Meflox Tablets

(Moxifloxacin Tablets USP)

میفلوکس گولیاں

(موکسی فلوکساسین)

COMPOSITION: Each film coated tablet contains:
Moxifloxacin Hydrochloride USP equivalent to Moxifloxacin ... 400mg. [USP Specs.]

PROPERTIES: Meflox (Moxifloxacin) is a fluoroquinolone antibacterial with a broad spectrum of activity and bactericidal action. Moxifloxacin has in vitro activity against a wide range of gram-positive and gram-negative organisms, anaerobes, acid-fast bacteria, and atypicals eg. Mycoplasma spp.,Chlamydia spp. and Legionella spp. Moxifloxacin is effective against β-lactam and macrolide resistant bacteria.

GRAM-POSITIVE MICROORAGANISMS: Streptococcus mitior, Streptococcus milleri, Streptococcus agalactiae, Streptococcus dysgalactiae, Staphylococcus cohnii, Staphylococcus epidermidis (including methicillin sensitive strains), Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus saprophyticus, Staphylococcus simulans, Corynebacterium diphtheriae.

GRAM-NEGATIVE MICROORGANISMS: Bordetella pertussis, Klebsiella oxytoca, Enterobacter aerogenes, Enterobacter agglomerans, Enterobacter intermedius, Enterobacter sakazakii, Proteus mirabilis, Proteus vulgaris, Morganella morganii, Providencia rettgeri, Providencia stuartii.

ANAEROBES: Bacteroides distasonis, Bacteroides eggerthii, Bacteroides fragilis, Bacteroides ovatus, Bacteroides thetaiotaomicron, Bacteroides uniformis, Fusobacterium spp., Porphyromonas spp., Porphyromonas anaerobius, Porphyromonas asaccharolyticus, Porphyromonas magnus, Prevotella spp., Propionibacterium spp., Clostridium perfringens, Clostridium ramosum.

ATYPICALS: Legionella pneumophila, Caxiella burnetii. The bactericidal action results from the interference with topoisomerase II and IV. Topoisomerases are essential enzymes which control DNA topology and assist in DNA replication, repair and transcription. Moxifloxacin exhibits concentration dependent bactericidal killing. Minimum bactericidal concentrations are generally similar to minimum inhibitory concentrations. Resistance mechanisms which inactivate penicillins, cephalosporins, aminoglycosides, macrolides and tetracyclines do not interfere with the antibacterial activity of Moxifloxacin. There is no cross-resistance between Moxifloxacin and these agents. Plasmid mediated resistance has not been observed to date. A very low overall frequency of resistance was demonstrated (10^{-7}-10^{-10}). Cross-resistance among quinolones has been observed. However, some Gram-positive and anaerobic organisms resistant to other quinolones are susceptible to Moxifloxacin.

INDICATIONS: Meflox tablets are indicated for the treatment of adults (>18 years of age) with upper and lower respiratory tract infections such as: Acute sinusitis, Acute exacerbations of chronic bronchitis, Community acquired pneumonia, Skin and soft tissue infections.

CONTRA-INDICATIONS: Known hypersensitivity to any component of the tablets or other quinolones. **Meflox** tablets are contra-indicated in children, growing adolescents and pregnant women. Quinolones are known to distribute well into breast milk of lactating women. Preclinical evidence indicates that small amount of Moxifloxacin may be secreted in human milk. There is no data available in lactating or nursing women. Therefore, the use of Moxifloxacin in pregnancy and nursing mothers is contra-indicated.

WARNINGS AND PRECAUTIONS: Seizures may occur with quinolone therapy. Moxifloxacin should be used with caution in patients with known or suspected CNS disorders which may predispose to seizures or lower the seizure threshold. As no pharmacokinetic/pharmacodynamic data is available in severe hepatic impairment (Child Pugh C), the use of Moxifloxacin in this patient group is not recommended. Moxifloxacin, as with some other quinolones and macrolides,has been shown to prolong the QT interval of the electrocardiogram in some patients. The drug should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia and patients receiving class 1A (e.g. quinidine, procainamide) or class III (e.g. amiodarone, sotalol) antiarrhythmic agents, due to the lack of clinical experience with the drug in these patient populations. An additive effect of Moxifloxacin and drugs that prolong the QT interval such as cisapride, erythromycin, antipsychotics, and tricyclic antidepressants can not be excluded. Therefore, Moxifloxacin should be used with caution when given concurrently with these drugs. Because of limited clinical experience, Moxifloxacin should be used with caution in patients with ongoing proarrhythmic conditions, such as clinically significant bradycardia or acute myocardial ischemia. The magnitude of QT prolongation may increase with increasing concentrations of the drug. Therefore, the recommended dose should not be exceeded. QT prolongation may lead to an increased risk for ventricular arrhythmias including torsades de pointes. No cardiovascular morbidity or mortality attributable to QTc prolongation occurred with Moxifloxacin treatment in over 4000 patients, however, certain predisposing conditions may increase the risk for ventricular arrhythmias. Tendon inflammation and rupture may occur with quinolone therapy, particularly in elderly patients and in those treated concurrently with corticosteroids. At the first sign of pain or inflammation, patients should discontinue treatment and rest the affected limb(s). Tendon ruptures have not been reported in clinical trials with Moxifloxacin. Pseudomembranous colitis has been reported with the use of broad spectrum antibiotics; therefore it is important to consider this diagnosis in patients who develop serious diarrhoea in association with antibiotic use. In this clinical situation adequate therapeutic measures should be initiated.

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No case of pseudomembranous colitis was observed in the clinical trial programme. In some instances, the hypersensitivity and allergic reactions already occurred after the first administration and the doctor should be informed immediately. Anaphylactic reactions in very rare instances can progress to a life threatening shock, in some instances after the first administration. In these cases Moxifloxacin has to be discontinued, medical treatment (e.g. treatment for shock) is required.

ADVERSE EFFECTS: Incidence of frequency>1%<10%; Abdominal pain, headache, nausea, diarrhoea, vomiting, dyspepsia, abnormal liver function test, taste perversion, dizziness, QT prolongation in patients with concomitant hypokalemia. **Incidence of frequency >0.1%<1%;** Asthenia, moniliasis, pain, back pain, malaise, lab test abnormal, chest pain, allergic reaction, leg pain, tachycardia, peripheral edema, hypertension, palpitation, QT prolongation, dry mouth, nausea and vomiting; flatulence, constipation, oral moniliasis, anorexia, stomatitis, gastrointestinal disorder, glossitis, GT increase, leukopenia, prothrombin decrease, eosinophilia, thrombocythemia, thrombocytopenia, anemia, amylase increased, arthralgia, myalgia, insomnia, vertigo, nervousness, somnolence, anxiety, tremor, paraesthesia, confusion, depression, rash, pruritus, sweating, urticaria, amblyopia, vaginal moniliasis and vaginitis.

INTERACTIONS: Food and dairy products: Absorption of Moxifloxacin was not altered by food intake. Therefore, Moxifloxacin can be taken independent from food intake. **Ranitidine:** The concomitant administration with ranitidine did not change the absorption characteristics of Moxifloxacin significantly. Absorption parameters (C_{max}, t_{max}, AUC) were very similar indicating absence of an influence of gastric pH on Moxifloxacin uptake from the gastrointestinal tract. **Antacids, minerals and multi-vitamins:** Concomitant ingestion of Moxifloxacin together with antacids, minerals and multi-vitamins may result in impaired absorption of the drug due to formation of chelate complexes with the multi-valent cations contained in these preparations. This may lead to plasma concentrations considerably lower than desired. Hence, antacids, anti-retroviral drugs and other preparations containing magnesium, aluminium and other minerals such as iron should be administered at least 4 hours before or 2 hours after ingestion of an oral Moxifloxacin dose. **Warfarin:** No interaction during concomitant treatment with warfarin on prothrombin time and other coagulation parameters has been observed. **Digoxin:** The pharmacokinetics of digoxin are not significantly influenced by Moxifloxacin (and vice versa). **Theophylline:** No influence of Moxifloxacin on theophylline pharmacokinetics (and vice versa) at steady state was detected, indicating that Moxifloxacin does not interfere with the 1 A2 subtypes of the cytochrome P450 enzymes; theophylline concentrations were not elevated at steady state during combined treatment with Moxifloxacin. Hence, no recommendations with respect to theophylline dosing need to be given. **Probenecid:** No significant effect on apparent total body clearance and renal clearance of Moxifloxacin was found in a clinical study investigating the impact of probenecid on renal excretion. Therefore, dosing adjustments need not be made when both drugs are administered concomitantly. **Antidiabetics:** No clinically relevant interaction was seen between glibenclamide and Moxifloxacin. **Photosensitivity:** Phototoxicity has been reported with other quinolones. However, a study in human volunteers concluded that Moxifloxacin has no measurable phototoxic potential.

OVERDOSE: Only limited data on overdose are available. Single doses of upto 800mg and multiple doses of 600mg over 10 days were administered to healthy subjects without any significant undesirable effects. In the event of overdosage it is recommended that appropriate supportive care should be instituted as dictated by the patient's clinical status.

POSOLOGY AND METHOD OF ADMINISTRATION: Range of dose, the recommended dose for Moxifloxacin is one tablet (400mg) once daily for all indications. **Method of Administration-Adults:** The tablets are swallowed whole with a glass of water. They can be taken independent of food intake.

Duration of treatment: The duration of treatment should be determined by the severity of the indication or clinical response. The following general recommendations for the treatment of upper and lower respiratory tract infections are made: Acute exacerbation of chronic bronchitis, 5 days; Community acquired pneumonia, 10 days; Acute sinusitis, 7 days. The recommended duration of treatment in skin and soft tissue infections is 7 days.

Elderly: No adjustment of dosage is required in the elderly.

Children: The use of Moxifloxacin in children and adolescents in the growth phase is not recommended.

Hepatic Impairment: No dosage adjustment is required in patients with slightly impaired liver function (Child-Pugh A,B). No pharmacokinetic data is available for patients with severely impaired liver function (Child-Pugh C).

Renal Impairment: No dose adjustment is required in patients with any degree of renal impairment (including creatinine clearance < 30ml/min/1.73m^2). There is no pharmacokinetic data available in patients on dialysis treatment.

Interethnic Differences: No adjustment of dosage is required in ethnic groups.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:
Meflox tablets 400mg are available in Alu Alu Pack of 5's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
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