فلم کوٹڈ گولیاں

جیمی زیک®

جیمی فلاکساسین میزیلیٹ

وسیع العمل اینٹی بائیوٹک

خوراک:

دواڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

* دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش:

جیمی زیک ۳۲۰ ملی گرام فلم کوٹڈ گولیاں (۱×۷) بلسٹر پیک میں دستیاب ہیں۔

Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Film Coated Tablets

GemiZak®

Gemifloxacin Mesylate

Broad Spectrum Antibiotic

COMPOSITION:
Each film coated tablet contains
Gemifloxacin (as Mesylate) Sch. Specs. ..... 320 mg.

Properties:
Gemifloxacin is a fluoroquinolone with broad spectrum of activity and bactericidal action.

Microbiological Activity:
Gemifloxacin has in vitro activity against a wide range of Gram-negative and Gram-positive microorganisms which includes,
Aerobic Gram-positive microorganisms
Streptococcus pneumoniae.
Aerobic Gram-negative microorganisms
Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae (many strains are only moderately susceptible), Moraxella catarrhalis
Other microorganisms
Chlamydia pneumoniae, Mycoplasma pneumoniae

CLINICAL PHARMACOLOGY
Mechanism of action
Gemifloxacin acts by inhibiting DNA synthesis through the inhibition of both DNA gyrase and topoisomerase IV (TOPO IV), which are essential for bacterial growth.
Pharmacokinetics
The pharmacokinetics of Gemifloxacin are approximately linear over the dose range from 40 mg to 640 mg. There was minimal accumulation of Gemifloxacin following multiple oral doses up to 640 mg a day for 7 days (mean accumulation < 20%). Following repeated oral administration of 320 mg Gemifloxacin once daily, steady-state is achieved by the third day of dosing.

Absorption
Gemifloxacin, given as an oral tablet, is rapidly absorbed from the gastrointestinal tract. Peak plasma concentrations of Gemifloxacin were observed between 0.5 and 2 hours following oral tablet administration and the absolute bioavailability of the 320 mg tablet averaged approximately 71%.
The pharmacokinetics of Gemifloxacin were not significantly altered when a 320 mg dose was administered with a high-fat meal. Therefore Gemifloxacin tablets may be administered without regard to meals.
Distribution
Gemifloxacin is widely distributed throughout the body after oral administration. Gemifloxacin penetrates well into lung tissue and fluids.
Metabolism
Gemifloxacin is metabolized to a limited extent by the liver. The unchanged compound is the predominant drug-related component detected in plasma (approximately 65%) up to 4 hours after dosing. All metabolites formed are minor (< 10% of the administered oral dose); the principal ones are N-acetyl Gemifloxacin, the E-isomer of Gemifloxacin and the carbamyl glucuronide of Gemifloxacin. Cytochrome P450 enzymes do not play an important role in Gemifloxacin metabolism, and the metabolic activity of these enzymes is not significantly inhibited by Gemifloxacin.
Excretion
Gemifloxacin and its metabolites are excreted via renal route of excretion.

INDICATIONS
Gemizak is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below.
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), Haemophilus influenzae, Moraxella catarrhalis, Mycoplasma pneumoniae, Chlamydia pneumoniae, or Klebsiella pneumoniae.

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

Infection	Daily Dose	Duration
Acute bacterial exacerbation of Chronic Bronchitis	320 mg O.D	5 days
Community-acquired pneumoniae (of mild to moderate severity)		
1. due to known or suspected S. pneumoniae, H. influenzae, M. pneumoniae, or C.pneumoniae infection.	320 mg O.D	5 days
2. due to known or suspected MDRSP*, K. pneumoniae, or M. catarrhalis infection.	320 mg O.D	7 days

Missed Dose:
If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up the missed dose.

Elderly patients:
No dosage adjustment required in elderly patients.
Children:
The use of Gemifloxacin in children and adolescents in growth phase is not recommended.
Dosage in patients with renal impairment
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.
Dosage in Patients with Hepatic impairment
No dosage adjustment is recommended in patients with hepatic impairment.

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

WARNINGS
Tendinopathy and Tendon Rupture: Fluoroquinolones, including Gemifloxacin, are associated with an increased risk of tendinitis and tendon rupture in all ages. This adverse reaction most frequently involves the Achilles tendon, and rupture of the Achilles tendon may require surgical repair.
QT Effects: 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 (hypokalemia or hypomagnesemia), and patients receiving Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic agents.
Hypersensitivity Reactions: Serious hypersensitivity and/or anaphylactic reactions have been reported in patients receiving fluoroquinolone therapy, including Gemifloxacin. Hypersensitivity reactions reported in patients receiving fluoroquinolone therapy have occasionally been fatal.

Clinical manifestations may include one or more of the following:
- fever, rash or severe dermatologic reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson Syndrome);
- vasculitis; arthralgia; myalgia; serum sickness;
- allergic pneumonitis;
- interstitial nephritis; acute renal insufficiency or failure;
- hepatitis; jaundice; acute hepatic necrosis or failure;
- anemia, including hemolytic and aplastic;
- thrombocytopenia, including thrombotic thrombocytopenic purpura; leukopenia agranulocytosis; pancytopenia; and/or other hematologic abnormalities.

The drug should be discontinued immediately at the first appearance of a skin rash, jaundice, or any other sign of hypersensitivity and supportive measures instituted.
Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.
CNS Effects: In clinical studies with Gemifloxacin, central nervous system (CNS) effects have been reported infrequently. As with other fluoroquinolones, Gemifloxacin should be used with caution in patients with CNS diseases such as epilepsy or patients predisposed to convulsions.

PRECAUTIONS:
To assure safe and effective use of Gemifloxacin, the following information and instruction should be communicated to the patient when appropriate; Patients should be advised;
- to contact their healthcare provider if they experience pain, swelling, or inflammation of a tendon, or weakness or inability to use one of their joints; rest and refrain from exercise; and discontinue Gemifloxacin treatment.
- not to take antacids containing magnesium and/or aluminum or products containing ferrous sulfate (iron), multivitamin preparations containing zinc or other metal cations, take 3 hours before or 2 hours after taking Gemifloxacin tablets;

PREGNANCY/ LACTATION:
Pregnancy:
The safety of Gemifloxacin in pregnant women has not been established. Gemifloxacin should not be used in pregnant women unless the potential benefit to the mother outweighs the risk to the fetus.
Nursing Mothers
Gemifloxacin should not be used in lactating women unless the potential benefit to the mother outweighs the risk.
Pediatric Use
Safety and effectiveness in children and adolescents less than 18 years of age have not been established.
Geriatric Use
Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as Gemifloxacin. This risk is further increased in patients receiving concomitant corticosteroid therapy.
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%; Cmax decreased 87%).
Sucralfate: When sucralfate (2 g) was administered 3 hours prior to Gemifloxacin, the oral bioavailability of Gemifloxacin was significantly reduced (53% decrease in AUC; 69% decrease in Cmax).
Cimetidine: Co-administration of a single dose of 320 mg Gemifloxacin with cimetidine 400 mg four times daily for 7 days resulted in slight average increases in Gemifloxacin AUC(0-inf) and Cmax of 10% and 6%, respectively.
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(0-inf) and Cmax of 10% and 11%, respectively.
Warfarin: Co-administration of repeated doses of Gemifloxacin (320 mg once daily for 7 days) with warfarin therapy had no significant effect on warfarin-induced anticoagulant activity.

ADVERSE REACTIONS:
Gemifloxacin appear to have a low potential for photosensitivity. Gemifloxacin has following adverse reactions including: abdominal pain, anorexia, arthralgia, constipation, dermatitis, dizziness, dry mouth, dyspepsia, fatigue, flatulence, fungal infection, gastritis, genital moniliasis, hyperglycemia, insomnia, leucopenia, moniliasis, pruritus, somnolence, taste perversion, thrombocythemia, urticaria, vaginitis and vomiting.

OVERDOSE
Any signs or symptoms of overdosage should be treated symptomatically. 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. Hemodialysis removes approximately 20 to 30% of an oral dose of Gemifloxacin from plasma.

STORAGE CONDITIONS:
* Store at 25ºC (77ºF); excursions permitted to 15 - 30ºC (59º-86ºF).
* Protect from heat, light and moisture.
* Keep all medicines out of the reach of children.

PRESENTATION:
Gemizak 320 mg film coated tablets are available in (1 x 7) blister pack.