

Gemiquin™

Gemifloxacin

Composition:

Gemiquin™ 320 Tablet: Each film coated tablet contains Gemifloxacin Mesylate INN equivalent to Gemifloxacin 320 mg.

Description:

Gemiquin™ (Gemifloxacin mesylate) is a synthetic broad spectrum antibacterial agent for oral administration. Gemifloxacin, a compound related to the fluoroquinolone class of antibiotics is available as the mesylate salt in the sesquihydrate form.

Indications:

Gemiquin™ is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below: Acute bacterial exacerbation of chronic bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae* or *Moraxella catarrhalis*. Community-acquired pneumonia (of mild to moderate severity) caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae* or *Klebsiella pneumoniae*.

Dosage & Administration:

Gemiquin™ can be taken with or without food and should be swallowed whole with a liberal amount of liquid.

The recommended dosage regimen of gemifloxacin: Acute bacterial exacerbation of chronic bronchitis (AECB): One 320 mg tablet daily for 5 days.

Community-acquired pneumonia (CAP) of mild to moderate severity-

Due to known or suspected *S pneumoniae*, *H. influenzae* *M. pneumoniae* or *C. pneumoniae* infections: One 320 mg tablet daily for 5 days.

Due to known or suspected MDRSP*, *K. pneumoniae* or *M. catarrhalis* infection: One 320 mg tablet daily for 7 days.

*MDRSP, multi-drug resistant *Streptococcus pneumoniae*.

Use in Renal Impaired Patients:

Creatinine Clearance (mL/min)	Dose
>40	See Usual Dosage Guideline
≥40	160 mg every 24 hours

Use in Hepatic Impaired Patients: No dosage adjustment is recommended in patients with mild, moderate or severe hepatic impairment. **Use in Elderly:** No dosage adjustment is recommended.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Nausea, stomach upset, loss of appetite, diarrhea, drowsiness, dizziness, headache, dry mouth, altered taste, constipation, or insomnia may occur. Seek immediate medical attention if you develop: abdominal or stomach pain/cramping, blood/mucus in your stool, persistent diarrhea. A serious allergic reaction to this drug is unlikely, but seeks immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, hives, itching, swelling, severe dizziness, breathing problem.

Precautions:

Before taking Gemifloxacin, tell your doctor if you are allergic to it; or to other quinolones such as ciprofloxacin, gatifloxacin, levofloxacin, or moxifloxacin; or if you have any other allergies. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure. Caution is advised when using this drug in children.

Use in pregnancy and Lactation: This medication should be used only when clearly needed during pregnancy. It is not known if this medication passes into breast milk. Consult your doctor before breast-feeding.

Contraindications:

Gemifloxacin is contraindicated in patients with a history of hypersensitivity to Gemifloxacin, fluoroquinolone antibiotic agents, or any of the product components.

Drug Interactions:

Concomitant administration of Gemifloxacin and Calcium carbonate, Cimetidine, Omeprazole, or an Estrogen/Progesterone oral contraceptive produce minor changes in the pharmacokinetics of Gemifloxacin. Concomitant administration of Gemifloxacin with Probenecid results in a 45% increase in systemic exposure to Gemifloxacin.

Storage Condition:

Keep in a cool and dry place below 25° C, protect from light. Keep out of the reach of children.

Presentation:

Gemiquin™ 320 Tablet: Box containing 2x4's tablets in blister pack.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.