SCIMOX 400 mg

(M o x i f l o x a c i n)

سائیموکس ۴۰۰ ملی گرام

(موکسی فلوکساسن)

Composition
Each film-coated tablet contains: Moxifloxacin Hydrochloride Eq. to Moxifloxacin 400mg.

Pharmacological Properties:

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 e.g. Mycoplasma spp. Chlamydia spp. and Legionella spp. Moxifloxacin is effective against (Beta-lactam and macrolide resistant bacteria. Studies in animal models of infection have demonstrated the high in vivo activity. Moxifloxacin has been shown to be active against most strains of the following microorganisms; both in vitro and in clinical infections:

Gram-positive Microorganisms:
Staphylococcus aureus (including methicillin-sensitive strains)
Streptococcus pneumonine (including penicillin and macrolide resistant strains) Streptococcus pyogenes (group A)

Gram-negative Microorganisms:
Haemophilus influenzae (including Beta-lactamase negative and positive strains) Haemophilus parainfluenzas
Klebsiella pneumoniae
Moraxella catarrhalis (including (Beta-lactamase negative and positive strains)
Escherichia coli
Enterobacter cloacae

Atypicals:
Chlamydia pneumoniae
Mycoplasma pneumoniae

According to in vitro studies, the following organisms are sensitive to moxifloxacin, however, the safety and effectiveness of moxifloxacin in treating clinical infections due to these microorganisms has not been established in adequate and well-controlled clinical trials.

Gram-positive microorganisms:
Streptococcus milled
Streptococcus mitiior
Streptococcus agalactiae
Streptococcus dysgalactiae
Staphylococcus cohnii
Staphylococcus epidermidis
(including methicillin sensitive strains).
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus saprophytics
Staphylococcus simulans
Corynebacterium Diphtheria

Gram-negative microorganisms:
Bordetella pertussis
Klebsiella oxytoca
Enterobacter aerogenes
Enterobacter agglomerans
Enterobacter intermedius
Enterobacter sakiazaki
Proteus mirabilis
Proteus vulgaris
Morganella morganii
Providencia rettgori

Anaerobes:
Bactemides distasonis
Bactemides eggerthii
Bactemides fragilis
Bactemides ovatus
Bactemides thetaiotaomicron
Bactemides uniformis
Fusobacterium spp
Porphyromonas spp
Porphyromonas anaerobius
Porphyromonas asacharolyticus
Porphyromonas magnus
Prevoteila spp
Propionibacterium spp
Clostridium perfringens
Clostridium ramosum

Atypicals:
Legionella pneumophila
Caxiella burnettii

Mode of Action
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.

Indications
Scimox 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 infection.
-Complicated intra-abdominal infections.

Contraindications
Known hypersensitivity to any component of the tablets or other quinolones.
Scimox tablets are contraindicated in children, growing adolescents and pregnant women.

Special warnings and special precautions for use
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 lowers the seizure threshold.
As no pharmacokinetic and pharmacodynamic data are 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.

Undesirable effects
In moxifloxacin clinical trials the majority of adverse drug reactions (ADRs) were described as mild to moderate (over 90%). The discontinuation rate of moxifloxacin treated patients due to ADRs was 3.8%. The most common adverse drug reactions (relationship defined as probable, possible or not assessable), based on all clinical studies with moxifloxacin are abdominal pain, headache, nausea, diarrhoea, dyspepsia, dizziness and prolongation of QT intervals.

Interaction with other medicines and other forms of interaction 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.

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 1A2 subtypes of the cytochrome P450 enzymes. Theophylline concentrations were not elevated at steady state during combined treatment with moxifloxacin (Cmax 10.5 vs 10.1mg/1, without theophylline). Hence, no adjustment is required with respect to Theophylline dosing pattern.

Overdose:
Only limited data on overdose is available. Single doses of up to 800 mg and multiple doses of 600 mg over 10 days were administered to healthy subjects without any significant, undesirable effects. In the event of over dosage, 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 (400 mg) once-daily for all indications.
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 are the general recommendations for the treatment of upper and lower respiratory tract infections:
Method of Acute exacerbation of chronic bronchitis: 5 days
Community acquired pneumonia: 10 days
Acute sinusitis: 7 days
Skin or soft tissue infection:7 days
Complicated intra-abdominal infections: 7 days

Moxiflocacin 400 mg tablets have been studied in clinical trials for up to 14 days treatment.

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 mild degree of renal impairment (including creatinine clearance a <30ml/min/1.73m2). There is no pharmacokinetic data available in patients on dialysis treatment.

Notes:
Protect from moisture, freezing and excessive heat.
KEEP All MEDICINES OUT OF THE REACH OF CHILDREN.

Presentation:
Pack of 5 film coated tablets in a ALU-ALU blister.

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