LOXIMED®
400 mg Tablets

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about LOXIMED
LOXIMED tablets for oral use contain moxifloxacin 400 mg (as moxifloxacin HCl) with the following excipients: lactose monohydrate, microcrystalline cellulose, povidone, and magnesium stearate.
Moxifloxacin is a broad-spectrum fluoroquinolone antibiotic.
LOXIMED is indicated for the treatment of adults with infections caused by susceptible strains of microorganisms in the conditions listed below:
- Acute bacterial sinusitis
- Acute bacterial exacerbation of chronic bronchitis
- Community acquired pneumonia
- Uncomplicated Skin and Skin Structure Infections
- Complicated Skin and Skin Structure Infections
- Complicated Intra-Abdominal Infections
- Plague, including pneumonic and septicemic plague

The way to take LOXIMED
Take LOXIMED as directed by your physician. Do not discontinue the treatment without consulting your doctor. Dosage and duration of treatment are individualized on the basis of the condition under treatment; the dosage must not be changed without medical advice.
The usual dose of LOXIMED is 400 mg (1 tablet of LOXIMED) once every 24 hours.
The duration of therapy depends on the type of infection as described in the table below:

Type of infection	Dose every 24 hours	Duration (days)
Acute bacterial sinusitis	400 mg	10
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg	5
Community acquired pneumonia	400 mg	7-14
Uncomplicated Skin and Skin Structure Infections	400 mg	7
Complicated Skin and Skin Structure Infections	400 mg	7-21
Complicated Intra-Abdominal Infections	400 mg	5-14
Plague	400 mg	10-14

LOXIMED tablets may be taken with or without food. Try to take the tablets at the same time each day and drink fluids liberally.
Duration of treatment
Although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may decrease the effectiveness of the immediate treatment and increase the likelihood that bacteria will develop resistance.
In case of overdose
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.
In case of missed dose
Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications
This drug is contraindicated in case of history of hypersensitivity associated with the use of moxifloxacin or any member of the quinolone antibiotics.
Precautions
- Inform your doctor and discontinue the treatment if you experience pain, swelling, inflammation or rupture of a tendon; the risk is increased in older patients (over 60 years of age), in those taking corticosteroid drugs, and in patients with kidney, heart or lung transplants.
- Use with caution in patients with hepatic impairment.
- This drug should be avoided in the following conditions: patients with known history of myasthenia gravis, known prolongation of the QT interval, ventricular arrhythmias including torsade de pointes, ongoing proarrhythmic conditions, uncorrected hypokalemia or hypomagnesemia and in patients taking class IA and class III antiarrhythmic agents and other drugs that may prolong QT interval such as cisapride, erythromycin, antipsychotics, and tricyclic antidepressants.
- In case of liver cirrhosis, ECG must be monitored.
- Discontinue the drug and inform your doctor at the first appearance of a skin rash, jaundice or any other sign of hypersensitivity, dizziness, confusion, tremors, hallucinations, depression, and suicidal thoughts or acts.
- Use with caution in patients with known or suspected central nervous system disorders that may predispose to seizures or lower the seizure threshold. This drug should be discontinued immediately if the patient experiences symptoms of peripheral neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation.
- Inform your doctor if diarrhea occurs.
- Careful monitoring of blood glucose is recommended in diabetic patients. If you have diabetes and you develop a hypoglycemic reaction while you are taking this drug, you should stop taking this medication and consult your doctor.
- Avoid prolonged exposure to sunlight, sunlamps, and tanning beds during the treatment.
- Consult your doctor before using this drug in case of pregnancy or lactation.
- The safety and efficacy of this drug in pediatric patients, adolescents (under 18 years) have not been established.
- Caution should be taken when driving a car or operating machinery until you are sure that this drug is not causing dizziness or lightheadedness.
Associations with other medications
Please inform your doctor if other medicines are being taken or have been taken recently.
This drug should be taken at least 4 hours before or 8 hours after antacids containing aluminum or magnesium, sucralfate, metal cations such as iron, multivitamins containing iron or zinc, and didanosine.
Blood clotting time should be monitored in case of co-administration with anticoagulants (warfarin or its derivatives).
Careful monitoring of blood glucose is recommended when taking antidiabetic agents.
Use with caution when using a nonsteroidal anti-inflammatory drug.
This drug should be avoided with drugs that may prolong QT interval.
Adverse reactions
Commonly reported adverse reactions include: nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, pyrexia, anemia, alanine aminotransferase increased, hypokalemia, headache, dizziness, and insomnia.
Less commonly reported adverse reactions include: blood and lymphatic system disorders, atrial fibrillation, palpitations, tachycardia, angina pectoris, cardiac failure, cardiac arrest, bradycardia, vertigo, tinnitus, vision blurred, dry mouth, flatulence, gastritis, gastroesophageal reflux disease, fatigue, chest and facial pain, asthenia, malaise, edema, chills, hepatic function abnormal, vulvovaginal pruritus, candidiasis, vaginal infection, fungal infection, laboratory changes, hyperglycemia, anorexia, hyperlipidemia, dehydration, back pain, pain in extremity, arthralgia, muscle spasms, musculoskeletal pain, dysgeusia, somnolence, tremor, lethargy, paresthesia, hypoesthesia, syncope, psychiatric disorders,

skin disorders, renal failure, dysuria, dyspnea, wheezing, asthma, bronchospasm, hypertension, hypotension, and phlebitis.
Please inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

LOXIMED, moxifloxacin 400 mg, pack of 7 tablets

Issue date: 06/2015
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