

Mebarg

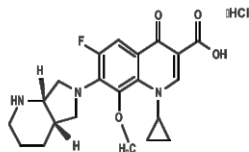
(Moxifloxacin)

میبرگ
(موکسی فلاکساسین)

Tablets 400mg

DESCRIPTION

Mebarg (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-fluoro-8-methoxy-1, 4-dihydro-4-oxo-3 quinolone carboxylic acid. The molecular formula is $C_{22}H_{24}FN_3O_4 \cdot HCl$ and the structural formula is:



Moxifloxacin HCl

QUALITATIVE & QUANTITATIVE COMPOSITION

Mebarg (Moxifloxacin) is available for oral administration as:

Mebarg Tablets 400mg

Each film-coated tablet contains:

Moxifloxacin HCl eq. 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-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
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 feces as unchanged drug. The sulphate conjugate is excreted primarily in the feces and the glucuronide exclusively in the urine.

THERAPEUTIC INDICATIONS

Mebarg (Moxifloxacin) tablets are indicated for the treatment of following bacterial infections:

- Acute bacterial sinusitis.
- Acute bacterial exacerbation of chronic bronchitis.
- Community acquired pneumonia.
- Complicated skin and skin structure infections.

DOSAGE AND ADMINISTRATION

The usual adult dose of Mebarg (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
Complicated skin and skin structure infections	400mg	7 to 21 days

ADVERSE REACTIONS

Moxifloxacin was usually well tolerated. Most adverse reactions were mild to moderate.

Common:

Headache, dizziness, abdominal pain, nausea, vomiting, QT prolongation in patients with hypokalemia, increase in transaminases, superinfection due to resistant bacteria and diarrhea.

Uncommon:

Anorexia, constipation, dyspepsia, flatulence, gastritis, increase amylase, QT prolongation, palpitations, tachycardia, atrial fibrillation, angina pectoris, dyspnea, hepatic impairment, increased bilirubin, increase gamma glutaryl 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, anemia, leucopenia, neutropenia and thrombocytopenia.

Rare:

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