W: 200 mm
L: 250 mm

# Kmi Tablet

Gemifloxacin INN 320 mg

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

**Description:**
Gemifloxacin mesylate is a synthetic broad spectrum fluoroquinolone antibiotic for oral administration. It is bactericidal with minimum bactericidal concentrations. Gemifloxacin acts by inhibiting DNA synthesis through inhibition of the bacterial type II topoisomerases, DNA gyrase and/or topoisomerase IV (TOPO IV) which are both essential for bacterial growth.
Gemifloxacin is rapidly absorbed after oral administration and is widely distributed throughout the body. It undergoes limited hepatic metabolism and is excreted as unchanged drug and metabolites in the faeces and urine. No dose adjustment is required based on gender.

**Indications:**
Kmi tablet is indicated for the treatment of the following bacterial infections in adults caused by sensitive organisms as follows:
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:**
Kmi (Gemifloxacin) tablet can be taken with or without food and should be swallowed whole with a liberal amount of liquid. The recommended dose of Kmi (Gemifloxacin) tablet is 320 mg daily, according to the following table:

| Indication | Dose & Duration |
|---|---|
| Acute bacterial exacerbation of chronic bronchitis | 320 mg tablet once daily for 5 days |
| Community-acquired pneumonia of mild to moderate severity due to ** | |
| a) Known or suspected *S. pneumoniae, H.influenzae, M. pneumoniae* or *C. pneumoniae* infection | 320 mg tablet once daily for 5 days |
| b) Known or suspected MDRSP*, *K. pneumoniae* or *M. catarrhalis* infection | 320 mg tablet once daily for 7days |

*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 ≥ 2 µg/ml), 2nd generation cephalosporins (e.g., cefuroxime), macrolides, tetracyclines and trimethoprim /sulfamethoxazole.
**Therapy may be extended to 14 days in cases of serious pneumonia. The recommended dose and duration of Kmi (Gemifloxacin) tablet should not be exceeded.

**Patients with renal impairment:**
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. The below mentioned table provides dosage guidelines for use in patients with renal impairment:

| Creatinine Clearance | Dose |
|---|---|
| > 40 mL/min | Usual Dosage (1 tablet daily) |
| ≤ 40 mL/min | 160 mg (1/2 tablet) every 24 hours |

Patients on haemodialysis or continuous ambulatory peritoneal dialysis therapy should receive 160 mg (1/2 tablet) once daily.

**Patients with hepatic impairment:**
Kmi tablet may be given to patients with hepatic impairment with no requirement for dose adjustment.

**Elderly patients:**
No dose adjustment is recommended.

**Side-effects:**
The general adverse events include abdominal pain, diarrhoea, headache, nausea, rash and vomiting, loss of appetite, drowsiness, altered taste, constipation and trouble in sleeping may occur. Some side effects have been infrequently reported such as fungal overgrowth in body, dizziness and insomnia, urticaria, pruritis and a maculopapular erythomatous skin rash. This medication may rarely cause a severe intestinal condition (psudomembranous colitis) due to resistant bacteria. This condition may occur while receiving therapy or even weeks after treatment has stopped. A serious allergic reaction to this drug is unlikely. If it occurs, symptoms of a serious allergic reaction include: rash, hives, itching, swelling, severe dizziness and trouble in breathing.

**Contraindications:**
Gemifloxacin is contraindicated in patients with a history of hypersensitivity to gemifloxacin and fluoroquinolone antibiotic agents. Gemifloxacin should not be used in children under 18 years of age.

**Special precaution:**
For patients with severe impairment of renal function, alteration of the dosage regimen to 160 mg once daily is necessary. Adequate hydration of patients receiving Gemifloxacin should be maintained to prevent the formation of a highly concentrated urine and crystalluria. Gemifloxacin may cause dizziness; if this occurs, patients should not operate an automobile or machinery or engage in activities requiring mental alertness or co-ordination. Avoid prolonged sun exposure. Caution is advised when using this drug in the elderly because they may be more sensitive to its side-sffects.

**Use in pregnancy and lactation:**
Gemifloxacin should not be used in pregnant or lactating women. The safety and efficacy of Gemifloxacin in pregnant or lactating women have not been established. 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.

**Warning:**
Tendinitis and tendon ruptures may occur in any age group during treatment with quinolones, including Gemifloxacin, but particularly in elderly patients or when corticosteroids are being co-administered. Gemifloxacin should be discontinued if tendinitis is suspected or at the first sign of pain or inflammation and the affected limb should be rested. Gemifloxacin should be used with caution in patients predisposed to QTc interval prolongation or in patients taking other medications that are known to prolong the QTc interval. Gemifloxacin should be used with caution in patients with epilepsy.

**Drug interactions:**
Gemifloxacin absorption is significantly reduced when aluminium or magnesium containing antacids and iron salts are concomitantly administered. Gemifloxacin should be taken at least 2 hours before or 3 hours after taking these agents. Gemifloxacin should be taken at least 2 hours before sucralfate administration. No clinically significant interactions have been observed when Gemifloxacin was co-administered with omeprazole, digoxin and oral contraceptives. May interact with blood thinners (e.g. warfarin), corticosteroids (e.g. prednisone), diabetes medications (e.g. insulin), probnecid, live vaccines. Patient should be advised to report the use of drugs which might increase seizure risk (decrease seizure threshold) when combined with gemifloxacin, such as phenothiazine (e.g. thioridazine), tricyclic antidepressants (e.g. amitriptyline), isoniazid (INH) or theophyline.

**Overdosage:**
Any signs or symptoms of overdosage should be treated symptomatically. No specific antidote is known. Dialysis does not remove Gemifloxacin sufficiently to be useful in overdose. 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, treated symptomatically and adequate hydration should be maintained.

**Pharmaceutical Precautions:**
Store in cool, dry place, away from light. Keep out of reach of children.

**Commercial Packs:**
Box containing 2X3 tablets in blister pack

**Manufactured by :**

KEMIKO PHARMACEUTICALS LTD.
Bangladesh