120 mm

210 mm

Mofest® Tablets / Infusion

(Moxifloxacin HCl)

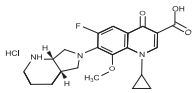
DESCRIPTION:

Mofest® containing moxifloxacin belongs to a class of drugs called fluoroquinolone. Moxifloxacin is synthetic broad spectrum antibacterial agent and is available as moxifloxacin tablets for oral administration and as moxifloxacin I.V. for intravenous administration

Chemical name: 1-cyclopropyl-7-{(S,S)-2,8-diaza-bicyclo[4.3.0]non-8-yl)-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid hydrochloride

Empirical formula: $C_{21}H_{24}FN_3O_4.HCl$

Structural formula:



COMPOSITION:

Mofest® 400mg Tablets:

Each film coated tablet contains:

Moxifloxacin HCl Ph. Eur. equivalent to Moxifloxacin.....400mg

Mofest® 400mg/250ml Infusion:

Each 250ml contains:

Moxifloxacin HCl Ph. Eur. equivalent to Moxifloxacin.....400mg

PHARMACOLOGY:

Mode of Action:

Moxifloxacin is a synthetic fluoroquinolone with a broad spectrum of activity and a bactericidal mode of action. It inhibits bacterial topoisomerase II (DNA gyrase) and topoisomerase IV. Topoisomerases are essential enzymes which play a crucial role in the replication and repairing of bacterial DNA

Absorption:

Moxifloxacin, given as an oral tablet, is well absorbed from the gastrointestinal tract. The absolute bioavailability of moxifloxacin is approximately 90%. Co-administration with a high fat meal (i.e. 500 calories from fat) does not affect the absorption of moxifloxacin

Distribution:

Moxifloxacin is approximately 30-50% bound to serum proteins, independent of drug concentration. The volume of distribution of moxifloxacin ranges from 1.7 to 2.7 L/kg

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

Metabolism:

Approximately 52% of an oral or intravenous dose of moxifloxacin is metabolized via glucuronide and sulfate conjugation. The cytochrome P450 system is not involved in moxifloxacin metabolism and is not affected by moxifloxacin. The sulfate conjugate (M1) accounts for approximately 38% of the dose and is eliminated primarily in the feces. Approximately 14% of an oral or intravenous dose is converted to a glucuronide conjugate (M2), which is excreted exclusively in the urine. Peak plasma concentrations of M2 are approximately 40% those of the parent drug, while plasma concentrations of M1 are generally less than 10% those of moxifloxacin

Excretion:

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

Microbiology:

Moxifloxacin has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections

Aerobic Gram-positive microorganisms:

Staphylococcus aureus (methicillin-susceptible strains only)
Streptococcus pneumoniae (including multi-drug resistant strains [MDRSP]*)
Streptococcus pyogenes
Enterococcus faecalis (many strains are only susceptible)
Streptococcus anginosus
Streptococcus constellatus

* **Note:** Penicillin-resistant S. pneumoniae are those strains with a penicillin MIC value of = 2µg/mL

Aerobic Gram-negative microorganisms:

Haemophilus influenzae
Haemophilus parainfluenzae
Klebsiella pneumoniae
Moraxella catarrhalis
Enterobacter cloacae
Escherichia coli
Proteus mirabilis

Anaerobic microorganisms:

Bacteroides fragilis
Bacteroides thetaiotaomicrom
Clostridium perfringens
Peptostreptococcus species

Other microorganisms:

Chlamydia pneumoniae
Mycoplasma pneumoniae

INDICATIONS AND USAGE:

Moxifloxacin tablets and I.V. are indicated for the treatment of adults (≥ 18 years of age) with infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

Acute Bacterial Sinusitis caused by Streptococcus pneumoniae, Haemophilus influenzae or Moraxella catarrhalis

Acute Bacterial Exacerbation of Chronic Bronchitis caused by Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Staphylococcus aureus or Moraxella catarrhalis

Community Acquired Pneumonia caused by Streptococcus pneumoniae (including penicillin resistant strains, MIC value for penicillin ≥ 2µg/mL), Haemophilus influenzae, Moraxella catarrhalis, Staphylococcus aureus, Klebsiella pneumoniae, Mycoplasma pneumoniae or Chlamydia pneumoniae

120 mm

210 mm

Uncomplicated Skin and Skin Structure Infections caused by methicillin-susceptible Staphylococcus aureus or Streptococcus pyogenes

Complicated Skin and Skin Structure Infections caused by methicillin-susceptible Staphylococcus aureus, Escherichia coli, Klebsiella pneumonia or Enterobacter cloacae

Complicated Intra-Abdominal Infections including polymicrobial infections such as abscess caused by Escherichia coli, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, Enterococcus faecalis, Proteus mirabilis, Clostridum perfringens, Bacteriodes thetaiotaomicron or Peptostreptococcus species

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

WARNINGS:

Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture. This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Physicians should advise patients, at the first sign of tendon pain, swelling, or inflammation, to stop taking the fluoroquinolone, to avoid exercise and use of the affected area, and to promptly contact their doctor about changing to a non-fluoroquinolone antimicrobial drug

Selection of a fluoroquinolone for the treatment or prevention of an infection should be limited to those conditions that are proven or strongly suspected to be caused by bacteria

SIDE EFFECTS:
Peripheral neuropathy: This serious nerve damage potentially caused by fluoroquinolones may occur soon after these drugs are taken and may be permanent If a patient develops symptoms of peripheral neuropathy, the fluoroquinolone should be stopped, and the patient should be switched to another, non-fluoroquinolones antibacterial drug, unless the benefit of continued treatement with a fluoroquinolone outweighs the risk

PRECAUTIONS:
Pregnancy: Teratogenic Effects - Pregnancy Category C:
Since there are no adequate or well-controlled studies in pregnant women, moxifloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Nursing Mothers:
Moxifloxacin is found in high concentration in the milk of breastfeeding mothers. Either the drug or the breastfeeding should be discontinued

Paediatric Use:
Safety and effectiveness in paediatric patients and adolescents less than 18 years of age have not been established

DOSAGE AND ADMINISTRATION:
The recommended dose for moxifloxacin tablets and moxifloxacin infusion is 400mg once daily for all indications. The duration of therapy and route of administration is dependent upon the type and severity of infection as described below:

Acute Bacterial Sinusitis:
IV/PO 400mg/day for 7 days

Acute Bacterial Exacerbation of Chronic Bronchitis:
IV/PO 400mg/day for 5 days

Community-Acquired Pneumonia:
IV/PO 400mg/day for 10 days

Complicated Skin and Skin Structure Infections:
IV/PO 400mg/day for 7 to 21 days

Uncomplicated Skin and Skin Structure Infections:
IV/PO 400mg/day for 7 days

Complicated Intra-Abdominal Infections:
IV/PO 400mg/day for 5-14 days

Uncomplicated Pelvic Inflammatory Disease:
IV/PO 400mg/day for 14 days

Impaired Renal Function:
No dosage adjustment is required in renally impaired patients, including those on either hemodialysis or continuous ambulatory peritoneal dialysis

Impaired Hepatic Function:
No dosage adjustment is required in patients with mild, moderate or severe hepatic insufficiency

OR
As directed by the physician

STABILITY:
See expiry on the pack

PRESENTATIONS:
Mofest® 400mg film coated tablets in a pack of 5's
Mofest® I.V. 400mg/250ml in a pack of 1's

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light, humidity and freezing
Store between 15 to 30°C
Improper storage may deteriorate the medicine

For I.V. Infusion only:
Infuse over a period of 60 minutes
Caution: Injection should not be used if container is leaking, solution is cloudy or it contains un-dissolved particle(s)
At cool temperature precipitation may occur, which will re-dissolve at room temperature

موفیسٹ ٹیبلٹ/انفیوژن

(موکسی فلاکساسن ہائیڈروکلورائیڈ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی، نمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

تنبیہ: انجکشن کے لیک ہونے، دُھندلا ہونے یا اس میں کوئی غیر حل پزیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

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