

Voxiquin[®]

(Levofloxacin)



Highnoon

COMPOSITION

Voxiquin 250 mg Tablet: Each film-coated tablet contains: Levofloxacin (as hemihydrate) 250 mg

Voxiquin 500 mg Tablet: Each film-coated tablet contains: Levofloxacin (as hemihydrate) 500 mg

DESCRIPTION

Voxiquin (Levofloxacin) is a synthetic broad spectrum antibacterial agent for oral administration. Levofloxacin, is the S- (-) isomer of the fluoroquinolone antibacterial ofloxacin.

MECHANISM OF ACTION

Levofloxacin is a member of the fluoroquinolone class of antibacterial agents. Levofloxacin is the L-isomer of the racemate, ofloxacin, a quinolone antimicrobial agent. The antibacterial activity of ofloxacin resides primarily in the L-isomer. The mechanism of action of levofloxacin and other fluoroquinolone antimicrobials involves inhibition of bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerases), enzymes required for DNA replication, transcription, repair and recombination. Levofloxacin has in vitro activity against Gram-negative and Gram-positive bacteria.

PHARMACOKINETICS

Levofloxacin is rapidly and almost completely absorbed after oral doses and peak plasma concentrations occur within 1 to 2 hours. Levofloxacin reaches its peak levels in skin tissues and in blister fluid of healthy subjects at about 3 hours. It is widely distributed into the body tissues including the bronchial mucosa and lungs, but penetration into CSF is relatively poor. Levofloxacin is about 30 to 40% bound to plasma protein. Only small amounts are metabolized to inactive metabolites. The elimination half life of levofloxacin is 6 to 8 hours, although this may be prolonged in patients with renal impairment. Levofloxacin is excreted largely unchanged, mainly in the urine with less than 5% as metabolites. It is not removed by haemodialysis or peritoneal dialysis.

INDICATIONS AND USAGE

It is indicated for the treatment of adults (≥18 years of age) with mild, moderate, and severe infections caused by susceptible isolates of the designated microorganisms in the conditions listed below;

Nosocomial Pneumonia

It is indicated for the treatment of nosocomial pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Escherichia coli*, *Klebsiella pneumoniae*, *Haemophilus influenzae*, or *Streptococcus pneumoniae*. Adjunctive therapy should be used as clinically indicated. Where *Pseudomonas aeruginosa* is a documented or presumptive pathogen, combination therapy with an antipseudomonal β-lactam is recommended.

Community-Acquired Pneumonia: 7-14 day Treatment Regimen

It is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae* (including multidrug-resistant *Streptococcus pneumoniae* [MDRSP]), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae*. MDRSP isolates are isolates resistant to two or more of the following antibacterials: penicillin (MIC ≥2 mcg/mL), 2nd generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim/sulfamethoxazole.

Community-Acquired Pneumonia: 5-day Treatment Regimen

It is indicated for the treatment of community-acquired pneumonia due to *Streptococcus pneumoniae* (excluding multi-drug-resistant isolates [MDRSP]), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Mycoplasma pneumoniae*, or *Chlamydia pneumoniae*.

Acute Bacterial Sinusitis: 5-day and 10–14 day Treatment Regimens

It is indicated for the treatment of acute bacterial sinusitis due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*.

Acute Bacterial Exacerbation of Chronic Bronchitis

It is indicated for the treatment of acute bacterial exacerbation of chronic bronchitis due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, or *Moraxella catarrhalis*.

Complicated Skin and Skin Structure Infections

It is indicated for the treatment of complicated skin and skin structure infections due to methicillin-susceptible *Staphylococcus aureus*, *Enterococcus faecalis*, *Streptococcus pyogenes*, or *Proteus mirabilis*.

Uncomplicated Skin and Skin Structure Infections

It is indicated for the treatment of uncomplicated skin and skin structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections, due to methicillin-susceptible *Staphylococcus aureus*, or *Streptococcus pyogenes*.

Chronic Bacterial Prostatitis

It is indicated for the treatment of chronic bacterial prostatitis due to *Escherichia coli*, *Enterococcus faecalis*, or methicillin-susceptible *Staphylococcus epidermidis*.

Complicated Urinary Tract Infections: 5-day Treatment Regimen

It is indicated for the treatment of complicated urinary tract infections due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*.

Complicated Urinary Tract Infections: 10-day Treatment Regimen

It is indicated for the treatment of complicated urinary tract infections (mild to moderate) due to *Enterococcus faecalis*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, or *Pseudomonas aeruginosa*.

Acute Pyelonephritis: 5 or 10-day Treatment Regimen

It is indicated for the treatment of acute pyelonephritis caused by *Escherichia coli*, including cases with concurrent bacteremia.

Uncomplicated Urinary Tract Infections

It is indicated for the treatment of uncomplicated urinary tract infections (mild to moderate) due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Staphylococcus saprophyticus*.

Inhalational Anthrax (Post-Exposure)

It is indicated for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*. The effectiveness of levofloxacin is based on plasma concentrations achieved in humans, a surrogate endpoint reasonably likely to predict clinical benefit. Levofloxacin has not been tested in humans for the post-exposure prevention of inhalation anthrax. The safety of levofloxacin in adults for durations of therapy beyond 28 days or in pediatric patients for durations of therapy beyond 14 days has not been studied. Prolonged Levofloxacin therapy should only be used when the benefit outweighs the risk.

Plague

Levofloxacin is indicated for treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (Y. pestis) and prophylaxis for plague in adults and pediatric patients, 6 months of age and older.

Culture and susceptibility testing

Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing the infection and to determine their susceptibility to levofloxacin. Therapy with Levofloxacin triate therapy should be selected. As with other drugs in this class, some isolates of *Pseudomonas aeruginosa* may develop resistance fairly rapidly during treatment with levofloxacin. Culture and susceptibility testing performed periodically during therapy will provide information about the continued susceptibility of the pathogens to the antimicrobial agent and also the possible emergence of bacterial resistance.

DOSEAGE AND ADMINISTRATION

Voxiquin (Levofloxacin) tablets administered orally every 24 hours. The dosage depends on the severity and the nature of the

infections and the sensitivity of presumed causative pathogens. The tablets should be swallowed without crushing; it can be administered without regard to the food. It should be administered at least two hours before and two hours after antacids containing magnesium, aluminium as well as sucralfate, metal cations such as iron and multivitamin preparation with zinc or didanosine chewable buffered tablets or the pediatric powder for oral solution.

Dosage in adult patients with normal renal function (Creatinine Clearance ≥ 50mL/min)

Type of Infection	Dose Every 24 hours	Duration (days)
Nosocomial Pneumonia	750 mg*	7–14
Community Acquired Pneumonia	500 mg	7–14
Community Acquired Pneumonia	750 mg*	5
Acute Bacterial Sinusitis	750 mg*	5
Acute Bacterial Exacerbation of Chronic Bronchitis	500 mg	7
Complicated Skin and Skin Structure Infections (SSSI)	750 mg*	7–14
Uncomplicated SSSI	500 mg	7–10
Chronic Bacterial Prostatitis	500 mg	28
Complicated Urinary Tract Infection or Acute Pyelonephritis	750 mg*	5
Complicated Urinary Tract Infection (1, 10) or Acute Pyelonephritis	250 mg	10
Uncomplicated Urinary Tract Infection	250 mg	3
Inhalational Anthrax (Post-Exposure), adult and pediatric patients > 50 kg **	500 mg	60 days**
Pediatric patients < 50 kg and ≥6 months of age	500 mg	60 days**
Plague, adult and pediatric patients > 50 kg	500 mg 8 mg/kg (not to exceed 250 mg per dose)	10-14 days

* The Voxiquin tablet 750mg is not marketed by Highnoon Laboratories.

** The safety of levofloxacin in adults for durations of therapy beyond 28 days or in pediatric patients for durations beyond 14 days has not been studied. An increased incidence of musculoskeletal adverse events compared to controls has been observed in pediatric patients.

Dosage in Patients ≥ 6 months of age

Type of Infection	Dose	Frequency once every	Duration
Inhalation Anthrax (Post Exposure): Pediatric patients > 50 kg	500mg	24 hrs	60 days
Inhalation Anthrax (Post Exposure): Pediatric patients < 50 kg and ≥ 6 months of age	8 mg/kg (not to exceed 250 mg per dose)	12 hrs	60 days
Plague: Pediatric patient > 50 kg	500mg	24 hrs	10 to 14 days
Plague: Pediatric patients < 50 kg and ≥ 6 months of age	8 mg/kg (not to exceed 250 mg per dose)	12 hrs	10 to 14 days

Dosage Adjustment in Adult Patients with Renal Impairment (creatinine clearance <50 mL/min)

Dosage in Normal Renal Function Every 24 hours	Creatinine Clearance 20 to 49 mL/min	Creatinine Clearance 10 to 19 mL/min	Hemodialysis or Chronic Ambulatory Peritoneal Dialysis (CAPD)
750 mg	750 mg every 48 hours	750 mg initial dose, then 500 mg every 48 hours	750 mg initial dose, then 500 mg every 48 hours
500 mg	500 mg initial dose, then 250 mg every 24 hours	500 mg initial dose, then 250 mg every 48 hours	500 mg initial dose, then 250 mg every 48 hours
250 mg	No dosage adjustment required	250 mg every 48 hours. If treating uncomplicated UTI, then no dosage adjustment is required	No information on dosing adjustment is available

DRUG INTERACTIONS

• Concomitant administration of other fluoroquinolones with theophylline has resulted in prolonged elimination half-life, elevated serum theophylline levels, and a subsequent increase in the risk of theophylline-related adverse reactions in the patient population. Therefore, theophylline levels should be closely monitored and appropriate dosage adjustments made when levofloxacin is co-administered. Adverse reactions, including seizures, may occur with or without an elevation in serum theophylline levels.

• While the chelation by divalent cations is less marked than with other fluoroquinolones, concurrent administration of levofloxacin tablets with antacids containing magnesium, or aluminum, as well as sucralfate, metal cations such as iron, and multivitamin preparations with zinc may interfere with the gastrointestinal absorption of levofloxacin, resulting in systemic levels considerably lower than desired. Tablets with antacids containing magnesium, aluminum, as well as sucralfate, metal cations such as iron, and multivitamin preparations with zinc or didanosine may substantially interfere with the gastrointestinal absorption of levofloxacin, resulting in systemic levels considerably lower than desired. These agents should be taken at least two hours before or two hours after oral levofloxacin administration.

• There have been reports in patients that levofloxacin enhances the effects of warfarin, Prothrombin time, International Normalized Ratio (INR), or other suitable anticoagulation tests should be closely monitored if levofloxacin is administered concomitantly with warfarin. Patients should also be monitored for evidence of bleeding.

• Disturbances of blood glucose, including hyperglycemia and hypoglycemia, have been reported in patients treated concomitantly with fluoroquinolones and an antidiabetic agent. Therefore, careful monitoring of blood glucose is recommended when these agents are co-administered. If a hypoglycemic reaction occurs.

• Concomitant administration of a nonsteroidal anti-inflammatory drug with a quinolone may increase the risks of CNS stimulation and convulsions.

• Elevated serum levels of cyclosporine have been reported in the patient population when co-administered with some other fluoroquinolones. The half life of cyclosporine was increased by 33% when coadministered with levofloxacin.

• Levofloxacin absorption and disposition kinetics were similar in the presence or absence of digoxin. Therefore, no dosage adjustment for levofloxacin or digoxin is required when administered concomitantly.

• Caution should be exercised when levofloxacin is co-administered with drugs that affect the tubular renal secretion such as probenecid and cimetidine, especially in renally impaired patients.

WARNINGS AND PRECAUTIONS

The following precaution & warning should be measured during Levofloxacin treatment;

• Fluoroquinolones, including levofloxacin are associated with an increased risk of tendinitis and tendon rupture in all ages. This adverse reaction most frequently involves the Achilles tendon, and rupture of the Achilles tendon may require surgical repair. Tendinitis and tendon rupture in the rotator cuff (the shoulder), the hand, the biceps, the thumb, and other tendon sites have also been reported. The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is further increased in older patients usually over 60 years of age, in those taking corticosteroid drugs, and in patients with

kidney, heart or lung transplants. Factors, in addition to age and corticosteroid use, that may independently increase the risk of tendon rupture include strenuous physical activity, renal failure, and previous tendon disorders such as rheumatoid arthritis. Tendinitis and tendon rupture have been reported in patients taking fluoroquinolones who do not have the above risk factors. Tendon rupture can occur during or after completion of therapy; cases occurring up to several months after completion of therapy have been reported. Levofloxacin should be discontinued if the patient experiences pain, swelling, inflammation or rupture of a tendon. Patients should be advised to rest at the first sign of tendinitis or tendon rupture, and to contact their healthcare provider regarding changing to a non-quinolone antimicrobial drug.

• Fluoroquinolones, including levofloxacin have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Avoid levofloxacin in patients with a known history of myasthenia gravis.

• Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with fluoroquinolones, including levofloxacin. These reactions often occur following the first dose. Some reactions have been accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat, or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath, and acute respiratory distress), dyspnea, urticaria, itching, and other serious skin reactions. Levofloxacin should be discontinued immediately at the first appearance of a skin rash or any other sign of hypersensitivity. Serious acute hypersensitivity reactions may require treatment with epinephrine and other resuscitative measures, including oxygen, intravenous fluids, antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated.

• Other serious and sometimes fatal events, some due to hypersensitivity, and some due to uncertain etiology, have been reported rarely in patients receiving therapy with fluoroquinolones, including levofloxacin. These events may be severe and generally occur following the administration of multiple doses. Clinical manifestations may include one or more of the following:

- o Fever, rash, or severe dermatologic reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson Syndrome);
- o Vasculitis; arthralgia; myalgia; serum sickness;
- o Allergic pneumonitis;
- o Interstitial nephritis; acute renal insufficiency or failure;
- o Hepatitis; jaundice; acute hepatic necrosis or failure;
- o Anemia, including hemolytic and aplastic;
- o thrombocytopenia, including thrombotic thrombocytopenic purpura; leukopenia;
- o agranulocytosis; pancytopenia; and/or other hematologic abnormalities.

The drug should be discontinued immediately at the first appearance of skin rash, jaundice, or any other sign of hypersensitivity and supportive measures instituted.

• Levofloxacin should be discontinued immediately if the patient develops signs and symptoms of hepatitis.

• Convulsions, toxic psychoses, increased intracranial pressure (including pseudotumor cerebri) have been reported in patients receiving fluoroquinolones, including levofloxacin. Fluoroquinolones may also cause central nervous system stimulation which may lead to tremors, restlessness or nervousness, delirium, disorientation, or disturbances in attention, anxiety, irritability, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and, rarely, suicidal thoughts or acts. These reactions may occur following the first dose. If these reactions occur in patients receiving Levofloxacin, the drug should be discontinued and appropriate measures instituted. As with other fluoroquinolones, Levofloxacin should be used with caution in patients with a known or suspected central nervous system (CNS) disorder that may predispose them to seizures or lower the seizure threshold (e.g., severe cerebral arteriosclerosis, epilepsy) or in presence of other risk factors that may predispose them to seizures or lower the seizure threshold (e.g., certain drug therapy, renal dysfunction).

• Epidemiologic studies report an increased rate of aortic aneurysm and dissection within two months following use of fluoroquinolones, particularly in elderly patients. The cause for the increased risk has not been identified. In patients with a known aortic aneurysm or patients who are at greater risk for aortic aneurysms, reserve Levofloxacin for use only when there are no alternative antibacterial treatments available.

• If you have Clostridium Difficile – Associated Diarrhea, the treatment should be stopped and appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

• Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dyesthesias and weakness have been reported in patients receiving fluoroquinolones, including levofloxacin. Symptoms may occur soon after initiation of levofloxacin and may be irreversible. Levofloxacin should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.

• Some fluoroquinolones, including levofloxacin, have been associated with prolongation of the QT interval on the electrocardiogram and infrequent cases of arrhythmia. Rare cases of torsade de pointes have been spontaneously reported during postmarketing surveillance in patients receiving fluoroquinolones, including levofloxacin. Levofloxacin should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, and patients receiving Class IA (quinidine, procainamide), or Class III (amiodarone, sotalol) antiarrhythmic agents. Elderly patients may be more susceptible to drug-associated effects on the QT interval.

• Fluoroquinolones, including Levofloxacin, have been associated with disturbances of blood glucose, including symptomatic hyperglycemia and hypoglycemia, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent (e.g., glyburide) or with insulin. In these patients, careful monitoring of blood glucose is recommended. Severe cases of hypoglycemia resulting in coma or death have been reported. If a hypoglycemic reaction occurs in a patient being treated with Levofloxacin, discontinue it and initiate appropriate therapy immediately.

• Levofloxacin is indicated in pediatric patients (6 months of age and older) only for the prevention of inhalational anthrax (post-exposure). An increased incidence of musculoskeletal disorders (arthralgia, arthritis, tendinopathy, and gait abnormality) compared to controls has been observed in pediatric patients receiving levofloxacin.

• As with other fluoroquinolones, disturbances of blood glucose, including symptomatic hyper- and hypoglycemia, have been reported with levofloxacin, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent (e.g., glyburide) or with insulin. In these patients, careful monitoring of blood glucose is recommended. If a hypoglycemic reaction occurs in a patient being treated with levofloxacin, Levofloxacin should be discontinued and appropriate therapy should be initiated immediately.

• Quinolone antibiotics may make your skin become more sensitive to sunlight or UV light. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a tanned or any other UV lamp while taking levofloxacin. Drug therapy should be discontinued if photosensitivity/phototoxicity occurs.

• Prescribing levofloxacin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is

unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

• Care should be taken - If you are taking any medicine that decreases your blood potassium levels.

• Care should be taken - If you have or have ever had any mental health problems.

• Care should be taken - If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease).

• Care should be taken - If you have a liver disease.

• Care should be taken - In children, levofloxacin may cause damage to the cartilage. Therefore, children should only take levofloxacin when his/her doctor or health care provider considers the benefit to outweigh the risks.

• Care should be taken - If you suffer from epilepsy or a condition which makes you likely to have convulsions.

CONTRAINDICATIONS

It is contraindicated in persons with known hypersensitivity to levofloxacin, or other quinolone antibacterials.

ADVERSE REACTIONS

The serious and important adverse reactions of Levofloxacin are tendinopathy and tendon rupture, Prolongation of the QT Interval, Exacerbation of Myasthenia Gravis, hypersensitivity reactions, hepatotoxicity, central nervous system effects, clostidium difficile-associated diarrhea, peripheral neuropathy, musculoskeletal disorders in pediatric patients, blood glucose disturbances, photosensitivity/phototoxicity, development of drug resistant bacteria and disabling and potentially irreversible serious reactions included tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). Crystalluria and cylindruria have been reported with quinolones, including Levofloxacin. Therefore, adequate hydration of patients receiving Levofloxacin should be maintained to prevent the formation of highly concentrated urine.

The other reported adverse effects include moniliasis, insomnia, headache, dizziness, dyspnea, nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, rash, pruritus, vaginitis, edema, chest pain, genital moniliasis, anemia, thrombocytopenia, granulocytopenia, pancytopenia, hemolytic anemia, leucopenia, aplastic anemia, hyperglycemia, hypoglycemia, anxiety, agitation, confusion, depression, hallucination, nightmare, sleep disorder, anorexia, abnormal dreaming, tremor, convulsions, paresthesia, vertigo, hypertonia, hyperkinesias, abnormal gait, somnolence, syncope, epistaxis, cardiac arrest, palpitation, ventricular tachycardia, ventricular arrhythmia, phlebitis, gastritis, stomatitis, pancreatitis, esophagitis, gastroenteritis, glossitis, pseudomembranous colitis, abnormal hepatic function, increased hepatic enzymes, increased alkaline phosphatase, urticaria, arthralgia, tendonitis, myalgia, skeletal pain, abnormal renal function and acute renal failure.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Because of the potential for serious adverse reactions in infants who are nursing from mothers taking levofloxacin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of six months have not been established.

Geriatric Use

Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as levofloxacin. This risk is further increased in patients receiving concomitant corticosteroid therapy. Tendinitis or tendon rupture can involve the Achilles, hand, shoulder, or other tendon sites and can occur during or after completion of therapy; cases occurring up to several months after fluoroquinolone treatment have been reported. Caution should be used when prescribing it to elderly patients especially those on corticosteroids. Patients should be informed of this potential side effect and advised to discontinue levofloxacin and contact their healthcare provider if any symptoms of tendinitis or tendon rupture occur.

Renal Impairment

Clearance of levofloxacin is substantially reduced and plasma elimination half-life is substantially prolonged in patients with impaired renal function (creatinine clearance < 50 mL/min), requiring dosage adjustment in such patients to avoid accumulation. Neither hemodialysis nor continuous ambulatory peritoneal dialysis (CAPD) is effective in removal of levofloxacin from the body, indicating that supplemental doses of levofloxacin are not required following hemodialysis or CAPD.

Hepatic Impairment

Pharmacokinetic studies in hepatically impaired patients have not been conducted. Due to the limited extent of levofloxacin metabolism, the pharmacokinetics of levofloxacin are not expected to be affected by hepatic impairment.

OVERDOSAGE

In the event of acute overdose, the stomach should be emptied and adequate hydration maintained. ECG monitoring is recommended due to the possibility of QT interval prolongation. The patient should be carefully observed and given supportive treatment.

Antacids may be used for the protection of gastric mucosa. Levofloxacin is not efficiently removed by hemodialysis or peritoneal dialysis.

DOSEAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in dry place. Protect from light.

PRESENTATION

Voxiquin 250mg Tablets:

Alu. PVC Blister pack of 1 x 10's.

Voxiquin 500mg Tablets:

Alu. PVC Blister pack of 1 x 10's.

ووکسیکوئن[®]

(لیو فلوکسائین)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخے کے مطابق ہی دوا فروخت اور استعمال کی جائے۔

بچوں کی پہنچ سے دور رکھیں۔ C° 30 سے زیادہ درجہ حرارت پر نہ رکھیں۔

خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

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