Maksifin 400 mg Tablets (Moxifloxacin) میکسیفن ۴۰۰ ملی گرام گولیاں

COMPOSITION
Each film coated tablet contains:
Moxifloxacin B.P. 400mg
(as hydrochloride)

DESCRIPTION
Maksifin (moxifloxacin hydrochloride) is a synthetic broad spectrum antibacterial agent belongs to a class of drugs called fluoroquinolone. Its chemical name is 1-cyclopropyl-7-{(S,S) -2,8-diaza-bicyclo[4.3.0]non-8-yl}-6-fluoro-8-methoxy-1,4-dihy dro-4-oxo-3-quinolinecarboxylic acid hydrochloride.

PHARMACOLOGY
Pharmacokinetics
Absorption: Following oral administration, moxifloxacin is absorbed rapidly and almost completely with an absolute bioavailability of approximately 90%. **Maksifin** can be administered independent from meals.
Distribution: Moxifloxacin is widely distributed throughout the body. Moxifloxacin has been detected in active form in the saliva, nasal and bronchial secretions, mucosa of the sinuses following oral or intravenous administration of 400mg.
Metabolism: The cytochrome P450 system is not involved in moxifloxacin metabolism and is not affected by moxifloxacin. M1 and M2 are the only metabolites relevant in humans and both are microbiologically inactive.
Elimination: Approximately 45% of an oral or intravenous dose is excreted as unchanged drug (~20% in urine and ~25% in faeces).

MICROBIOLOGY
Mechanism of Action
Moxifloxacin is an 8-methoxyfluoroquinolone antibiotic with a broad spectrum of activity and bactericidal action. The bactericidal action results from the inhibition of topoisomerase II or DNA gyrase and topoisomerase IV required for bacterial DNA replication, transcription, repair and recombination.

The mechanism of action for quinolones, including moxifloxacin, is different from that of macrolides, beta-lactams, aminoglycosides, or tetracyclines; therefore, microorganisms resistant to these classes of drugs may be susceptible to moxifloxacin. There is no known cross-resistance between moxifloxacin and other classes of antibiotics. Although cross-resistance has been observed between moxifloxacin and other fluoroquinolones against gram-negative bacteria, gram-positive bacteria resistant to other fluoroquinolones may be susceptible to moxifloxacin.
Moxifloxacin has been shown to be active against most strains of the following microorganisms.

Gram-positive bacteria
Enterococcus faecalis
Staphylococcus aureus
Streptococcus anginosus
Streptococcus constellatus
Streptococcus pneumoniae (including multi-drug resistant isolates)
Streptococcus pyogenes

Gram-negative bacteria
Enterobacter cloacae
Escherichia coli
Haemophilus influenzae
Haemophilus parainfluenzae
Klebsiella pneumoniae
Moraxella catarrhalis
Proteus mirabilis
Yersinia pestis

Anaerobic bacteria
Bacteroides fragilis
Bacteroides thetaiotaomicron
Clostridium perfringens
Peptostreptococcus species

Other microorganisms
Chlamydophila pneumoniae
Mycoplasma pneumoniae

INDICATIONS
Maksifin (moxifloxacin hydrochloride) tablets are indicated for the treatment of adults with infections caused by susceptible organisms in the conditions:

- Acute sinusitis
- Community acquired pneumonia
- Acute exacerbations of chronic bronchitis
- Un-complicated skin and skin structure infections
- Complicated skin infections and skin structure infections
- Complicated intra-abdominal infections including polymicrobial infections

DOSAGE (Adults)
The dosage of **Maksifin** (Moxifloxacin) is 400mg Tablet once daily. The duration of therapy depends on the type of infections as described below:

Infections	Daily Dose	Duration
Acute Sinusitis	400mg	10 Days
Acute Exacerbation of Chronic Bronchitis	400mg	5 Days
Community Acquired Pneumonia	400mg	7-14 Days
Complicated Skin & Skin Structure Infections	400mg	7-21 Days
Complicated Intra-Abdominal Infections	400mg	5-14 Days

For complicated Intra-Abdominal infections, therapy should usually be initiated with the intravenous formulation. When switching from intravenous to oral dosage administration, no dosage adjustment is necessary.

CONTRAINDICATIONS

Known hypersensitivity to any component of moxifloxacin or to any other quinolones or any of the excipients.

Because of an effect of moxifloxacin on the QTc interval of the electrocardiogram and a lack of clinical experience with the drug in the mentioned patient populations, the drug is contraindicated in patients with known prolongation of the QTc interval, patients with uncorrected hypokalaemia and patients receiving Class IA (e.g. quinidine, procainamide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic agents.

Paediatric use

Moxifloxacin should not be used in paediatric patients.

Geriatric use

No dosage adjustment is necessary based on age.

Use in pregnancy

There are no adequate or well-controlled studies in pregnant women therefore moxifloxacin therapy during pregnancy is not recommended.

Use in lactation

Small amounts of moxifloxacin may be secreted in human milk. Because of the potential for serious adverse reactions in infants nursing from mothers taking moxifloxacin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Renal impairment

The pharmacokinetics of moxifloxacin are not significantly changed by renal impairment (including creatinine clearance < 30 mL/min/1.73m^2) and in patients on chronic dialysis i.e. haemodialysis and continuous ambulatory peritoneal dialysis. No dose adjustment is therefore required in patients with any degree of renal impairment (including creatinine clearance < 30 mL/min/1.73m^2).

Hepatic impairment

Moxifloxacin plasma concentrations of patients with mild to severe hepatic impairment did not reveal clinically relevant differences compared to healthy volunteers or patients with normal hepatic function. As limited clinical data are available in severe hepatic impairment, the use of moxifloxacin in this patient group is not recommended.

Drug-drug interactions

No clinically significant drug-drug interactions were found with theophylline, warfarin, digoxin, probenecid, ranitidine or glibenclamide, but, as with all other quinolones, iron and antacids significantly reduced the bioavailability of orally administered moxifloxacin.

Concomitant ingestion of moxifloxacin together with antacids, minerals and multi-vitamins may result in impaired absorption of the drug due to the formation of chelate complexes with the multivalent cations contained in these preparations. This may lead to lower than desired plasma concentrations. Hence, oral doses of moxifloxacin should be administered at least 2 hours before or four hours after ingestion of antacids, and other preparations containing magnesium, aluminium, sucralfate and other minerals such as iron or zinc.

ADVERSE REACTIONS

Moxifloxacin was usually well tolerated. The most common adverse reactions were nausea and diarrhoea.

Common:

Abdominal pain, headache, dizziness, vomiting, QT prolongation in patients with hypokalaemia, increase in transaminases, superinfection due to resistant bacteria.

Uncommon:

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

Rare:

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

OVERDOSAGE

Only limited data on overdose are available. In the event of overdosage it is recommended that appropriate supportive care should be instituted as dictated by the patient's clinical status. The administration of activated charcoal as soon as possible after oral overdose may prevent excessive increase in systemic moxifloxacin exposure. Due to the potential for moxifloxacin to cause QT prolongation, patients should be carefully monitored following an overdose.

PRESENTATION AND STORAGE CONDITIONS

Maksifin (moxifloxacin) Tablets 400mg are available in Alu Alu blister pack of 5 tablets.

Store between 15-30°C, avoid exposure to sunlight, heat and moisture. Keep all medicines out of the reach of children.

خوراک و ہدایات:

ڈاکٹر کے مشورے کے مطابق استعمال کریں۔

روشنی سے محفوظ، 15-30°C درجہ حرارت پر رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور، ٹھنڈی اور خشک جگہ پر رکھیں۔

Manufactured by:
Macquin's
MACQUIN'S INTERNATIONAL
F-2/H, S.I.T.E., Karachi
ISO 9001 : 2000 Certified Company

Marketed by:
CENRJY
Pharmaceuticals