VOLCIDIN®
500 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 VOLCIDIN
Each VOLCIDIN tablets for oral administration contains 500 mg levofloxacin (as levofloxacin hemihydrate) with the following excipients: microcrystalline cellulose, magnesium stearate, and talc.
Levofloxacin is a broad-spectrum fluoroquinolone antibiotic. Levofloxacin has bactericidal activity against a wide-range of gram-negative and gram-positive microorganisms.
VOLCIDIN is indicated for the treatment of adults with mild, moderate and severe infections caused by susceptible strains of microorganisms in the conditions listed below:
- Acute bacterial sinusitis
- Acute bacterial exacerbation of chronic bronchitis
- Nosocomial pneumonia
- Community-acquired pneumonia
- Complicated Skin and Skin Structure Infections
- Uncomplicated skin and skin-structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, and wound infections.
- Chronic bacterial prostatitis
- Urinary tract infections
- Acute pyelonephritis
- Inhalational anthrax
- Plague

This medicine may be used to treat other conditions as well.
The way to take VOLCIDIN
Take VOLCIDIN 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 VOLCIDIN is 250 mg or 500 mg or 750 mg administered orally once every 24 hours.
The following dosage recommendations can be given for adults with normal renal function:

Indication	**Dose**	**Duration**
Acute bacterial sinusitis	500 mg (one tablet) every 24h	10 to 14 days
Acute bacterial sinusitis	750 mg (one and a half tablet of 500 mg) every 24 h	5 days
Acute bacterial exacerbation of chronic bronchitis	500 mg (1 tablet) every 24h	7 days
Nosocomial pneumonia	750 mg (one and a half tablet of 500 mg) every 24h	7 to 14 days
Community-acquired pneumonia	500 mg (one tablet) every 24h	7 to 14 days

Community-acquired pneumonia	750 mg (one and a half tablet of 500 mg) every 24h	5 days
Complicated skin and skin-structure infections	750 mg (one and a half tablet of 500mg) every 24h	7 to 14 days
Uncomplicated skin and skin-structure infections	500 mg (1 tablet) every 24h	7 to 10 days
Chronic bacterial prostatitis	500 mg (1 tablet) every 24h	28 days
Complicated urinary tract infections or acute pyelonephritis	250 mg (half a tablet of 500 mg) every 24h	10 days
Complicated urinary tract infections or acute pyelonephritis	750 mg (one and a half tablet of 500mg) every 24h	5 days
Uncomplicated urinary tract infections	250 mg (half a tablet of 500 mg) every 24h	3 days
Inhalational anthrax (post-exposure)	500 mg (1 tablet) every 24h	60 days
Plague	500 mg (1 tablet) every 24h	10 to 14 days

VOLCIDIN tablets may be taken on an empty stomach or with meals. Try to take the tablets at the same time each day and drink fluids liberally.
Dosage adjustment is necessary in case of renal impairment (creatinine clearance < 50 mL/min).

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 case of history of hypersensitivity associated with the use of levofloxacin or any member of the quinolone antibiotics

Precautions

- Inform your doctor if any symptom of an allergic reaction occurs or if severe diarrhea occurs during treatment.
- Inform your doctor if any signs or symptoms of hepatitis occur.
- Discontinue the drug immediately if you experience pain, swelling, inflammation or rupture of a tendon; the risk of developing fluoroquinolone-associated tendinitis and tendon rupture is increased in patients over 60 years of age, in those taking corticosteroid drugs, and in patients with kidney, heart or lung transplants.
- Discontinue the drug immediately if you experience pain, burning, tingling, and numbness.
- This drug should be used with caution in patients with a known or suspected CNS disorder that may predispose to seizures or in the presence of other risk factors that may predispose to seizures (e.g.,

certain drug therapy, renal dysfunction.), in patients with history of psychiatric disease, and in patients with glucose-6-phosphate dehydrogenase deficiency.
- This drug should be avoided in patients with history of myasthenia gravis and in the presence of risk factors for prolongation of QT interval (e.g., congenital long QT syndrome, concomitant use of drugs that are known to prolong the QT interval, uncorrected electrolytes imbalance, elderly, cardiac disease).
- 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 during the treatment.
-Adequate hydration of patients receiving this drug should be maintained to prevent the formation of highly concentrated urine.
- Coagulation tests should be monitored when this drug is co-administrated with Vitamin K antagonists.
- Caution should be taken when driving a car or operating machinery until you are sure that this drug is not causing dizziness or lightheadedness.
- Inform your doctor before taking this drug in case of pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.
Sucralfate, iron, didanosine, multivitamins containing zinc and antacids containing aluminum, calcium or magnesium should not be taken within the two-hour period before or after taking this drug.
Use with caution with non-steroidal anti-inflammatory drugs, theophylline, oral anticoagulants, antidiabetic agents, some antiarrhythmics, and drugs that are known to prolong the QT interval.

Adverse reactions

The most reported adverse reactions include: nausea, vomiting, abdominal pain, dyspepsia, diarrhea, constipation, headache, insomnia, dizziness, dyspnea, rash, pruritus, and vaginal infections.
Other reported adverse reactions include: photosensitivity, phototoxicity, blood glucose disturbances, musculoskeletal disorders, prolongation of QT interval, hepatotoxicity, allergic reactions, exacerbation of myasthenia gravis, central nervous system effect, peripheral neuropathy, tendinitis and tendon rupture, crystalluria and cylindruria.
Please inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store below 30°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

VOLCIDIN, levofloxacin 500 mg, pack of 7 tablets

Issue date: 06/2024

VOLT5/002