

Moxavidex®

Film-coated Tablets

Company:

Utopia Pharmaceuticals

Composition:

Each film-coated tablet contains:

Active Ingredients:

Moxifloxacin hydrochloride equivalent to 400mg moxifloxacin.

Inactive Ingredients:

- Lactose anhydrous
- Avicel PH101
- Magnesium stearate
- PEG 6000
- H.P.M.C
- Titanium dioxide

Pharmacological Action:

Moxavidex® tablets has an activity against a wide range of gram (+) and gram (-) bacteria. Its action results from the inhibition of topoisomerase 2 (DNA gyrase) and topoisomerase 4 required for bacterial replication, transcription, repair and recombination.

Pharmacokinetics:

Absorption:

- Moxifloxacin, given as an oral tablet, is well absorbed from the gastrointestinal tract.
- The absolute bioavailability of moxifloxacin is approximately 90 percent.

Distribution:

Moxifloxacin is widely distributed throughout the body, with tissue concentration often exceeding plasma concentration. Moxifloxacin has been detected in the saliva, nasal and bronchial secretions, mucosa of the sinuses, skin blister fluid, subcutaneous tissue and skeletal muscles following oral administration of 400 mg.

Metabolism:

Moxifloxacin is metabolized via glucuronide and sulfate conjugation. The cytochrome p450 system is not involved in moxifloxacin metabolism and is not affected by moxifloxacin. It is eliminated primarily in the feces; approximately 14% of an oral dose is excreted in the urine.

Excretion:

Approximately 45% of an oral dose of moxifloxacin is excreted as unchanged drug (20% in the urine and 25% in feces.)
A total of 96% +/- 4% of an oral dose is excreted as either unchanged drug or known metabolites.

Indications and Usage:

- Moxavidex® 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 moxifloxacin is one 400 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 | 400 mg | 10 days |
| Acute Bacterial Exacerbation of Chronic Bronchitis | 400 mg | 5 days |
| Community Acquired Pneumonia | 400 mg | 7-14 days |
| Uncomplicated Skin and Skin Structure Infections | 400 mg | 7 days |
| Complicated Skin and Skin Structure Infections | 400 mg | 7-21 days |
| Complicated Intra-abdominal Infections | 400 mg | 5-14 days |

****due to the designated pathogens, oral doses of moxifloxacin should be administered at least 4 hours before or 8 hours after antacids containing metal cations such as iron and multivitamin preparations with zinc.**

Contraindications:

Moxifloxacin is contraindicated in persons with a history of hypersensitivity to moxifloxacin or any member of the quinolone class of antimicrobial agents.

Pregnancy & Lactation:

Moxifloxacin is contraindicated during pregnancy and is category C & also contraindicated during lactation as it has a teratogenic effect.

Adverse Reactions:

Rare adverse reactions such as: nausea, diarrhea, dizziness, headache, abdominal pain, vomiting, taste perversion, abnormal liver function tests and dyspepsia.

Drug-drug**Interactions:**

There was no clinically significant effect of moxifloxacin on theophylline, warfarin, digoxin, or glyburide kinetics. However, as with all other quinolones, iron and antacids significantly reduce the bioavailability of moxifloxacin.

Precautions:

- In General, quinolones may cause nervousness, insomnia, anxiety or nightmares.
- Renal insufficiency: The pharmacokinetic parameters of moxifloxacin are not significantly altered by mild, moderate or severe renal impairment.
- The pharmacokinetics of moxifloxacin with moderate and severe hepatic insufficiency has not been adequately studied. Due to the lack of clinical data, the use of moxifloxacin is not recommended with moderate and severe hepatic insufficiency.
- Moxifloxacin should be administered at least 4 hours before or 8 hours after antacids containing metal cations such as iron and multivitamin preparations with zinc.

Package:

Carton box contains (PVDC/Aluminum) strip of 5 film-coated tablets (5 days treatment.)

Storage:

- Store at a temperature not exceeding 30 °C in a 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 question, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Produced by Medizen for **Utopia** Pharmaceuticals