

PACKAGE LEAFLET: INFORMATION FOR THE USER

Levo-Tech

film-coated tablets 500mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Levo-Tech is and what it is used for
2. What you need to know before you take Levo-Tech
3. How to take Levo-Tech
4. Possible side effects
5. How to store Levo-Tech
6. Contents of the pack and other information

1. What Levo-Tech is and what it is used for

Levo-Tech contains a drug called levofloxacin. Levofloxacin is an antibiotic which is used to treat bacterial infections of the

- sinuses
- lungs, in people with long-term breathing problems or Pneumonia
- urinary tract, including your kidneys or bladder

In urinary tract, including kidneys or bladder infections, lungs, in people with long-term breathing problems or Pneumonia, sinuses. Levo-Tech should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.

- prostate gland, where you have a long lasting infection
- skin and underneath the skin, including muscles. This is sometimes called ‘soft tissue’

In some special situations, Levo-Tech may be used to lessen the chances of getting a pulmonary disease named anthrax or worsening of the disease after you are exposed to the bacteria causing anthrax.

2. What you need to know before you take Levo-Tech

Do not take Levo-Tech and tell your doctor if:

You are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or ofloxacin or to any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

You have ever had epilepsy

You have ever had a problem with your tendons such as tendonitis that was related to treatment with a 'quinolone antibiotic'. A tendon is the cord that joins your muscle to your skeleton.

You are a child or a growing teenager

You are pregnant, trying to become pregnant or are breast-feeding

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Levo-Tech.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including levofloxacin, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

Talk to your doctor or pharmacist before taking Levo-Tech if:

You are 60 years of age or older.

You are using corticosteroids, sometimes called steroids (see section "Other medicines and Levo-Tech").

You have ever had a fit (seizure).

You have had damage to your brain due to a stroke or other brain injury.

You have kidney problems.

You have something known as 'glucose – 6 – phosphate dehydrogenase deficiency'.

You are more likely to have serious problems with your blood when taking this medicine.

You have ever had mental health problems.

You have ever had 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 *Other medicines and Levo-Tech*).

- if you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).
- You are diabetic
- You have ever had liver problems
- You have myasthenia gravis.
- If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.

When taking this medicine

Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of levofloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Levofloxacin, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking levofloxacin and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including Levofloxacin, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects after taking Levofloxacin, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

Other warnings

□ Levofloxacin may rarely cause pain and inflammation in tendons. Particularly if you are elderly or are taking steroid medicines (such as cortisone or hydrocortisone). If you have any problems with your tendons whilst or shortly after taking levofloxacin, seek medical advice at once and rest the affected limb (leg or arm). Do not take the next dose of levofloxacin unless your doctor tells you to. In such as cases, you experience swelling or pain in the area of affected tendon. It may be necessary to stop treatment.

□ If you start having severe, persistent and/or bloody diarrhoea during or after treatment with levofloxacin, tell your doctor immediately. This could mean you have serious inflammation of your bowel (pseudomembranous colitis), which can sometimes occur after antibiotic treatment. You may need to stop taking levofloxacin and for your doctor to give you another medicine.

□ Whilst taking Levo-Tech you are advised to stay out of strong sunlight and not to use a sun lamp. This is because some patients may become more sensitive to light whilst taking the tablets and get a sun-burn like reaction.

□ Levofloxacin should be discontinued if the patient experiences symptoms Burning, tingling, pain or numbness. These may be signs of something called ‘neuropathy’.

□ Levofloxacin is not a optimal therapy for most severe cases of Pneumococcal pneumonia.

□ Infections got from a hospital during treatment due to P.aeruginosa may require combination therapy.

□ Levofloxacin is not effective against infections caused by MRSA. In infections suspicious for MRSA levofloxacin should be combined with an agent approved to treat MRSA infections.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Levo-Tech.

Other medicines and Levo-Tech

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Levo-Tech can affect the way some other medicines work. Also some medicines can affect the way Levo-Tech work.

In particular, tell your doctor if you are taking any of the following medicines. This is because it can increase the chance of you getting side effects, when taken with Levo-Tech:

Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or rupture of your tendons.

Warfarin - used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.

Theophylline - used for breathing problems. You are more likely to have a fit (seizure) if taken with Levo-Tech

Non-steroidal anti-inflammatory drugs (NSAIDS) - used for pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with Levo-Tech

Ciclosporin - used after organ transplants. You may be more likely to get the side effects of ciclosporin

Medicines known to affect the way your heart beats. This includes medicines used for abnormal heart rhythm (antiarrhythmics such as quinidine, hydroquinidine, disopyramide, sotalol, dofetilide, ibutilide and amiodarone), for depression (tricyclic antidepressants such as amitriptyline and imipramine), for psychiatric disorders (antipsychotics), and for bacterial infections (‘macrolide’ antibiotics such as erythromycin, azithromycin and clarithromycin)

Probenecid – used for gout and cimetidine – used for ulcers and heartburn. Special care should be taken when taking either of these medicines with Levo-Tech. If you have kidney problems, your doctor may want to give you a lower dose.

Do not take Levo-Tech at the same time as the following medicines. This is because it can affect the way Levo-Tech work:

Iron tablets (for anemia), zinc supplements, magnesium or aluminum-containing antacids (for acid or heartburn), didanosine, or sucralfate (for stomach ulcers). See section 3 “If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate” below.

Urine tests for opiates

Urine tests may show ‘false-positive’ results for strong painkillers called ‘opiates’ in people taking Levo-Tech. If your doctor is due to take a urine test, tell them you are taking Levo-Tech.

Tuberculosis tests

This medicine may cause “false negative” results for some tests used in laboratory to search for the bacteria causing tuberculosis.

Taking Levo-Tech with food and drink

Take without regard to meals. Take with water, drink with plenty of water. Taking this product with orange juice can result in reduced quinolone plasma levels.

Pregnancy and breast-feeding

You must not take Levo-Tech if you are pregnant, trying to become pregnant or are breast feeding.

Driving and using machines

You may get side effects after taking this medicine, including feeling dizzy, sleepy, a spinning feeling (vertigo) or changes to your eyesight. Some of these side effects can affect you being able to concentrate and your reaction speed. If this happens, do not drive or carry out any work that requires a high level of attention.

Levo-Tech contains alcohol

This medicine contains 176.40 mcl of alcohol (ethanol). The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Levo-Tech

Always take Levo-Tech exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- The tablets may be taken during meals or at any time between meals

Protect your skin from sunlight

Keep out of direct sunlight while taking this medicine and for 2 days after you stop taking it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:

- Make sure you use high factor sun cream
- Always wear a hat and clothes which cover your arms and legs

Avoid sun beds

If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate

- Do not take these medicines at the same time as Levo-Tech. Take your dose of these medicines at least 2 hours before or after Levo-Tech.

How much to take

- Your doctor will decide on how many Levo-Tech tablets you should take
- The dose will depend on the type of infection you have and where the infection is in your body.
- The length of your treatment will depend on how serious your infection is.
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

Adults and the elderly

Sinuses infection

- one tablet of Levo-Tech, once each day

Lungs infection, in people with long-term breathing problems

- one tablet of Levo-Tech, once each day

Pneumonia

- one tablet of Levo-Tech, once or twice each day

Infection of urinary tract, including your kidneys or bladder

- 1/2 or one tablet of Levo-Tech, each day

Prostate gland infection

- one tablet of Levo-Tech, once each day

Infection of skin and underneath the skin, including muscles

- one tablet of Levo-Tech, once or twice each day

Adults and the elderly with kidney problems

Your doctor may need to give you a lower dose.

Children and adolescents

This medicine must not be given to children or teenagers.

If you take more Levo-Tech than you should

If you accidentally take more tablets than you should, tell a doctor or get other medical advice straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: convulsive fits (seizures), feeling confused, dizzy, less

conscious, having tremor and heart problems - leading to uneven heart beats as well as feeling sick (nausea) or having stomach burning.

If you forget to take a dose of Levo-Tech

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not double-up the next dose to make up for the missed dose.

If you stop taking Levo-Tech

Do not stop taking Levo-Tech just because you feel better. It is important **that you complete** the course of tablets **that your doctor has prescribed for you.** **If you stop taking the tablets too soon,** the infection may **return, your condition may get worse or the bacteria may become resistant to the medicine.**

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

4. Possible side effects

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

Stop taking Levo-Tech and see a doctor or go to a hospital straight away if you notice the following side effect:

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as an allergic reaction (the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue), tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Rare (may affect up to 1 in 1,000 people)

- Watery diarrhoea which may have blood in it, possibly with stomach cramps and a high temperature. These could be signs of a severe bowel problem
- Pain and inflammation in your tendons or ligaments, which could lead to rupture. The Achilles tendon is affected most often
- Fits (convulsions)

Very rare (may affect up to 1 in 10,000 people)

- Burning, tingling, pain or numbness. These may be signs of something called ‘neuropathy’
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Other:

- Severe skin rashes which may include blistering or peeling of the skin around your lips, eyes, mouth, nose and genitals
- Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen). These may be signs of liver problems which may include a fatal failure of the liver

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking Levo-Tech, consult an eye specialist immediately.

Tell your doctor if any of the following side effects gets serious **or** lasts longer than a few days:

Common (may affect up to 1 in 10 people)

- Sleeping problems • Headache, feeling dizzy
- Feeling sick (nausea, vomiting) and diarrhoea
- Increase in the level of some liver enzymes in your blood

Uncommon (may affect up to 1 in 100 people)

- Changes in the number of other bacteria or fungi, infection by fungi named Candida, which may need to be treated
- Changes in the number of white blood cells shown up in the results of some blood tests (leukopenia, eosinophilia)
- Feeling stressed (anxiety), feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling (vertigo)
- Shortness of breath (dyspnoea)
- Changes in the way things taste, loss of appetite, stomach upset or indigestion (dyspepsia), pain in your stomach area, feeling bloated (flatulence) or constipation
- Itching and skin rash, severe itching or hives (urticaria), sweating too much (hyperhidrosis)
- Joint pain or muscle pain
- Blood tests may show unusual results due to liver (bilirubin increased) or kidney (creatinine increased) problems
- General weakness

Rare (may affect up to 1 in 1,000 people)

- Bruising and bleeding easily due to a lowering in the number of blood platelets (thrombocytopenia)
- Low number of white blood cells (neutropenia)
- Exaggerated immune response (hypersensitivity)

- Lowering of your blood sugar levels (hypoglycaemia). This is important for people that have diabetes.
- Seeing or hearing things that are not there (hallucinations, paranoia), change in your opinion and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions
- Feeling depressed, mental problems, feeling restless (agitation), abnormal dreams or nightmares
- Tingly feeling in your hands and feet (paraesthesia)
- Problems with your hearing (tinnitus) or eyesight (blurred vision)
- Unusual fast beating of your heart (tachycardia) or low blood pressure (hypotension)
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system).
- Changes in the way your kidney works and occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis.
- Fever

Very rare

Cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Other side effects include:

- Lowering in red blood cells (anemia): this can make the skin pale or yellow due to damage of the red blood cells; lowering in the number of all types of blood cells (pancytopenia)
- Fever, sore throat and a general feeling of being unwell that does not go away. This may be due to a lowering in the number of white blood cells (agranulocytosis).
- Loss of circulation (anaphylactic like shock)
- Increase of your blood sugar levels (hyperglycaemia) or lowering of your blood sugar levels leading to coma (hypoglycemic coma). This is important for people that have diabetes.
- Changes in the way things smell, loss of smell or taste (parosmia, anosmia, ageusia)
- Problems moving and walking (dyskinesia, extrapyramidal disorders)
- Temporary loss of consciousness or posture (syncope)
- Temporary loss of vision
- Impairment or loss of hearing

- Abnormal fast heart rhythm, life-threatening irregular heart rhythm including cardiac arrest, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart)
- Difficulty breathing or wheezing (bronchospasm)
 - Allergic lung reactions
 - Pancreatitis
 - Inflammation of the liver (hepatitis)
 - Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
 - Inflammation of the vessels that carry blood around your body due to an allergic reaction (vasculitis)
 - Inflammation of the tissue inside the mouth (stomatitis)
 - Muscle rupture and muscle destruction (rhabdomyolysis)
 - Joint redness and swelling (arthritis)
 - Pain, including pain in the back, chest and extremities
 - Attacks of porphyria in people who already have porphyria (a very rare metabolic disease)
 - Persistent headache with or without blurred vision (benign intracranial hypertension)

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the «Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan» CJSC via www.pharm.am or call the hotline numbers: (+374 0) 20 05 05 and (+374 96) 22 05 05. Side effects can also be reported to the holder of the marketing authorisation: «Pharmatech» CJSC Telephone: +374 10 743620, +374 10 741410, E-mail: office@pharmatech.am.

5. How to store Levo-Tech

- Store between 8°C-25°C.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister strip after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Levo-Tech contains

Each tablet contains 500 mg of levofloxacin as active substance corresponding to 512.00 mg of levofloxacin hemihydrate.

The other ingredients are:

Core tablet: corn starch, cellulose microcrystalline, croscarmellose sodium, povidone (PVPK-30), purified water, crospovidone, colloidal silicon dioxide, magnesium stearate, talc.

Tablet coating: ethyl cellulose, methylene chloride, isopropyl alcohol, polyethylene glycol 6000, hypromellose E-15, color titanium dioxide, alcohol, talc, color red iron oxide lake, color yellow iron oxide lake.

What Levo-Tech looks like and contents of the pack

Brown biconvex oval shaped tablets, scored on one side and plain on the other side.

Tablets are packed in PVC/aluminium blisters.

For 500 mg, the tablets are provided in pack size of 10 tablets in blister.

1 blister in a carton printed box with leaflet.

7. Legal Category

Prescription only.

8. Marketing authorization holder and Manufacturer

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