

PATIENT INFORMATION LEAFLET LEVOFLOXACIN TABLETS 250 / 500 / 750 mg

1. What Levofloxacin tablets are and what they are used for?

Levofloxacin tablets contain a medicine called levofloxacin.

Levofloxacin is a “fluoroquinolone” antibiotic.

Levofloxacin tablets are used to treat infections due to bacteria against which the medicine is active. Levofloxacin can be used to treat infections of the:

- sinuses
- lungs, in people with long-term breathing problems or pneumonia
- urinary tract, including your kidneys or bladder
- prostate gland, where you have a long lasting infection
- skin and underneath the skin, including muscles. This is sometimes called “soft tissue”.

2. Before you take?

Do not take Levofloxacin tablets if you

- are allergic (hypersensitive) to levofloxacin, any other quinolone antibiotic or to any of the other ingredients of Levofloxacin tablets (listed in section 6).
- have ever had epilepsy.
- have had tendon problems (e.g. tendinitis) related to treatment with an “fluoroquinolone antibiotic”.
- are pregnant, might become pregnant or think you may be pregnant.
- are breast-feeding.
- are a child or growing adolescent.

Take special care with Levofloxacin tablets Serious allergic reaction is a very rare side effect of Levofloxacin tablets. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. If you experience any of these signs, stop taking Levofloxacin tablets immediately and contact a doctor.

Cases of liver problems have been reported with use of Levofloxacin tablets. Symptoms of such problems may include loss of appetite, skin and eyes becoming yellow in colour (jaundice), dark coloured urine, itching and tender stomach (abdomen). You should stop taking Levofloxacin tablets immediately and contact a doctor if you experience any of these symptoms.

During treatment with Levofloxacin tablets do not stay out in strong sunlight for unnecessarily long periods and do not use a sun-lamp or solarium. This is because some patients may become more sensitive to light whilst taking Levofloxacin tablets.

Levofloxacin tablets may in rare cases cause pain and inflammation in tendons, particularly in elderly patients or in patients taking corticosteroids. If you experience any tendon complaints whilst or shortly after taking the tablet, seek medical advice immediately and rest the affected limb to avoid tendon damage.

The risk of getting “fits” (seizures) may be increased if you have in the past experienced brain damage (such as stroke or severe brain injury).

If you have bloody diarrhoea during or after treatment with Levofloxacin tablets, contact your doctor immediately. This may be sign of serious bowel inflammation (pseudomembranous colitis) which can occur following treatment by antibiotics.

If you have ever had mental problems, you should consult your doctor before taking Levofloxacin tablets. Patients with some abnormalities of an enzyme called glucose-6-phosphate dehydrogenase (G6-PD) (a rare hereditary disease) may be prone to destruction of red blood cells (haemolysis) when treated with quinolone antibacterial agents, therefore Levofloxacin tablets should be used with precaution in these patients.

Since levofloxacin is mainly excreted by the kidneys, the dose of Levofloxacin tablets should be adjusted in patients with impaired kidney function. Diabetic patients receiving concomitant treatment with Levofloxacin tablets and insulin or oral hypoglycemic agents, may be at risk for low blood sugar. In these diabetic patients, careful monitoring of blood sugar is recommended.

Treatment with Levofloxacin tablets may cause a certain type of nerve damage, that can have a sudden onset. If you experience partial loss of sensation or diminished sensibility, please contact a doctor and discontinue the treatment, to prevent the development of an irreversible condition. Urine tests may show “false-positive” results for strong painkillers called “opiates” in people taking Levofloxacin tablets.

If your doctor is due to take a urine test, tell him you are taking Levofloxacin tablets.

Before taking levofloxacin

Heart problems - Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called ‘bradycardia’), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section Taking other medicines).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This applies particularly to the following medicines:

- iron salts (used to treat anaemia), magnesium- or aluminium-containing antacids (medicines against heartburn and stomach pain) and sucralfate (medicine for protecting the stomach wall) should be taken 2 hours before or after intake of Levofloxacin tablets. Otherwise they may reduce the absorption and efficacy of levofloxacin.
- Theophylline (to treat asthma), fenbufen or similar non-steroidal anti-inflammatory drugs (NSAIDs) given at the same time with levofloxacin may increase the risk of getting “fits” (seizures).
- Probenecid (to treat arthritis) and cimetidine (to reduce stomach acid production) reduce your kidneys abilities to get rid of levofloxacin, especially in renally impaired (kidney damaged) patients.
- Ciclosporin (an anti-rejection drug) - Levofloxacin may prolong the effect of ciclosporin.
- Vitamin K antagonists (e.g. warfarin which is a medication to prevent blood clots). Levofloxacin leads to increased bleeding in patients taking vitamin K antagonists. Coagulation tests should be monitored in patients treated with vitamin K antagonists.
- Some antibiotics can in rare cases reduce the efficacy (effectiveness) of contraceptive pills. You must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

Taking Levofloxacin tablets with food and drink

Levofloxacin tablets can be taken with or without food Pregnancy and breast-feeding

Do not take Levofloxacin tablets if you are pregnant, might become pregnant or think you may be pregnant.

Do not take Levofloxacin tablets if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

Driving and using machines

Levofloxacin tablets has minor or moderate influence on the ability to drive and use machines.

Some side-effects like dizziness, drowsiness, visual disturbance may impair your ability to concentrate and react. Do not drive or operate machinery if you feel that your ability to concentrate and react is impaired.

Important information about some of the ingredients of Levofloxacin tablets Levofloxacin tablets contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take

Always take Levofloxacin tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The duration of treatment depends on the type and severity of your infection. The usual dose is one or two tablets per day.

Patients with reduced kidney activity (renal insufficiency) may need lower doses than patients with normal kidney activity.

Iron salts (used to treat anaemia), magnesium- or aluminium-containing antacids (medicines against heartburn and stomach pain) and sucralfate (medicine for protecting the stomach wall) should be taken 2 hours before or after intake of Levofloxacin tablets. Otherwise they may reduce the absorption and efficacy of levofloxacin.

The tablets may be taken during meals or at any time between meals. Swallow the tablets with a glass of water.

If you take more Levofloxacin tablets than you should

If you take too many Levofloxacin tablets, contact your doctor or emergency unit in the nearest hospital. Symptoms of an overdose can be dizziness, confusion, impairment of consciousness, convulsive seizures, heart problems and nausea.

If you forget to take Levofloxacin tablets

If you have forgotten to take one dose of Levofloxacin tablets take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose of Levofloxacin tablets.

If you stop taking Levofloxacin tablets

It is important to finish your course of tablets as prescribed by your doctor. Do not stop, even if you begin to feel better before you have finished them all. If you stop taking the tablets too soon your infection may return, your condition may get worse or the bacteria may become resistant to the medicine. If you feel you have to stop because of a side-effect, tell a doctor immediately to get advice before taking the next dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Levofloxacin tablets can cause side effects, although not everybody gets them. Serious allergic reaction is a very rare side effect of Levofloxacin tablets. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. If you experience any of these signs, stop taking Levofloxacin tablets immediately and contact a doctor. The following side-effects have been observed with use of Levofloxacin tablets, arranged according to frequency:

Common (affects 1 to 10 users in 100):

- Nausea and diarrhoea.
- Increase in the level of some liver enzymes in your blood. Uncommon (affects 1 to 10 users in 1,000):
- Increase of resistant microorganisms, e.g. fungal infection.
- Alteration in blood tests relating to increase or reduction of white blood cells.
- Headache, dizziness, vertigo, nervousness, drowsiness and difficulty in sleeping.
- Loss of appetite, vomiting, stomach pain, flatulence, constipation and indigestion.
- Alteration in blood tests relating to abnormalities in liver function (increase in bilirubin which is a waste product).
- Itching, rash.
- Alteration in blood tests relating to abnormalities in kidney function.
- Weakness or loss of strength.

Rare (affects 1 to 10 users in 10,000):

- Decrease in the number of neutrophils (a type of white blood cell) in the blood.
- Decreased number of blood platelets.
- Numbness, tingling or pins and needles.
- Involuntary shakiness.
- Generalised fear (anxiety).
- Feeling extreme sadness (depression).
- Restlessness (agitation).
- Seeing, hearing or believing in things that are not there or other symptoms of lack of contact with reality (psychotic disorder).

Confusion.

- Uncontrollable contractions of muscles (convulsion).
- A rapid heart rate.
- Low blood pressure.
- Narrowing of the airways, e.g. asthma and difficulty breathing.

- Bloody diarrhoea which in very rare cases may be indicative of inflammation of the small and large intestine which can cause severe and painful diarrhoea.
- Itchy skin rash.
- Joint pain.
- Muscle pain.
- Tendon disorders including inflammation of tendons.

Very rare (affects less than 1 user in 10,000):

- Severe, acute deficiency in neutrophils (type of white blood cell).

Symptoms include high temperature and ulcers in the mouth and throat.

- Seeing or hearing things that are not there.
- Change in opinion and thoughts (psychotic reactions) with a chance of having suicidal thoughts or actions.
- Severe allergic reaction. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. • Circulatory collapse (anaphylactic like shock).
- Decrease in blood sugar to a too low level (hypoglycaemia) which may be of special importance in patients treated for diabetes.
- Burning, tingling, pain or numbness. These may be signs of something called “neuropathy”.
- Allergic lung reactions.
- Inflammation of the liver.
- Increased sensitivity of the skin to sun and ultraviolet light may occur.
- Problems with your hearing or eyesight or changes in the way things taste and smell.
- Tendon rupture; this undesirable effect may occur within 48 hours of starting treatment and may be bilateral (can affect both left and right).
- Muscular weakness, which may be of special importance in patients with myasthenia gravis (a rare disease of the nervous system).
- Acute kidney failure due to allergic kidney reactions (interstitial nephritis).
- Fever.

Not known (frequency cannot be estimated from the available data):

- Severe bullous (blister-type) eruptions such as Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell’s syndrome which is a blistering and peeling of the

skin) and erythema multiforme (blisters or lesions). Muco-cutaneous (e.g. hives or flushing) may sometimes occur even after the first dose.

- Sweating too much (hyperhidrosis).
- Ringing or buzzing in the ears (tinnitus).
- Decrease in red blood cells (anaemia) due to blood cell damage.
- Decrease in the number of all types of blood cells.
- Exaggerated immune response (hypersensitivity).
- Heart problems: Abnormal fast heart rhythm, life-threatening

irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart).

- Muscle reactions with muscle cell damage (rhabdomyolysis).
- Severe liver injury, including cases with acute liver failure, have been reported with levofloxacin, primarily in patients with severe underlying diseases (e.g. septicemia).
- Yellowing of the skin or whites of the eyes (jaundice).
- Pain, including pain in the back, chest and extremities.

Other undesirable effects which have been associated with fluoroquinolone administration include:

- Hypersensitivity vasculitis (inflammation of small blood vessels).
- Extrapyrimalidal (neurological) symptoms and other disorders of muscular coordination.
- Attacks of porphyria (disease affecting the metabolism) in patients with porphyria.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store

Keep out of the reach and sight of children.

Do not use Levofloxacin tablets after the expiry date which is stated on the carton, blister and tablet container. The expiry date refers to the last day of that month. This medicinal product does not require special storage conditions.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Levofloxacin tablets 250 mg:

Each film-coated tablet of contains

Levofloxacin USP-- 250 mg

Levofloxacin tablets 500 mg:

Each film-coated tablet of contains

Levofloxacin -- 500 mg

Levofloxacin tablets 750 mg:

Each film-coated tablet of contains

Levofloxacin -- 750 mg