Flogem®

Gemifloxacin

Description
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.

Mode of action
Gemifloxacin is a DNA gyrase inhibitor and also inhibits topoisomerase IV. DNA gyrase (topoisomerase IV) is an essential bacterial enzyme that maintains the superhelical structure of DNA. DNA gyrase is required for DNA replication and transcription, DNA repair, recombination, and transposition; bactericidal.

Pharmacokinetics
Gemifloxacin is rapidly absorbed from the gastrointestinal tract with an absolute bioavailability of about 71%. Peak plasma concentrations occur 0.5 to 2 hours after an oral dose. Gemifloxacin is widely distributed into body tissues including the bronchial mucosa and lungs, and is about 55 to 73% bound to plasma proteins. It undergoes limited hepatic metabolism and has an elimination half-life of about 7 hours. It is excreted as unchanged drug and metabolites in the faeces and urine. Urinary excretion is by active tubular secretion and is reduced by probenecid. Distribution into milk has been found in rats.

Composition: Flogem® 320 mg Tablet: Each film coated tablet contains Gemifloxacin 320 mg as Gemifloxacin Mesylate INN.

Indications
Gemifloxacin 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* (including multi-drug resistant strains [MDRSP])*, *Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, Chlamydia pneumoniae,* or *Klebsiella pneumoniae*.
- *Acute sinusitis*
- *Uncomplicated urinary tract infections*
- *Acute pyelonephritis*

Dosage & administration
Gemifloxacin can be taken with or without food and should be swallowed whole with a liberal amount of liquid. The recommended dose of Gemifloxacin is 320 mg daily, according to the following table.

INDICATION	DOSE	DURATION
Acute bacterial exacerbation of chronic bronchitis (AECB)	One 320 mg tablet daily	5 days
Acute sinusitis		5 days
Community-acquired pneumonia (CAP)		5-7 days*
Uncomplicated urinary tract infections		3 days
Acute pyelonephritis		10 days

* Therapy may be extended to 14 days of therapy in cases of serious pneumonia.
The recommended dose and duration of Gemifloxacin should not be exceeded.
Use in Renally Impaired Patients: Dose adjustment in patients with creatinine clearance >40 ml/min is not required. Modification of the dosage is recommended for patients with creatinine clearance ≤ 40 ml/min.

Recommended Doses for Patients with Renal Impairment

Creatinine Clearance (ml/min)	Dose
>40	See Usual Dosage
≤40	160 mg every 24 hours

Use in Hepatically Impaired Patients: No dosage adjustment is recommended in patients with mild (Child-Pugh Class A), moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. *Use in Elderly:* No dosage adjustment is recommended

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

Use in pregnancy & Lactation
There are no adequate and well-controlled studies in pregnant women. Reports of arthropathy (observed in immature animals and reported rarely in humans) have limited the use of fluoroquinolones in pregnancy. Reversible fetal growth retardation was observed with gemifloxacin in some animal studies. Based on limited data, quinolones are not expected to be a major human teratogen. Although quinolone antibiotics should not be used as first-line agents during pregnancy, when considering treatment for life-threatening infection and/or prolonged duration of therapy, the potential risk to the fetus must be balanced against the severity of the potential illness.
Excretion in breast milk is unknown. So, Gemifloxacin is not recommended in lactating women.

Side effects
Nausea, stomach upset, loss of appetite, diarrhea, drowsiness, dizziness, headache, dry mouth, altered taste, constipation, or trouble sleeping may occur. This medication may rarely cause a severe intestinal condition (pseudomembranous colitis) due to resistant bacteria. This condition may occur while receiving therapy or even weeks after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have the following symptoms because these products may make them worse. 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, trouble breathing.

Drug interactions
Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: "blood thinners" (e.g., warfarin), corticosteroids (e.g., prednisone), diabetes medications (e.g., glyburide, insulin), probenecid & live vaccines. Report the use of drugs which might increase seizure risk (decrease seizure threshold) when combined with gemifloxacin, such as phenothiazines (e.g., thioridazine), tricyclic antidepressants (e.g., amitriptyline), isoniazid (INH), or theophylline. Other drugs besides gemifloxacin which may affect the heart rhythm include amiodarone, dofetilide, pimozide, quinidine, sotalol, procainamide, and sparfloxacin among others. QTc prolongation can infrequently result in serious, rarely fatal, irregular heartbeats. Consult your doctor or pharmacist for details. Ask for instructions about whether you need to stop any other QTc-prolonging drugs you may be using in order to minimize the risk of this effect. Do not start or stop any medicine without doctor or pharmacist approval.

Precautions
Before taking gemifloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolones such as ciprofloxacin, gatifloxacin, levofloxacin, or moxifloxacin; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain or nervous system disorders (e.g., cerebral arteriosclerosis, tumors & increased intracranial pressure), heart problems (e.g., cardiomyopathy, slow heart rate, torsades de pointes, QTc prolongation), history of seizures, kidney disease, liver disease, muscle/joint/tendon problems, untreated mineral imbalance (e.g., low potassium or magnesium). This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths or sunlamps. Caution is advised when using this drug in the elderly because they may be more sensitive to its side effects. Caution is advised when using this drug in children. Contact your doctor for more information. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known if this medication passes into breast milk. Consult your doctor before breast-feeding.

Over dosage
Any signs or symptoms of overdosage should be treated symptomatically. No specific antidote is known. In the event of acute oral overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage; the patient should be carefully observed and treated symptomatically with appropriate hydration maintained. Hemodialysis removes approximately 20 to 30% of an oral dose of gemifloxacin from plasma.
Mortality occurred at oral gemifloxacin doses of 1600 mg/kg in rats and 320 mg/kg in mice. The minimum lethal intravenous doses in these species were 160 and 80 mg/kg, respectively. Toxic signs after administration of a single high oral dose (400 mg/kg) of gemifloxacin to rodents included ataxia, lethargy, piloerection, tremor, and clonic convulsions.

Storage
Store in a cool and dry place, protected from light.

Packaging
Flogem® 320 mg Tablet: Each carton containing 6X1 tablets in Alu-Alu blister pack.

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