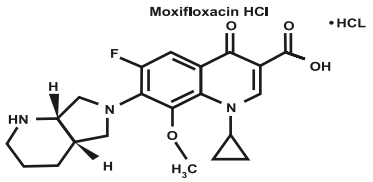
IMOX 400mg Tablets
(Moxifloxacin)

آئی موکس

DESCRIPTION
IMOX (Moxifloxacin) is a new oral 8 - methoxyfluoroquinolone 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 $C_{21}H_{24}FN_3O_4HCl$ and the structural formula is



QUALITATIVE & QUANTITATIVE COMPOSITION
IMOX (Moxifloxacin) is available for oral administration as:

IMOX Tablets 400mg Each film-coated tablet contains:
Moxifloxacin..... 400mg (as hydrochloride)
(USP Specification)

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- fluoroquinolones 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
Mycolplasma 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
IMOX (Moxifloxacin) tablets are indicated for the treatment of following bacteriai 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 IMOX (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 diarrhoea.

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

Uncommon:
Anorexia, constipation, dyspepsia, flatulence, gastritis, increased amylase, QT prolongation, palpitations, tachycardia, artrial fibrillation, angina pectoris, dyspnea, hepatic impairment,

increased bilirubin, increased gamma glutarryl tranferase, increase in blood alkaline phosphate, 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 disorder, 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 quinolone and any components of this medication.
- Less than 18 years of age.
- Pregnancy and lactation.
- With history of tendon disease/disorder related to quinolones 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.

PRECAUTIONS
- As with all quinolones, moxifloxacin should be used with caution in patients with known or suspected CNS disorder 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 diarrhoea 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 disorder 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.

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 this derivatives.
- Concomitant administration of NSAIDs with quinolones may increase the risks of CNS stimulation and convulsions.

STORAGE
Store below 30°C.
Protect from heat, sunlight and moisture.
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED
IMOX (Moxifloxacin) Tablets 400mg are available in blister pack of 5's

Keep out of reach of children.

خوراک: ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
ہدایات: دوا کو دھوپ، گرمی اور نمی سے بچائیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
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