

Gatifloxacin

Introduction: Gatifloxacin is used to reduce the development of drug-resistant bacteria and maintain the effectiveness of Gatifloxacin and other antibacterial drugs, Gatifloxacin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Mechanism of Action: Gatifloxacin is a DNA gyrase inhibitor, and also inhibits topoisomerase IV. DNA gyrase (topoisomerase II) 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; inhibition is bactericidal.

Pharmacology:

Absorption: Oral: Well absorbed;

Distribution: Vd: 1.5-2.0 L/kg; concentrates in alveolar macrophages and lung parenchyma

Metabolism: Only 1%; no interaction with CYP

Excretion: Urine (70% as unchanged drug, <1% as metabolites); feces (5%)

Special population:

Gender: The effects of age, race, and gender are not statistically significant.

Renal Impairment: Old age and renal impairment are significant contributing factors for the hyperglycemic adverse event from gatifloxacin.

Hepatic impairment: No dosage adjustment is recommended for patients with moderate hepatic impairment.

Indications: Treatment of the following infections when caused by susceptible bacteria: Acute bacterial exacerbation of chronic bronchitis; acute sinusitis; community-acquired pneumonia including pneumonia caused by multidrug-resistant *S. pneumoniae* (MDRSP); uncomplicated skin and skin structure infection; uncomplicated urinary tract infections (cystitis); complicated urinary tract infections; pyelonephritis; uncomplicated urethral and cervical gonorrhea; acute, uncomplicated rectal infections in women.

Dosage: Doses of Gatifloxacin are administered once every 24 hours. These recommendations apply to all patients with a creatinine clearance 40 mL/min. For patients with a creatinine clearance 40 mL/min.

Gatifloxacin Dosage Guidelines		
Infection	Daily Dose	Duration
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg	5 days

Acute Sinusitis	400 mg	10 days
Community-acquired Pneumonia	400 mg	7-14 days
Uncomplicated Skin and Skin Structure Infections	400 mg	7-10 days
Uncomplicated Urinary Tract Infections (cystitis)	400 mg or 200 mg	Single dose or 3 days
Complicated Urinary Tract Infections	400 mg	7-10 days
Acute Pyelonephritis	400 mg	7-10 days
Uncomplicated Urethral Gonorrhea in Men; Endocervical and Rectal Gonorrhea in Women	400 mg	Single dose

Impaired Renal Function: Since gatifloxacin is eliminated primarily by renal excretion, a dosage modification is recommended for patients with creatinine clearance <40 mL/min, including patients on hemodialysis and on CAPD. The recommended dosage of Gatifloxacin is:

Recommended Dosage of Gatifloxacin in Adult Patients with Renal Impairment			
Creatinine Clearance	Initial Dose	Subsequent Dose	
≥40 mL/min	400 mg	400 mg every day	
<40 mL/min	400 mg	200 mg every day	
Hemodialysis	400 mg	200 mg every day	
Continuous peritoneal dialysis	400 mg	200 mg every day	

Chronic Hepatic Disease: No adjustment in the dosage of Gatifloxacin is necessary in patients with moderate hepatic impairment (Child-Pugh Class B). There are no data in patients with severe hepatic impairment.

Side effects:

Local reactions include: Back pain; change in taste; constipation; depression; diarrhea; dizziness; gas; headache; indigestion; itching; nausea; pain; pain or redness at the injection site; restlessness; runny nose; sinus inflammation; sleeplessness; sore throat; tiredness; vomiting.

Other side effects: Severe allergic reactions are bloody stools; chest pain or pounding in the chest; confusion; excessive hunger, thirst, or urination; fainting; fast or irregular heartbeat; hoarseness; lightheadedness; loss of consciousness; nightmares; paranoia; seizures; severe or continuous diarrhea; stomach pain/cramps; sudden onset of sweating, pale skin, or blurred vision; tendon or joint pain or swelling; tremors; unusual or severe drowsiness or dizziness.

Precautions: Use with caution in patients with significant bradycardia or acute myocardial ischemia. Use caution in patients with known prolongation of QT interval, uncorrected hypokalemia, or concurrent administration of other medications known to prolong the QT interval may cause increased CNS stimulation, increased intracranial pressure, convulsions, or psychosis. Use with caution in individuals at risk of seizures. Discontinue in patients who experience significant CNS adverse effects (dizziness, hallucinations, suicidal ideation or actions). Use caution in renal dysfunction (dosage adjustment required) and in severe hepatic insufficiency.

Pregnancy: There are no controlled data in human pregnancies.

Nursing mothers: It is not known whether this drug is excreted in human milk. Caution should be exercised when gatifloxacin is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of gatifloxacin in pediatric populations have not been established.

Geriatric use: Elderly patients are more likely to have decreased renal function and the risk of toxic reactions may be greater, therefore care should be taken in dose selection and it may be useful to monitor renal function. Elderly patients who may have unrecognized diabetes, age-related decrease in renal function, underlying medical problems, and/or are taking concomitant glucose-altering medications may be at particular risk for serious dysglycemia.

Contraindications: Hypersensitivity to gatifloxacin, other quinolone antibiotics, or any component of the formulation.

How supplied: Customized as per request.