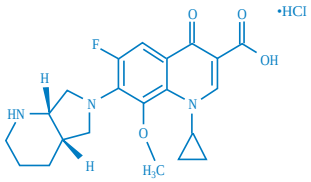
# MOXIGET™

(Moxifloxacin HCl Tablets 400mg)

## Tablets 400mg

### DESCRIPTION

MOXIGET (Moxifloxacin) is a new oral 8-methoxyfluroquinolone antibacterial agent. Chemically, moxifloxacin is a monohydrate salt of 1-cyclopropyl-7-[(S, S)-2, 8-diazabicyclo [4.3.0] non-8-yl]-6-flouro-8-methoxy-1, 4-dihydro-4-oxo-3 quinolone carboxylic acid. The molecular formula is $C_{21}H_{24}FN_3O_4$•HCl and the structural formula is:




Moxifloxacin HCl

### QUALITATIVE & QUANTITATIVE COMPOSITION

MOXIGET (Moxifloxacin) is available for oral administration as:

MOXIGET Tablets 400mg
Each film-coated tablet contains:
Moxifloxacin hydrochloride Ph. Eur. equivalent to Moxifloxacin ... 400mg

### CLINICAL PHARMACOLOGY

**Mechanism of Action**

Moxifloxacin is bactericidal against a range of Gram-positive and Gram-negative organisms. Such activity arises through the inhibition of DNA gyrase (topoisomerase II) and topoisomerase IV, which bacteria require for DNA replication, transcription, repair, and recombination. Moxifloxacin contains the C8-methoxy moiety that augments its antibacterial activity and reduces the possibility of Gram-positive mutations. Because the 8-fluroquinolones use a different mechanism of action than do the aminoglycosides, beta-lactams, macrolides, or tetracyclines, there has been no cross resistance between the quinolones and these antimicrobial agents.

**Microbiology:**

Aerobic Gram-positive micro-organisms:
*Staphylococcus aureus* (methicillin-susceptible)
*Streptococcus pneumoniae, Streptococcus pyogenes*
*Streptococcus epidermidis* (methicillin-susceptible)
*Streptococcus anginosus*

Aerobic Gram-negative micro-organisms:
*Haemophilus influenzae*
*Haemophilus parainfluenzae*
*Klebsiella pneumoniae*
*Moraxella catarrhalis*
*Enterobacter cloacae*
*Escherichia coli*
*Proteus mirabilis*

Anaerobic micro-organisms:
*Fusobacterium* species
*Prevotella* species
*Peptostreptococcus species*

Others:
*Chlamydia pneumoniae*
*Mycoplasma pneumoniae*
*Legionella pneumophila*
*Mycobacterium leprae*

**Pharmacokinetics**

Moxifloxacin is readily absorbed from the gastrointestinal tract with an absolute bioavailability of about 90%. It is widely distributed throughout the body tissues and is approximately 50% bound to plasma proteins. Moxifloxacin has an elimination half life of approximately 12 hours, allowing once daily dosing. It is metabolised principally via sulphate and glucuronide conjugation. About 45% of the drug is excreted in the urine and the faeces as unchanged drug. The sulphate conjugate is excreted primarily in the faeces and the glucuronide exclusively in the urine.

### THERAPEUTIC INDICATIONS

MOXIGET (Moxifloxacin) tablets are indicated for the treatment of following bacterial infections:
– Acute bacterial sinusitis.
– Acute bacterial exacerbation of chronic bronchitis.
– Community acquired pneumonia.
– Un-complicated skin and skin structure infections.
– Complicated skin and skin structure infections.

### DOSAGE AND ADMINISTRATION

The usual adult dose of MOXIGET (Moxifloxacin) is 400mg once every 24 hours. The duration of therapy depends on the type and severity of infection as described in the table below.

| Infection | Daily Dose | Duration |
|---|---|---|
| Acute bacterial sinusitis | 400mg | 7 days |
| Acute bacterial exacerbation of chronic bronchitis | 400mg | 5-10 days |
| Community acquired pneumonia | 400mg | 10 days |
| Uncomplicated skin and skin structure infections | 400mg | 7 days |
| Complicated skin and skin structure infections | 400mg | 7 – 21 days |

### ADVERSE REACTIONS

Moxifloxacin was usually well tolerated. Most adverse reactions were mild to moderate. The most common adverse reactions were nausea and diarrhea.

*Common:*
Headache, dizziness, abdominal pain, vomiting, QT prolongation in patients with hypokalemia, increase in transaminases, superinfection due to resistant bacteria.

*Uncommon:*
Anorexia, constipation, dyspepsia, flatulence, gastritis, increase amylase, QT prolongation, palpitations, tachycardia, artrial fibrillation, angina pectoris, dyspnea, hepatic impairment, increased bilirubin, increase gamma glutarryl transferase, increase in blood alkaline phosphatase, pruritis rash, urticaria, dry skin, arthralgia, myalgia, dehydration, visual disturbances, anxiety reactions, psychomotor hyperactivity, taste disorder, paresthesia/dysesthesia, confusion, disorientation, hyperlipidemia, allergic reaction, anaemia, leucopenia, neutropenia, thrombocytopenia.

*Rare:*
Dysphagia, pseudomembranous colitis, ventricular tachyarrhythmias, syncope, hypertension, hypotension, vasodilatation, tinnitus, hypoesthesia, smell disorder, abnormal dreams, disturbed coordination, seizures, disturbed attention, speech disorders, amnesia, anaphylaxis, allergic edema/angioedema, hyperglycaemia, hyperuricemia, emotional liability, depression, hallucination, prothrombin time prolonged.

## CONTRAINDICATIONS

Moxifloxacin is contraindicated in patients:

- With hypersensitivity to moxifloxacin or other quinolones and any components of this medication.
- Less than 18 years of age.
- Pregnancy and lactation.
- With history of tendon disease/disorder related to quinolone treatment.
- With impaired liver function and in patients with transaminases >5 fold ULN.
- With congenital or documented acquired QT prolongation.
- With electrolyte disturbances, particularly in uncorrected hypokalaemia.
- With clinically relevant bradycardia.
- With clinically relevant heart failure with reduced left-ventricular ejection fraction.
- With previous history of symptomatic arrhythmias.
- Receiving Class IA (e.g. quinidine, procainamide) or Class III (amiodarone, sotalol) antiarrhythmic agents or other drugs that prolong the QT interval.
- With rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

## WARNING

Fluoroquinolones, including moxifloxacin are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants.

## PRECAUTIONS

- As with all quinolones, moxifloxacin should be used with caution in patients with known or suspected CNS disorders or in the presence of other risk factors that may predispose to seizures or lower the threshold.
- Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.
- Tendon inflammation and/or rupture have been reported with quinolone antibiotics. Risk may be increased with concurrent corticosteroids, particularly in the elderly. Discontinue at first signs or symptoms of tendon pain.
- Use with caution in diabetes as glucose regulation may be altered.
- Patients with a family history of, or actual glucose-6-phosphate dehydrogenase deficiency are prone to haemolytic reactions when treated with quinolones. Therefore, moxifloxacin should be used with caution in these patients.
- Severe hypersensitivity reactions, including anaphylaxis, have occurred with quinolone therapy. If an allergic reaction occurs discontinue drug immediately.
- Quinolones should be used with caution as they may exacerbate myasthenia gravis.
- Peripheral neuropathy may rarely occur.
- Elderly patients with renal disorders should use moxifloxacin with caution if they are unable to maintain adequate fluid intake, because dehydration may increase the risk of renal failure.
- Liver function tests/investigations should be performed in cases where indications of liver dysfunction occur.
- If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.
- Moxifloxacin may result in an impairment of the patient's ability to drive or operate machinery due to CNS reactions (e.g. dizziness; acute, transient loss of vision) or acute and short lasting loss of consciousness. Patients should be advised to see how they react to moxifloxacin before driving or operating machinery.

## Drug Interactions

- Moxifloxacin should be taken at least 4 hours before or 8 hours after *antacids* containing *magnesium, calcium* or *aluminium*, as well as *sucralfate, metal cations* such as *iron,* and *multivitamin preparations with zinc or didanosine*.
- Medication that can reduce potassium levels should be used with caution in patients receiving moxifloxacin.
- Concomitant administration of *charcoal* with an oral dose of 400mg moxifloxacin leads to a pronounced prevention of drug absorption and a reduced systemic availability of the drug by more than 80%. Therefore, the concomitant use of these two drugs is not recommended (except for overdose cases).
- The prothrombin time, International Normalized Ratio (INR), or other suitable anticoagulation tests should be closely monitored if a quinolone is administered concomitantly with *warfarin* or its *derivatives*.
- Concomitant administration of *NSAIDs* with quinolones may increase the risks of CNS stimulation and convulsions.

## STORAGE

Do not store above 30°C.
Protect from sunlight and moisture.
The expiration date refers to the product correctly stored at the required conditions.

## HOW SUPPLIED

MOXIGET (Moxifloxacin) Tablets 400mg are available in blister pack of 5's.

*Keep out of reach of children.*

*To be sold on prescription of a registered medical practitioner only.*

Please read the contents carefully before use.
This package insert is continually updated from time to time.

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Getz pharma (PVT) LIMITED
www.getzpharma.com
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