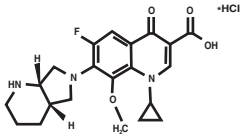
MOXEF

(Moxifloxacin) USP 400mg Tablets

Description:
Moxef (Moxifloxacin) is a new oral 8-methoxyfluroquineclone antibacterial agent. Chemically, moxifloxacin is a monohydrate salt of 1-cyclopropyl-7-[(S, S)-2, B-diazabicycla {4.3.0] non-6-yl] -6-flcuro-8-methoxy-1, 4-dihydra-4-oxo-3 quinolone carboxylic acid. The molecular formula is C21H24FN3O4*HCl and the structural formula is:



Moxifloxacin HCl

QUALITATIVE & QUANTITATIVE COMPOSITION:
MOXEF (Moxifloxacin) is available for oral administration as:
MOXEF Tablets 400mg
Each film-coated tablet contains:
Moxifloxacin (USP) 400mg
(as hydrochloride)

CLINICAL PHARMACOLOGY:
Mechanism of Action:
Moxifloxacin is bactericidal against a range of Gram-positive and Gram-negative organisms. Such activity ansea 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 molety that augments its antibacterial activity and reduces the possibility of Gram-positive mulations. Because the B-fluroqunolones use a different mechanism of action than do the aminoglycosides, beta-lactams, macrolides or tetracycline, there has been no cross resistance between the qulnolones and these antimicrobial agents.

Microbiology:
Aerobic Gram-positive micro-organisms:
Staphylococcus aureus (methicillin-susceptible)
Streptococcus pneumoniae, Streplococcus pyogenes
Streptococcus epidemidis (methicillin-susceptible)
Streptococcus anginosus
Aerobic Gram-negative micro-organisms:
Haemophilus influenzae
Haemophilus parainfluenzae
Ktebsialla pneumoniae
Moraxella catarrhallis
Escherichia coll
Proteus mirabillis
Anaerobic micro-organisms:
Fusobacterium species
Peptostreptococcus species
Other:
Chlamydia pneumoniae
Mycoplasma pneumoniae
Legionelle pneumophila
Mycrobacterium 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 ellmination 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:
Moxef (Moxifloxacin) is 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.
-Uncomplicated Skin and Skin Structure Infections.
-Plague.

Dosage and Administration:
The usual adult dose of Moxef (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.

Type of Infection	Daily Dose	Duration
Acute bacterial sinusitis	400mg	10 days
Acute bacterial exacerbation of chronic bronchitis	400mg	5 days
Community acquired Pneumonia	400mg	7-14 days
Cemplicated intra Abdominal Infections	400mg	5-14 days
Complicated skin and skin structure Infections	400mg	7-21 days
Uncomplicated Skin and Skin Structure infections (SSSI)	400mg	7 days
Plague	400mg	5 days

Adverse Reactions:
Moxifloxacin was usually well tolerated. Most adverse reaction were mild to moderate.
Common:
Pyrexia, headache, dizziness, nausea, vomiting, gastrointestinal and abdominal pains, QT prolongation in patients with hypokalemia, increase in transaminases, superinfection due to resistant bacteria or fungle e.g. oral and vaginal candidiasis and diarrhea.
Uncommon:
Anorexia, consipation, dyspepsia, flatulence, gastritis, increase amytase, QT prolongation, palpitations, tachycardia, artial fibrillation, angina pectoris, dyspnea, hepatic impairment, increased bilirubin, increase gamma glularryl transferase, increase in blood alkaline phosphatase, blood triglycerides increase, blood uric acid increased hamatororit decreased, pruritis, rash, urticaria, dry skin arthralgla, myalgia, dehydration, visual disturbances, anxiety reactions, psychomotor hyperactivity/agitation, dysgeusia, taste disorder, decreased appetite and food intake, paresthesia/dysesthesia, confusion, disorientation, hyperlipidemia, allergic reaction, anemia, leucopenia, leucocytosis, cardiac failure, cardiac arrest, facial pain, chest discomfort, chillis, asthenia, malaise, phlebitis, night sweats, wheezing, asthma, malaise,bronchospasm, neutropenia, thrombocytopenia, thrombocythemia, blood eosinophilia and prothrombin time prolonged/NR increased.
Rare:
Dyspepsia, psaudomembranous colitis, ventricular tachyarrhythmias. syncope, hypertension, hypotension, vasodilatation, tinnitus, hypoesthesia, small disorder, abnormal dreams, disturbed coordination, seizures, muscle cramp, muscle twitching, muscle weakness, hepatitis, dirturbed attention, polyneuropathy, speach disorders, amnesia, anaphyiaxis, allergic edema/angicedema, renal impairment, renal failure, hyperglycemia, hyperuricemia, emotional liability, depression, allucination and prothrombin time prolonged.

Contraindications:
With hypersensivity 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.
With impaired liver function and in patients with transaminases >5 fold ULN.
With congenital or documented acquired QT prolonged. With elect/clyte disturbances, particularly in uncorreted hypokalemia.
With clinically relevant bradycardia.
With clinically relevant heart failure with reduced left-ventricula ejection fraction.
With previous history of symptomatic arrhyhmias.
Receiving Class, IA (e.g., quinidine, procainamide) or Class III (amiodarone, sotalol) antiarrhythmia 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.

Warning:
SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS.
Fluoroquinolones, including moxifloxacin, have been associated with disabling and potentially irreversible senous adverse reaction that have occurred together including:
1. Tendinitis and tendon rupture.
2. Penpheral Neuropathy.
3. Central nervous system effects.
Discontinue moxifloxation immediately and avoid the use of Fluoroquinolones, including moxifloxacin in patients who experience any of these serious adverse reactions.
any of these serious adverse reactions.
Fluoroqulnolones, including moxifloxacin may exacerbate muscle weakness in patients with myasthenia gravis. Avoid moxifloxacin in patients with known history of myasthenia gravis.
As fluoroqulnolones, including moxifloxacin have been associated with serious adverse reactions, reserve moxifloxacin for use in patients who have no alternative treatment options for the following indications.
1. Acute exacerbation of chronic bronchitis.
2. Acute sinusitis.

Precautions:
Cases of bullous skin reaction like Stevens-Johnson syndrome or toxic epidermal necrolysis have been reported with moxifloxacin. Patients should be advised to contact their doctor immediately prior to continuing treatment if skin and/ormucosal reactions occur.
Due to adverse effects on the cartilage in juvenile animals the use of moxifloxacin in children and adolescents < 18 years is contraindicated.
Patients with a family history of or actual glucose-6-phosphate dehydrogenase deficiency are prone to hemolytic reactions when treated with quinolones. Therefore, moxifloxacin should be used with caution in these patients.
Elderly patients with renal disorders 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.
Fluoroquinolones, including moxifloxacin, have been associated with disablingand potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches and confusion). These reactions can occur within hours to weeks after starting moxifloxacin. Discontinue moxifloxacin immediately at the first signs or symptoms of any serious adverse reaction.
Fluoroquinolones, including moxifloxacin, have been associated with an increased risk of tendinitis and tendon rupture in all ages. Tendinitis or tendon rupture can occur within hours or days of starting moxifloxacin or as long as several months after completion of therapy Discontinue moxifloxacin immediately. If the patient experiences pain, swelling, inflammation or rupture of a tendon. Avoid fluoroquinolones, including moxifloxacin, in patients who have a history of tendon disorders or who have experienced tendinitis or tendon rupture.
Fluoroqulnolones, including moxifloxacin, have been associated with an increased risk of peripheral neuropathy. Discontinue moxifloxacin immediately if the patient experiences symptoms of peripheral neuropathy including pain, burning, tinling, numbness and/or weakness or other allerations of sensation including light touch, pain, tempreture, position sense and vibratoy sensation. Avoid fluoroquinolones, including moxifloxacin, in patients who have previously esperienced peripheral neuropathy.
Fluoroquinolones, including moxifloxacin, have been associated with an increased risk of central nervous system (CNS) reactions, including: convulsion and increased intracranial pressure, (including pseudotumor cerebri) and toxic psychosis, Fluoroquinolones may also cause CNS reactions of nervousness, aditation, insominia, anxiety, nightmares, paranoia, dizziness, confusion, tremors, hallucinations, depression and suicidal thoughts or acts. It these reactions occur in patients receiving moxifloxacin, discontinue moxifloxacin immediately and institute appropriate measures.
Fluoroquinolones, including moxifloxacin, have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis. Avoid moxifloxacin in patients with known history of myasthenia gravis.
Moxifloxacin has been shown to prolong the QT interval of the electrocardiogram in some patients. The magnitude of QT prolongation may increase with increasing concentrations of the drug or increasing rates of infusion of the intravenous formulation. Therefore, the recommended dose or infusion rate should not be exceeded. Avoid moxifloxacin in patients with the following risk factors in these patient populations:
Known prolongation of the QT interval.
Ventricular arrhythmias including torsade de pointes because QT prolongation may lead to an increased risk for these conditions. Ongoing proarrhythmic conditions, such as clinically significant bradycardia and acute myocardial ischemia.
Uncorrected hypokalemia or hypomagnesemia.
Class IA (for example, quinidine, procainamide) or Class III (for example, amlodarone, sotalol) antiarrhythmic agents. Other drugs that prolong the QT interval such as cisapride, erythromycin, antipsychotics and tricyclic antidepressants. Other serious and sometimes fatal adverse reactions, some due to hypersensitivity and some due to uncertain etiology have been reported in patients receiving therapy with fluoroquinolones, including moxifloxacin. Discontinue moxifloxacin immediately at the first appearance of a skin rash, jaundice or any other sign of hypersensitivity and institute supportive measures.
Serious anaphylactic reactions, some following the first dose, have been reported in patients receiving fluoroquinolone therapy, including moxifloxacin. Discontinue moxifloxacin at the first appearance of a skin rash or any other sign of hypersensitivity. appearance of a skin rash or any other sign of hypersensitivity.
Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including moxifloxacin and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile and surgical evaluation should be instituted as clinically indicated.
Moderate to severe photosensitivity/phototoxicity reactions can be associated with the use of fluoroquinolones, including moxifloxacin, after sun or UV light exposure. Therefore, excessive exposure to these sources of light should be avoided. Moxifloxacin should be discontinued if phototoxicity occurs.
Prescribing moxifloxacin in the absence of a proven or strongly suspected bacterial infection or a prohylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

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.
Mecation 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 preventation of drug absoption 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 prothombin time, international Normalized Ratio (INR) or other suitable anticoagulation tests should be closely monitored if a quinolone is administered of NSAIDs with quinolones may increase the risks of CNS stimulation and convulsions.

Overdose:
No specific countermeasures after accidental overdose are recommended in the event of oversdose, symplomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. Concomitant administration availability of the drug by more than 30%. The use of charcoal early during absorption may be useful to prevent excessive increase in the systemic exposure to moxifloxacin in cases of oral overdose.

Storage:
Store below 25°C. Protect from heat, light and moisture.
Keep all medicines out of the reach of children.
To be sold on prescription only.

How Supplied:
Moxef (Moxifloxacin) Tablet 400mg are available in blister pack of 5's.

موکسیف ٹیبلٹس

موکسی فلوکساسین (ہوایس پی) 400 ملی گرام

25° سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔
گرمی، روشنی اور نمی سے بچائیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

MANUFACTURED BY :
PHARMEDIC LABORATORIES (PVT) LIMITED.
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