GEMITAB

GEMIFLOXACIN MESYLATE

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

Pharmacology:
Gemifloxacin Mesylate INN is a synthetic broad-spectrum fluoroquinolone antibiotic. 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 which are both essential for bacterial growth.

Dosage And Administration:
The recommended dose of Gemifloxacin is 320 mg daily, according to the following table. Recommended Dosage Regimen: The clinical decision regarding the use of a 5 days or 7 days regimen should be guided by results of the initial sputum culture. Acute exacerbation of chronic bronchitis 5 days Community acquired pneumonia 5-7* days Acute bacterial sinusitis 5 days Otitis Media 7 days Uncomplicated Urinary tract infections 3 days. * Due to known or suspected MDRSP, K pneumoniae, or M catarrhalis infection. 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. > 40: See Usual Dosage < 40: 160 mg every 24 hours

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

Warning And Precaution:
Before taking Gemifloxacin, cautions should be taken if patients are allergic to it; or to other quinolones. This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid prolonged sun exposure. Caution is advised when using this drug in elderly because they may be more sensitive to its side effects. Increased risk of tendinitis and tendon ruptures may occur in any age group during treatment with quinolones (including Gemifloxacin).

Side Effects:
Nausea, stomach upset, loss of appetite, diarrhea, drowsiness, dizziness, headache, dry mouth, altered taste, constipation, or trouble sleeping may occur. A serious allergic reaction to this drug is unlikely. The risk of Retinal detachment may also occur.

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, should not be used in lactating women unless the potential benefit to the mother outweighs the risk.

Drug Interaction:
Gemifloxacin absorption is significantly reduced when aluminum 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. No clinically significant interactions have been observed when Gemifloxacin was co-administered with omeprazole theophylline, digoxin, warfarin and oral contraceptives.

Overdosage:
The recommended dose and duration of Gemifloxacin should not be exceeded. No specific antidote is known. 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 and treated symptomatically with appropriate hydration maintained.

Storage:
Store in cool and dry place (below 30°C), protect from light. Keep out of reach of children.

Packing:
Each box containing 1x10 tablets in Alu-Alu blister pack

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.