Geminox®

Gemifloxacin INN Film Coated Tablet

DESCRIPTION

GEMINOX® is the preparation of Gemifloxacin Mesylate, a synthetic broad-spectrum antibacterial agent for oral administration. Gemifloxacin, a compound related to the fluoroquinolone class of antibiotics. The bacterial action of Gemifloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair and recombination.

INDICATIONS

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 ADMINISTRATIONS

Gemifloxacin can be taken with or without food and should be swallowed whole with a liberal amount of liquid. The recommended dose of **GEMINOX®** is 320 mg daily, according to following table:

INDICATION	DOSE/DURATION
Acute bacterial exacerbation of chronic bronchitis	**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	One 320 mg tablet daily for 5 days
due to known or suspected MDRSP*, *K. pneumoniae* or *M. catarrhalis infection*	One 320 mg tablet daily for 7 days
*MDRSP: multi-drug resistant *Streptococcus pneumoniae*, includes isolates previously known as PRSP (penicillin-resistant *Streptococcus pneumoniae*) 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.	

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.

Creatinine Clearance (mL/min)	Dose
> 40	320 mg every 24 hours
≤ 40	160 mg every 24 hours

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

SIDE-EFFECTS

Commonly rash, nausea, diarrhea, urticaria and vomiting. Comparator antibiotics were discontinued because of an adverse event at an overall comparable rate of 2.1%, primarily due to diarrhea, nausea, vomiting, rash, abdominal pain and vertigo.

PRECAUTIONS

General: Prescribing Gemifloxacin in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Rash: In clinical studies, rash occurred more often with Gemifloxacin than with therapy with comparator agents. Increasing incidence of rash was associated with younger age (especially below 40), female gender, use of hormone replacement therapy and longer durations of therapy. Urticarial reactions, some of which were not classified as rash, were more common in Gemifloxacin patients than in comparator patients. Gemifloxacin should be discontinued in patients developing a rash or urticaria while on treatment. Gemifloxacin should not be used in children under 18 years of age.

CONTRAINDICATIONS

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

WARNING

Fluoroquinolones, including Gemifloxacin, are associated with an increased risk of tendinitis and tendon rupture in all ages. The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is further increased in older patients usually over 60 years of age, in those taking corticosteroid drugs. Fluoroquinolones may prolong the QT interval in some patients. Gemifloxacin should be avoided in patients with a history of prolongation of the QTc interval, patients with uncorrected electrolyte disorders.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C

Gemifloxacin should not be used in pregnant women unless the potential benefit to the mother outweighs the risk to the fetus. There are no adequate and well-controlled studies in pregnant women.

Gemifloxacin is excreted in the breast milk of rats. There is no information on excretion of Gemifloxacin into human milk. Therefore, Gemifloxacin should not be used in lactating women unless the potential benefit to the mother outweighs the risk.

DRUG INTERACTIONS

Antacids/Di- and Trivalent Cations: The systemic availability of Gemifloxacin is significantly reduced when an aluminum- and magnesium- containing antacid is concomitantly administered (AUC decreased 85%; C_{max} decreased 87%). Administration of an aluminum- and magnesium- containing antacid or ferrous sulfate (325 mg) at 3 hours before or at 2 hours after Gemifloxacin did not significantly alter the systemic availability of Gemifloxacin. Calcium carbonate (1000 mg) given either 2 hr before or 2 hr after Gemifloxacin administration showed no notable reduction in Gemifloxacin systemic availability.

Omeprazole: Co-administration of a single dose of 320 mg Gemifloxacin with Omeprazole 40 mg once daily for 4 days resulted in slight average increases in Gemifloxacin AUC and Cmax of 10% and 11%, respectively.

PHARMACEUTICAL PRECAUTIONS

Keep in a dry place and away from light. Keep out of reach of children.

PACKAGING

GEMINOX® Tablet: Box containing 2 strips of 4 tablets each. Each film-coated tablet contains Gemifloxacin Mesylate INN equivalent to 320 mg Gemifloxacin.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED.

GAZIPUR, BANGLADESH

PM02668 V01