OFLACIN

Ofloxacin BP 200mg & 400mg Tablet

Composition : Oflacin-200 : Each film coated tablet contains Ofloxacin BP 200mg.
Oflacin-400 : Each film coated tablet contains Ofloxacin BP 400mg.

Pharmacology : Ofloxacin is a quinolone antimicrobial agent. The mechanism of action of ofloxacin and other fluoroquinolone antimicrobials involves inhibition of bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerases), enzymes required for DNA replication, transcription, repair and recombination. In vitro, approximately 32% of the drug in plasma is protein bound. Following oral administration, the bioavailability of ofloxacin in the tablet formulation is approximately 98%. Maximum serum concentrations are achieved one to two hours after an oral dose. Absorption of ofloxacin after single or multiple doses of 200 to 400 mg is predictable, and the amount of drug absorbed increases proportionately with the dose. Ofloxacin has biphasic elimination. Following multiple oral doses at steady-state administration, the half-lives are approximately 4-5 hours and 20-25 hours. However, the longer half-life represents less than 5% of the total AUC. Accumulation at steady-state can be estimated using a half-life of 9 hours. The total clearance and volume of distribution are approximately similar after single or multiple doses. Elimination is mainly by renal excretion.

Indications : The following infections caused by Ofloxacin susceptible *Staphylococcus, Streptococcus pyogenes, Hemolytic streptococci, Streptococcus pneumoniae, Peptostreptococcus sp., Neisseria gonorrhoeae, Escherichia coli, Citrobacter sp., Shigella sp., Klebsiella pneumoniae, Enterobacter sp., Serratia sp., Proteus sp., Pseudomonas aeruginosa, Haemophilus influenzae, Acinetobacter sp., and Campylobacter sp.,*

a) Pneumonia, Chronic Bronchitis, Diffuse panbronchiolitis, Bronchiectasis with infection, Secondary infections of chronic respiratory diseases.
b) Pharyngolaryngitis, Tonsillitis and Acute bronchitis.
c) Pyelonephritis, Cystitis, Prostatitis, Epididymitis, Gonococcal urethritis, Non-gonococcal urethritis.
d) Intrauterine infection, Adnexitis, Bartholinitis.
e) Folliculitis, Furuncle, Furunculosis, Carbuncle, Erysipelas phlegmon, Lymphangitis, Felon, Subcutaneous abscess, Spiradenitis, Acne conglobata, Infectious atheroma, Perianal abscess.
f) Mastadenitis, Superficial secondary infections after traumas, Burns, Surgery, Traumas.
g) Cholecystitis, Cholangitis.
h) Otitis media, Sinusitis.
i) Blepharitis, Hordeolum, Dacryocystitis, Tarsadenitis, Keratohelcosis.
j) Bacillary dysentery, Enteritis.
k) Periodontitis, Pericoronitis, Gnathitis.
l) Skin & soft tissue infections.

Dosage and administration : General dosage recommendation: The dose of OFLACIN is determined by the type and severity of the infection. The dosage range of 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. OFLACIN 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 Infections : 200-400mg daily preferably in the morning.
Upper Urinary Tract Infections : 200-400mg daily preferably in the morning, increasing, if necessary, to 400mg twice daily.
Lower Respiratory Tract Infections : 400mg daily preferably in the morning increasing, if necessary, to 400mg twice daily.
Uncomplicated Urethral and Cervical Gonorrhoea : A single dose of 400mg.
Non Gonococcal Urethritis and Cervicitis : 400mg daily in single or divided doses.
Impaired renal function : 100mg should be given every 48 hours, when creatinine clearance is less than 20ml/minute (serum creatinine greater than 5mg/dl).
Elderly : No adjustment of dosage is required in the elderly.
Duration of treatment : The usual treatment period is 5-10 days except in uncomplicated gonorrhoea where a single dose is recommended. Or, as directed by the registered physician.

Contraindication : Patients with hypersensitivity to Ofloxacin.
Precautions : The safety and efficacy of Ofloxacin in children, pregnant women and lactating women have not been established.
Side effects : The most common adverse reactions are nausea, rash, vomiting, abdominal pain, diarrhoea, headache, dizziness & insomnia.

Use in pregnancy and lactation : There are however, no adequate and well-controlled studies in pregnant women. Ofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It can be presumed that Ofloxacin will be excreted in human milk. Because of the potential for serious adverse reaction from Ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Use in Child : There is no data available.
Drug Interactions : There is no data available.
Overdose : There is no data available.
Storage : Store below 30°C in a dry place.
Packing : Oflacin-200 : Each box contains 20's tablets in blister pack.
Oflacin-400 : Each box contains 20's tablets in blister pack.

Manufactured by
DRUG INTERNATIONAL LTD.
Tongi, Gazipur, Bangladesh