Orasquin®

Gemifloxacin 320 mg

Presentation

Orasquin® Tablet: Each film coated tablet contains Gemifloxacin Mesylate INN equivalent to Gemifloxacin 320 mg.

Description

Gemifloxacin is a fluoroquinolone antibiotic. It is bactericidal with minimum bactericidal concentrations. Gemifloxacin acts by inhibiting DNA synthesis through inhibition of both DNA gyrase and topoisomerase IV (TOPO IV) which are essential for bacterial growth.

Gemifloxacin is rapidly absorbed after oral administration. It is widely distributed throughout the body. Studies in healthy subjects showed that gemifloxacin is distributed rapidly into target tissues and body fluids such as the lung (epithelial lining fluid, alveolar macrophages, bronchial tissue) and nasal secretions.

Following oral administration of Gemifloxacin, approximately 36% and 61% of the dose is excreted in the urine and feces, respectively, as unchanged drug and metabolites. AUC values were generally only slightly higher (approx. 10%) in women than in men. No dose adjustment is required based on gender.

Indications

Gemifloxacin 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

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

Indications		Dose/ Duration
Acute bacterial exacerbation of chronic bronchitis		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	320 mg tablet daily for 5 days
	Due to known or suspected MDRSP*, *K. pneumoniae or M. catarrhalis* infection	320 mg tablet daily for 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 ≥2 µg/mL), 2nd generation cephalosporins (e.g., cefuroxime), macrolides, tetracyclines and trimethoprim/ sulfamethoxazole.		

Renal impairment: Dose adjustment in patients with mild/moderate renal impairment is not required. Some modification of dosage is recommended for patients with severe renal dysfunction according to the following table-

Creatinine clearance (ml/min)	Dose
≥40	Usual dose
<40	160 mg once daily

Patients on haemodialysis or continuous ambulatory peritoneal dialysis therapy should receive 160 mg once daily.

Hepatic impairment: Gemifloxacin may be given to patients with hepatic impairment, with no requirement for dose adjustment.

Elderly patients: Dose adjustment is not required.

Side effects

The general adverse events include abdominal pain, diarrhea, headache, nausea, vomiting and rash. There is a risk of retinal detachment. Some side effects have been infrequently reported such as fungal overgrowth in body, dizziness and insomnia, urticaria, pruritis and a maculopapular erythematous skin rash.

Use in Pregnancy and Lactation

The safety and efficacy of Gemifloxacin in pregnant or lactating women have not been established. Gemifloxacin should not be used in pregnant or lactating women.

Contraindication

Known hypersensitivity to Gemifloxacin and other quinolones and patients who have previously suffered tendon damage with fluoroquinolones. Gemifloxacin should not be used in children under 18 years of age.

Precaution

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. 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. In clinical studies with Gemifloxacin a small mean increase in QTc interval was observed. 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-Interaction

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 these agents. Gemifloxacin should be taken at least 2 hours before sucralfate administration.

Overdosage

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.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack

Orasquin® Tablet: Each box contains 8 tablets in Alu-Alu blister strips.

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Savar, Dhaka, Bangladesh
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