

Quinabiotic

Gemifloxacin 320mg Film-coated Tablets

Company:

Medizen Pharmaceutical Industries

Composition:

Each film-coated tablet contains:

Active ingredients:

Gemifloxacin mesylate 400 mg equivalent to 320mg gemifloxacin.

Inactive ingredients:

lactose anhydrous - avicel PH101- magnesium stearate – polyethyleneglycol (PEG 6000) – hydroxypropylmethylcellulose (H.P.M.C)
- Titanium dioxide.

Pharmacological Action:

Quinabiotic has an activity against a wide range of gram positive and gram-negative bacteria which cause many diseases. Its action results from inhibition of topoisomerase 2 (DNA gyrase) and topoisomerase 4 required for bacterial replication, transcription, repair and recombination.

Pharmacokinetics:

Absorption:

Gemifloxacin oral tablets is well absorbed from the gastrointestinal tract. The absolute bioavailability of gemifloxacin is approximately 90%.

Distribution:

Gemifloxacin is widely distributed throughout the body, with tissue concentration often exceeding plasma concentration.

Metabolism :

Gemifloxacin is metabolized via glucuronide and sulfate conjugation. 38% is eliminated in the feces and approximately 14% of the oral dose is excreted in the urine.

Excretion:

Approximately 45% of an oral dose of gemifloxacin is excreted unchanged (20% in the urine and 25% in feces).

Indications and Usage:

Quinabiotic tablets are indicated for the treatment of adults with infections caused by susceptible strains of the designated microorganism in the following conditions:

- Acute Bacterial Sinusitis
- Acute Bacterial Exacerbation of Chronic Bronchitis
- Community Acquired Pneumonia
- Uncomplicated Skin and Skin Structure Infections
- Complicated Intra-Abdominal Infections
- Complicated Skin and Skin Structure Infections

Dosage and Administration:

The dosage of gemifloxacin is one 320 mg tablet taken orally every 24 hours.
- The duration of therapy depends on the type of infection as described below:

Infection*	Daily Dose	Duration
Acute Bacterial Sinusitis	320 mg	10 days
Acute Bacterial Exacerbation of Chronic Bronchitis	320 mg	5 days
Community Acquired Pneumonia	320 mg	7-14 days
Uncomplicated Skin and Skin Structure Infections	320 mg	7 days
Complicated Skin and Skin Structure Infections	320 mg	7-21 days
Complicated Intra-Abdominal Infections	320 mg	5-14 days

It is advised that Quinabiotic is to be taken orally at the same time every day. Gemifloxacin should also be administered at least 4 hours before or 8 hours after antacids containing metal cations such as magnesium, aluminum and sucruflate, and iron and multivitamin preparations with zinc.

Contraindications :

Gemifloxacin is contraindicated in people with hypersensitivity to gemifloxacin or any member of the quinolone class of antimicrobial agents.

It is also contraindicated for those under 18 years of age.

Pregnancy & lactation :

Gemifloxacin is contraindicated during pregnancy and is categorized as category C. It is also contraindicated during lactation.

Adverse Reactions:

Rare adverse reactions include nausea, diarrhea, dizziness, headache, abdominal pain, vomiting, taste perversion, abnormal liver function tests besides dyspepsia, photosensitivity, tendonitis and rupture of tendons.

Drug – drug Interactions:

As with all other quinolones, iron and antacids significantly reduce the bioavailability of gemifloxacin.

Precautions :

- In general, quinolones may cause nervousness, insomnia, anxiety or nightmares.
- The use of gemifloxacin is not recommended with moderate and severe hepatic or renal insufficiency.

Package:

Carton box containing (pvdc/aluminium) strip of 5 or 7 film-coated tablets.

Storage:

Store at a temperature not exceeding 30°C in a cool, dry place.

Keep out of reach of children.

Information for Patients:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, kindly refer to your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others even if their symptoms are the same as yours because it may harm them.
- If any of the side effects gets serious, or if you notice any side effects not listed in

this leaflet, please inform your doctor or pharmacist.

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