

## Gati<sup>™</sup> 400<sup>®</sup>

### Presentation

Gati<sup>™</sup> 400 tablet: Each film-coated tablet contains Gatifloxacin INN 400 mg.

### Description

Gatifloxacin is a synthetic broad spectrum 8-methoxyfluoroquinolone antibacterial agent. Gatifloxacin has in vitro activity against a wide range of gram negative and gram positive organisms.

### Indication

Gati<sup>™</sup> 400 (gatifloxacin) is indicated for the treatment of infections due to susceptible strains of the designated microorganisms in the conditions listed below:

Acute bacterial exacerbation of chronic bronchitis due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, or *Staphylococcus aureus*.

Acute sinusitis due to *Streptococcus pneumoniae* or *Haemophilus influenzae*.

Community-acquired pneumonia due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, or *Legionella pneumophila*.

Uncomplicated skin and skin structure infections (i.e., simple abscesses, furuncles, folliculitis, wound infections, and cellulitis) due to *Staphylococcus aureus* (methicillin-susceptible strains only) or *Streptococcus pyogenes*.

Uncomplicated urinary tract infections (cystitis) due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*.

Complicated urinary tract infections due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*.

Pyelonephritis due to *Escherichia coli*.

Uncomplicated urethral and cervical gonorrhea due to *Neisseria gonorrhoeae*.

Acute, uncomplicated rectal infections in women due to *Neisseria gonorrhoeae*.

### Dosage and Administration

Acute bacterial exacerbation of chronic bronchitis, 400 mg once daily for 5 days.

Acute sinusitis, 400 mg once daily for 10 days.

Community-acquired pneumonia, 400 mg once daily for 7-14 days.

Uncomplicated skin and skin structure infections, 400 mg once daily for 7-10 days.

Uncomplicated urinary tract infections (cystitis), 400 mg single dose or 200 mg once daily for 3 days.

Complicated urinary tract infections, 400 mg once daily for 7-10 days.

Pyelonephritis, 400 mg once daily for 7-10 days.

Uncomplicated urethral and cervical gonorrhea, 400 mg single dose.

Acute, uncomplicated rectal infections in women, 400 mg single dose.

In case of renal insufficiency: If the creatinine clearance is  $<40$  ml/min, hemodialysis occurred or continuous peritoneal dialysis is present the starting dose will be 400 mg and subsequent daily dose will be 200 mg.

Impaired Hepatic Function: No adjustment in the dosage of gatifloxacin is necessary in patients with moderate hepatic impairment. There are no data in patients with severe hepatic impairment.

Gati 400 tablet may be taken with or without meals.

#### Contraindications

Gatifloxacin is contraindicated in persons with a history of hypersensitivity to gatifloxacin or any member of the quinolone class of antimicrobial agents.

#### Precautions

The following measures should be taken during administration of Gatifloxacin:

Gatifloxacin may produce changes in the electrocardiogram (QTc interval prolongation).

Gatifloxacin should be used with caution in patients receiving drugs that may affect the QTc interval such as cisapride, erythromycin, antipsychotics, and tricyclic antidepressants.

In patients with impaired renal function (creatinine clearance  $<40$  ml/min), adjustment of the dosage regimen is necessary.

Disturbances of blood glucose, including symptomatic hyper- and hypoglycemia, have been reported with gatifloxacin, usually in diabetic patients. Therefore, careful monitoring of blood glucose is recommended when gatifloxacin is administered to patients with diabetes.

#### Side-Effects

Gatifloxacin is generally well tolerated. The most common side effects that can occur while taking this drug are usually mild and include nausea, vomiting, stomach pain, diarrhea, dizziness, and headache.

#### Use in Pregnancy and Lactation

The safety and effectiveness of gatifloxacin in pregnant women, and lactating mother have not been established.

#### Use in Children

The safety and effectiveness of gatifloxacin in pediatric patients, adolescents (less than 18 years of age) have not been established.

#### Drug Interactions

Probenecid: Concomitant administration of Gatifloxacin with probenecid resulted in increase in AUC and a longer half-life of gatifloxacin.

**Iron:** When Gatifloxacin was administered concomitantly with ferrous sulfate, bioavailability of gatifloxacin was reduced. Administration of Gatifloxacin 2 hours after or 2 hours before ferrous sulfate did not significantly alter the oral bioavailability of gatifloxacin.

**Antacids:** An aluminum/magnesium-containing antacid did not have a clinically significant effect on the pharmacokinetics of gatifloxacin when administered 4 hours after gatifloxacin administration.

**Milk, Calcium, and Calcium-containing Antacids:** No significant pharmacokinetic interactions occur when milk or calcium carbonate is administered concomitantly with Gatifloxacin.

**Zinc, Magnesium, or Iron:** Gatifloxacin can be administered 4 hours before the administration of dietary supplements containing zinc, magnesium, or iron (such as multivitamins).

**Digoxin, Cimetidine, Midazolam, Theophylline, Warfarin, or Glyburide**  
No significant pharmacokinetic interactions occur when digoxin, cimetidine, midazolam, theophylline, warfarin, or glyburide is administered concomitantly with Gatifloxacin.

#### Over Dosage

Gatifloxacin exhibits a low potential for acute toxicity in animal studies. The minimum lethal oral doses in rats and dogs were greater than 2000 mg/kg and 1000 mg/kg, respectively. Clinical signs observed included decreased activity and respiratory rate, vomiting, tremors, and convulsions.

#### Storage Condition

Store at a cool and dry place, protected from light & moisture.

#### How Supplied

Gati 400 tablet : Box contains 2 x 10 tablets in blister pack.