

# Gemicin®

Gemifloxacin INN



## Composition

Gemicin® Tablet : Each film coated tablet contains Gemifloxacin Mesylate INN equivalent to 320 mg of Gemifloxacin.

## Description

Gemicin® 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

Gemicin® 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*.

## Dosage And Administration

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

*Acute bacterial exacerbation of chronic bronchitis*

Dose / Duration: One 320 mg tablet daily for 5 days

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

- Due to known or suspected *S. pneumoniae*, *H. influenzae*, *M. pneumoniae*, or *C. pneumoniae* infection

Dose / Duration: One 320 mg tablet daily for 5 days

- Due to known or suspected multi-drug resistant *Streptococcus pneumoniae*, *K. pneumoniae*, or *M. catarrhalis* infection

Dose / Duration: One 320 mg tablet daily for 7 days

The recommended dose and duration of Gemicin® 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. In this case, the dose should be 160mg every 24 hours.
- Patients requiring routine hemodialysis or continuous ambulatory peritoneal dialysis (CAPD) should receive 160 mg every 24 hours.

Use in Hepatically Impaired Patients:

No dosage adjustment is recommended in patients with mild, moderate or severe hepatic impairment.

Use in Elderly:

No dosage adjustment is recommended.

## Contraindications

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

## Adverse effects

Gastrointestinal: nausea, upper GI discomfort  
CNS: headache, insomnia, dizziness; hallucinations, depression, psychotic reaction (rare)

Renal: interstitial nephritis

Cardiovascular: QTC prolongation, torsades de pointes, arrhythmias

Skin: Rash

## Precautions

- Prolongation of QT interval; avoid concurrent use with other drugs that prolong QT interval and in patients with risk factors for torsades de pointes (hypokalemia, significant bradycardia, cardiomyopathy)
- Renal insufficiency
- Patients with glucose 6-phosphate dehydrogenase deficiency.
- Excessive exposure to sunlight should be avoided
- Diabetes mellitus; disturbance of blood glucose have been reported, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent or with insulin

## Drug Interactions

Divalent cations: aluminum, magnesium zinc, iron, calcium, antacids, sucralfate- reduced bioavailability of quinolones (can cause therapeutic failure)

Pregnancy:

Category C: Risk unknown. Human studies inadequate.

## Pack

Gemicin® Tablet : Each box contains 7 tablets in Alu-Alu blister pack.

## Storage

Store in a cool and dry place below 30 °C. Protect from light.

Medicine: Keep out of reach of children



Healthcare

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