LEVOFLOXACIN

LEGREAT
500 mg Film-Coated Tablet
Antibacterial

Formulation:
Each tablet contains:
Levofloxacin (as hemihydrate), USP..... 500mg
Product Description:
Orange coloured oblong film coated tablets with cut line on one side and McOLSON engraved on other side.

Pharmacokinetics:
Levofloxacin is rapidly and almost completely absorbed following oral administration with peak plasma concentration achieved within an hour of a dose. It is distributed into body tissues including the bronchial mucosa and lungs, but penetration into cerebrospinal fluid is relatively poor. Levofloxacin is approximately 30-40% bound to the plasma proteins. It is only metabolized to a small degree to inactive metabolites. The elimination $t_{1/2}$ of levofloxacin is 6-8 hrs, although this may be prolonged in patients with renal impairment. Levofloxacin is excreted largely unchanged, primarily in the urine. It is not removed by hemodialysis or peritoneal dialysis.

Indications:
It is active against Gram-positive and Gram-negative organisms. It is used in the treatment of community-acquired pneumonia, acute bacterial sinusitis, acute exacerbations of chronic bronchitis, complicated urinary tract infections (including pyelonephritis), chronic bacterial prostatitis and skin and soft tissue infections.

Dosage & Administration:
Usual Adult Dose: 250-500mg once or twice daily
Doses should be reduced in patients with renal impairment.

Contraindications:
Levofloxacin should not be used in children, adolescents, pregnant women or breastfeeding mothers.

Precautions:
Levofloxacin should be used with caution in patients with epilepsy or a history of CNS disorder. Care is necessary in patients with impaired hepatic or renal-function, glucose-6-phosphate-dehydrogenase deficiency or myasthenia gravis. Adequate fluid intake should be maintained during treatment to avoid excessive alkalinity of urine because of the risk of crystalluria. Exposure to strong sunlight should also be avoided. Tendon damage may occur and treatment should be discontinued if patients experience tendon pain, inflammation or tendon ruptures.

Effects on the ability to Drive or operate Machinery:
The ability to drive or operate machinery may be impaired specially, when alcohol is also taken.

Interactions:
Effect of other medicinal products on Levofloxacin
Iron salts, magnesium- or aluminium-containing antacids
Levofloxacin absorption is significantly reduced when iron salts, or magnesium- or aluminum containing antacids are administered concomitantly with Legreat tablets. It is recommended that preparations containing divalent or trivalent cations such as iron salts, or magnesium- or aluminum-containing antacids should not be taken 2 hours before or after Levofloxacin tablet administration. No interaction was found with calcium carbonate.

Sucralfate
The bioavailability of Legreat tablets is significantly reduced when administered together with sucralfate.
If the patient is to receive both sucralfate and Legreat, it is best to administer sucralfate 2 hours after the Legreat tablet administration.

Theophylline, fenbufen or similar non-steroidal anti-inflammatory drugs
No pharmacokinetic interactions of levofloxacin were found with theophylline in a clinical study. However, a pronounced lowering of the cerebral seizure threshold may occur when quinolones are given concurrently with theophylline, non-steroidal anti-inflammatory drugs, or other agents, which lower the seizure threshold.
Levofloxacin concentrations were about 13% higher in the presence of fenbufen than when administered alone.

Probenecid and cimetidine
Probenecid and cimetidine had a statistically significant effect on the elimination of levofloxacin. The renal clearance of levofloxacin was reduced by cimetidine (24%) and probenecid (34%). This is because both drugs are capable of blocking the renal tubular secretion of levofloxacin. However, at the tested doses in the study, the statistically significant kinetic differences are unlikely to be of clinical relevance.

Caution should be exercised when levofloxacin is coadministered with drugs that affect the tubular renal secretion such as probenecid and cimetidine, especially in renally impaired patients.

Other relevant information
Clinical pharmacology studies have shown that the pharmacokinetics of levofloxacin were not affected to any clinically relevant extent when levofloxacin was administered together with the following drugs: calcium carbonate, digoxin, glibenclamide, ranitidine.

Effect of Levofloxacin on other medicinal products
Ciclosporin
The half-life of ciclosporin was increased by 33% when coadministered with levofloxacin.

Vitamin K antagonists
Increased coagulation tests (PT/INR) and/or bleeding, which may be severe, have been reported in patients treated with levofloxacin in combination with a vitamin K antagonist (e.g. warfarin). Coagulation tests, therefore, should be monitored in patients treated with vitamin K Antagonists.

Drugs known to prolong QT interval
Levofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, tricyclic antidepressants, macrolides).

Other forms of interactions
Meals
There is no clinically relevant interaction with food. Legreat tablets may therefore be administered regardless of food intake.

ADVERSE EFFECTS:
Gastrointestinal disturbances include nausea, vomiting, diarrhea, abdominal pain and dyspepsia are the most frequent adverse effects. Headache, dizziness and restlessness are among the commonest effects of the CNS. In addition to rash and pruritus, hypersensitivity-type reactions affecting the skin have included, rarely, vasculitis, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reactions is necessary. Healthcare professionals are encouraged to report any suspected adverse reaction/s directly to the importer/distributor and/or to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

OVERDOSE AND TREATMENT:
According to toxicity studies in animals or clinical pharmacology studies performed with supra-therapeutic doses, the most important signs to be expected following acute overdosage of Levofloxacin tablets are central nervous system symptoms such as confusion, dizziness, impairment of consciousness, and convulsive seizures, increases in QT interval as well as gastro-intestinal reactions such as nausea and mucosal erosions.

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. Antacids may be used for protection of gastric mucosa. Haemodialysis, including peritoneal dialysis and CAPD, are not effective in removing levofloxacin from the body. No specific antidote exists.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Storage Condition:
Store at temperatures not exceeding 30°C.

Availability:
Alu-Alu Blister Pack x 5's (Box of 10's and 30's)

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