals. Tarivid tablets should be swallowed with liquid; they should not be taken within two hours of magnesium/aluminium containing antacids, sucralfate 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 a day.
Lower respiratory tract infection: 400 mg daily increasing, if necessary, to 400 mg twice daily.
Uncomplicated urethral and cervical gonorrhoea: A single dose of 400 mg.
Non-gonococcal urethritis and cervicitis: 400 mg daily in single or divided doses.
Skin and soft tissue infections: 400 mg twice daily.

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 (serum creatinine 1.5--5.0 mg/dl) the dosage should be reduced by half (100--200 mg daily). If creatinine clearance is less than 20 ml/minute (serum creatinine greater than 5 mg/dl) 100 mg should be given every 24 hours.
In patients undergoing haemodialysis or peritoneal dialysis, 100 mg should be given every 24 hours.

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

Elderly: No adjustment of dosage is required in the elderly, other than that imposed by consideration of renal or hepatic function.

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

Duration of treatment: Duration of treatment is dependent on the severity of the infection and the response to treatment. The usual treatment period is 5--10 days except in uncomplicated gonorrhoea, where a single dose is recommended.

Treatment should not exceed 2 months duration.

Mode Of Administration
Oral-
Oflomac tablets should be swallowed without chewing with sufficient amounts of liquid (approx 1/2 glass) .They should be taken on an empty stomach.

Contraindication
Ofloxacin should not be used in patients with known hypersensitivity to 4-quinolone antibacterials or any of the tablet excipients. Ofloxacin should not be used in patients with a past history of tendinitis. Ofloxacin, like other 4-quinolones, is contra-indicated in patients with a history of epilepsy or with a lowered seizure threshold. Ofloxacin is contra-indicated in children or growing adolescents, and in pregnant or breast-feeding women, since animal experiments do not entirely exclude the risk of damage to the cartilage of joints in the growing subject.

Patients with latent or actual defects in glucose-6-phosphate dehydrogenese activity may be prone to haemolytic reactions when treated with quinolone antibacterial agents.

Warning and Precautions
Patients being treated with ofloxacin should not expose themselves unnecessarily to strong sunlight and should avoid UV rays (sun lamps, solaria). Caution is recommended if the drug is to be used in psychotic patients or in patients with a history of psychiatric disease.

Administration of antibiotics, especially of prolonged, may lead to proliferation of resistant microorganisms. The patient's condition must therefore be checked at regular intervals. If a secondary infection occurs, appropriate measures must be taken.

Interactions With Other Medicaments
Co-administered magnesium/aluminium antacids, sucralfate or iron preparations can reduce absorption. Therefore, ofloxacin should be taken 2 hours before such preparations. Prolongation of bleeding time has been reported during concomitant administration of Tarivid and anticoagulants.

There may be a further lowering of the cerebral seizure threshold when quinolones are given concurrently with other drugs which lower the seizure threshold, e.g. theophylhine. However ofloxacin is not thought to cause a pharmacokinetic interaction with theophylhine, unlike some other fluoroquinolones.

Further lowering of the cerebral seizure threshold may also occur with certain nonsteroidal antiinflammatory drugs.

Ofloxacin may cause a slight increase in serum concentrations of glibenclamide administered concurrently; patients treated with this combination should be closely monitored.

With high doses of quinolones, impairment of excretion and an increase in serum levels may occur when co-administered with other drugs that undergo renal tubular secretion (e.g. probenecid,cimetidine, frusemide and methotrexate).

Interaction with laboratory tests: Determination of opiates or porphyrins in urine may give falsepositive results during treatment with ofloxacin.

Pregnancy and Lactation
The safety of this medicinal product for use in human pregnancy has not been established.
Reproduction studies performed in rats and rabbits did not reveal any evidence of teratogenicity, impairment of fertility or impairment of peri- and post-natal development. However, as with other quinolones, ofloxacin has been shown to cause arthropathy in immature animals and therefore its use during pregnancy is not recommended. Studies in rats have indicated that ofloxacin is secreted in milk. It should therefore not be used during lactation.

Side Effects
The overall frequency of adverse reactions from the clinical trial data base is about 7%. The commonest events involved the gastrointestinal system (about 5.0%) and the nervous system (about 2.0%).
The following provides a tabulation based on post marketing experience where occasional represents a frequency of 0.1 - 1.0%, rare <0.1%, very rare <0.01% and isolated cases <0.01%:
Digestive and Liver side effects:
Occasional: Nausea and vomiting, diarrhoea, abdominal pain, gastric symptoms. (Diarrhoea may sometimes be a symptom of enterocolitis which may, in some cases, be haemorrhagic).
Rare: Loss of appetite, increase in liver enzymes and/or bilirubin.
Very rare: cholestatic jaundice; hepatitis or severe liver damage may develop. A particular form of enterocolitis that can occur with antibiotics is pseudomembranous colitis (in most cases due to Clostridium difficile). Even if Clostridium difficile is only suspected, administration of ofloxacin should be discontinued immediately, and appropriate treatment given. Drugs that inhibit peristalsis should not be administered in such cases.
Central nervous system:
Occasional: Headache, dizziness, sleep disorders, restlessness.
Rare: Confusion, nightmares, anxiety, depression, hallucinations and psychotic reactions, drowsiness, unsteady gait and tremor (due to disorders of muscular co-ordination), neuropathy, numbness and paraesthesia or hypaesthesiae, visual disturbances, disturbances of taste and smell (including, in exceptional cases, loss of function), extrapyramidal symptoms.
Very rare: Convulsions, hearing disorders (including, in exceptional cases, loss of hearing).
These reactions have occurred in some patients after the first dose of ofloxacin. In such cases, discontinue treatment immediately.
Isolated cases: Psychotic reactions and depression with self-endangering behaviour including suicidal ideation or acts.
Cardiovascular system:
Tachycardia and a temporary decrease in blood pressure have been reported.
Rare : circulatory collapse (due to pronounced drop in blood pressure).
Haematological side effects:
Very rare: anaemia, leucopenia (including agranulocytosis), thrombocytopenia, pancytopenia. Only in some cases are these due to bone marrow depression. In very rare cases, haemolytic anaemia may develop.
Renal side effects:
Rare: Disturbances of kidney function.
Isolated cases: Acute interstitial nephritis, or an increase in serum creatinine, which may progress to acute renal failure.
Allergic and skin side effects:
Occasional: Skin rash, itching.
Very rare: Rash on exposure to strong sunlight, other severe skin reactions. Hypersensitivity reactions, immediate or delayed, usually involving the skin (e.g. erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome, and vasculitis) may occur. In exceptional circumstances, vasculitis can lead to skin lesions including necrosis and may also involve internal organs. There are rarely other signs of anaphylaxis such as tachycardia, fever, dyspnoea, shock, angioneurotic oedema, vasculitic reactions, eosinophilia. In these cases treatment should be discontinued immediately and where appropriate, supportive treatment given.
Isolated cases: Pneumonitis.
Other side effects:
Rare: Malaise.
Very rare: Excessive rise or fall in blood-sugar levels. Weakness, joint and muscle pains (in isolated cases these may be symptoms of rhabdomyolysis).
Isolated cases: Tendon discomfort including inflammation and rupture of tendons (e.g. the Achilles tendon) particularly in patients treated concurrently with corticosteroids. In the event of signs of inflammation of a tendon, treatment with Oflomac must be halted immediately and appropriate treatment must be initiated for the affected tendon.
The possibility cannot be ruled out that ofloxacin may trigger an attack of porphyria in predisposed patients.

Except in very rare instances (e.g. isolated cases of smell, taste and hearing disorders) the adverse effects observed subsided after discontinuation of ofloxacin.

Symptoms And Treatment of Overdose
The most important signs to be expected following acute overdosage are CNS symptoms such as confusion, dizziness, impairment of consciousness and convulsive seizures as well as gastrointestinal reactions such as nausea and mucosal erosions.
In the case of overdose steps to remove any unabsorbed ofloxacin eg gastric lavage, administration of adsorbants and sodium sulphate, if possible during the first 30 minutes, are recommended; antacids are recommended for protection of the gastric mucosa.
Elimination of ofloxacin may be increased by forced diuresis.

Storage Condition
Store below 30°C in a dry place. Protect from light.

Keep medicine out of reach of children
Jauhkan ubat daripada Kanak-Kanak

Shelf Life
36 Months

Presentation:
Blisters of 10 Tablets.

MACLEODS

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