

GEMIMED TABLETS

(Gemifloxacin)

DESCRIPTION: Gemimed is a formulation of Gemifloxacin in the form of film coated Tablets.

COMPOSITION:

Each film coated tablet contains Gemifloxacin (as mesylate)......320mg (Medley's Specs.)

PHARMACODYNAMICS:

Inhibits DNA gyrase in susceptible organisms. Inhibits relaxation of super coiled DNA and promotes breakage of double stranded DNA.

PHARMACOKINETICS:

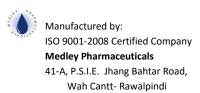
Well absorbed following the oral administration. Bioavailability is about 71%. The maximum blood concentration is reached just within 0.5 to 2.0 hrs after ingestion. Gemifloxacin is widely distributed throughout the body after its oral administration. In vitro binding of Gemifloxacin to plasma proteins in healthy personals is 60 to 70% and is concentration independent. After repeated doses, the in vivo plasma protein binding in healthy subjects ranges from 55% to 73%. Gemifloxacin can penetrate well into lung tissue and fluids. Gemifloxacin is present in high concentration at the sites of infections e.g. in the body fluids and tissues. Gemifloxacin and its metabolites are excreted via dual routes of excretion. Following oral administration about 61±9.5% of the dose is excreted in the feces and 36±9.3% in the urine as unchanged drug and its metabolites.

INDICATIONS:

Treatment of documented or suspected infections of the lower respiratory tract, sinuses, skin/skin structure, bones/ joints and urinary tract including prostatitis due to susceptible bacterial strains. Chronic bacterial prostatitis, infectious diarrhea, complicated gram negative and anaerobic intra abdominal infections (with metronidazole) due to E.coli (Enteropathic strains), B.fragilis, P.marabilis, K.pneumonia, P. aeruginosa, Campylobacter jejuni or Shigella; approved for acute sinusitis caused by H.influenzae or M.catarrhalis, also used to treat typhoid fever due to Salmonella typhi (although eradication of the chronic typhoid carrier stage has not been proven), Osteomyelitis when parentral therapy is not feasible, and sexually transmitted diseases such as uncomplicated cervical and urethral gonorrhea due to Neisseria gonorrhoeae.

CONTRAINDICATIONS:

Hypersensitivity to Gemifloxacin and to other Quinolone chemotherapeutics.



MEDLEY PHARMACEUTICALS

DOSAGE:

320mg once daily for all indications, in community acquired pneumonia for 7 days, in acute exacerbation of chronic bronchitis for five days, in acute bacterial sinusitis for five days, in acute pyelonephritis for ten days, in uncomplicated urinary tract infections for three days or as directed by the physician.

DRUG INTERACTIONS:

Gemifloxacin does not cause drug interactions with compounds mediated by CYP450 enzymes. Aluminum or magnesium containing antacids, iron or sucralfate may effect on the absorption of Gemifloxacin.

SIDE EFFECTS:

Abdominal pain, diarrhea, headache, nausea, vomiting, skin rashes, dizziness and insomnia.

PRECAUTIONS:

May prolong QT interval, avoid use in patients with uncorrected hypokalaemia. Should not be used in pregnant or lactating women. For patients with severe impairment of renal function, alteration of the dosage regimen to 160mg q24hr is necessary or as adjusted by the Pharmacist according to renal condition.

PACK AND PRESENTATION:

GEMIMED 350mg Tablets: Alu-Alu pack of 1x7's.

STORAGE:

Store at 15°C to 30°C at dry place. Protect from light. Keep out of the reach of children.



For further information please contact Manufactured by: ISO 9001-2008 Certified Company **Medley Pharmaceuticals** 41-A, P.S.I.E Jhang Bahtar road, Wah Cantt- Rawalpindi