

# Geoflox

Gemifloxacin Mesylate INN

## COMPOSITION :

**Geoflox tablet:** Each film coated tablet contains Gemifloxacin Mesylate INN equivalent to Gemifloxacin 320 mg.

## PHARMACOLOGY:

**Gemifloxacin** is an oral broad-spectrum compound related to the fluoroquinolone class of antibiotics is available as the mesylate salt in the sesquihydrate form. Gemifloxacin is bactericidal and its mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required to replicate one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian. Gemifloxacin is active against both Gram-positive and Gram-negative bacteria.

## INDICATION:

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 (CAP) [of mild to moderate severity] caused by *Streptococcus pneumoniae* (including multi-drug resistant strains-MDRS), *Haemophilus influenzae*, *Moraxella catarrhalis*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae* or *Klebsiella pneumoniae*.

## 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)	320 mg daily	5 days
<b>Community-Acquired Pneumonia (CAP) [of mild to moderate severity]</b>		
due to known or suspected <i>S. pneumoniae</i> , <i>H. influenzae</i> , <i>M. pneumoniae</i> , or <i>C. pneumoniae</i> infection	320 mg daily	5 days
due to known or suspected MDRSP*, <i>K. pneumoniae</i> , or <i>M. catarrhalis</i> infection		7 days

\*MDRSP, multi-drug resistant *Streptococcus pneumoniae*, includes isolates previously known as PRSP (penicillin-resistant *Streptococcus pneumoniae*), and are strains resistant to two or more of the following antibiotics: penicillin (MIC  $\geq$  2 mcg/mL), 2nd generation cephalosporins (e.g., cefuroxime), macrolides, tetracyclines and trimethoprim/sulfamethoxazole. The recommended dose and duration of Gemifloxacin should not be exceeded.

## USE IN RENAL IMPAIRED PATIENTS:

Dose adjustment in patients with creatinine clearance  $\geq$  40 mL/min is not required. Modification of the dosage is recommended for patients with creatinine clearance  $\leq$  40 mL/min. Dosage guidelines for use in patients with renal impairment is given in the table:

Creatinine Clearance (mL/min)	Dose
$\geq$ 40	See Usual Dosage
$\leq$ 40	160 mg every 24 hours

When only the serum creatinine concentration is known, the following formula may be used to estimate creatinine.

$$\text{Men: Creatinine Clearance (mL/min)} = \frac{(140 - \text{age}) \times (\text{actual body wt in kg})}{72 \times (\text{Serum Creatinine})}$$

Women: 0.85 x the value calculated for men.

## 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.

## CONTRAINDICATIONS:

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

## SIDE EFFECT:

Nausea, stomach upset, loss of appetite, diarrhea, drowsiness, dizziness, headache, dry mouth, altered taste, constipation or sleeping trouble may occur. A serious allergic reaction to this drug is unlikely.

## USE IN PREGNANCY & LACTATION:

This medication should be used only when clearly needed during pregnancy. The risks and benefits should be discussed with doctor. It is not known if this medication passes into breast milk. Breast feeding mother should consult with doctor before taking it.

## PRECAUTIONS:

Before taking Gemifloxacin, one should tell his/her doctor or pharmacist if he/she is allergic to it; or to other quinolones such as ciprofloxacin, gatifloxacin, levofloxacin, or moxifloxacin; or if the person has any other allergies. Before using this medication, he/she should tell doctor or pharmacist their medical history, especially of: brain or nervous system disorders (e.g., cerebral arteriosclerosis, tumors and increased intracranial pressure), heart problems (e.g., cardiomyopathy, slow heart rate, 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 the patient dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Alcoholic beverages should be limited. This medication may make the person more sensitive to the sun. Prolonged sun exposure, tanning booths or sunlamps should be avoided. 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. Consult with doctor for more information.

## DRUG INTERACTIONS:

May interact with blood thinners (e.g., warfarin), corticosteroids (e.g., prednisolone), diabetes medications (e.g., insulin), probenecid and live vaccines. Report the use of drugs which might increase seizure risk (decrease the seizure threshold) when combined with gatifloxacin, such as phenothiazines (e.g., thioridazine), tricyclic antidepressants (e.g., amitriptyline), Isoniazide (INH) or theophylline.

## OVERDOSE:

No specific antidote is known. In the event of acute oral over dosage, the stomach should be emptied by inducing vomiting or gastric lavage; the patient should be carefully observed and treated symptomatically with appropriate hydration maintained.

## STORAGE:

Store in a cool & dry place, protected from light. Keep out of the reach of children.

## PACKING :

**Geoflox Tablet:** Box containing 1x4's/2x4's/3x4's tablets in alu- alu blister pack.

Manufactured by:



**Sharif Pharmaceuticals Ltd**  
 Rupganj, Narayanganj, Bangladesh.