

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Levo

Tablets

Composition:

Each film-coated tablet contains:

Levofloxacin (as hemihydrate) 500 mg

For the list of inactive and allergenic ingredients in the preparation, please see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for children or adolescents.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat the following infections in adults:

- Acute inflammation of the kidney and renal pelvis and complicated urinary tract infections
- Prolonged bacterial prostatitis

Levo should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections:

- Acute bacterial sinusitis
- Acute exacerbations of chronic obstructive pulmonary disease, including bronchitis
- Community-acquired pneumonia
- Complicated skin and soft tissue infections.

Levo may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous levofloxacin.

Therapeutic group: An antibiotic belonging to the 'fluoroquinolone' family.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to levofloxacin, to any other quinolone antibiotic, e.g., moxifloxacin, ciprofloxacin or ofloxacin, or to any of the additional ingredients contained in the medicine (see section 6 "Further Information"). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- you are suffering, or have suffered in the past, from epilepsy.

- you are suffering, or have suffered in the past, from tendon problems, such as tendinitis, resulting from treatment with antibiotics from the 'quinolone' group. The tendon connects between the muscle and the bone.
- you are a child or adolescent.
- you are pregnant, may become pregnant, or think you are pregnant.
- you are breastfeeding.

Do not take the medicine if any of the above conditions apply to you. If you are uncertain, talk to the doctor or pharmacist before taking **Levo**.

Special warnings regarding use of the medicine

Before treatment with Levo, tell the doctor if:

- you are 60 years of age or older.
- you are taking corticosteroids, which are sometimes called steroids (see in section 2 "Drug interactions").
- you have undergone a transplantation.
- you have ever had a seizure.
- you suffered from brain damage due to stroke or other brain injury.
- you have kidney problems.
- you suffer from a deficiency of the glucose-6-phosphate dehydrogenase (G6PD) enzyme. It is likely that you will suffer from severe blood problems when taking this medicine.
- you suffer, or have suffered in the past, from mental problems.
- you suffer, or have suffered in the past, from heart problems. Exercise caution when taking this medicine if you were born with or have a family history of QT interval prolongation (seen in an ECG test, a recording of the electrical activity of the heart), if you suffer from a blood electrolyte imbalance (especially low blood potassium or magnesium levels), if your heart rate is very slow (called "bradycardia"), if you have heart failure, if you experienced a myocardial infarction (heart attack) in the past, if you are a woman or elderly or if you are taking other medicines which cause abnormal changes in ECG (see in section 2 "Drug interactions").
- you have diabetes.
- you suffer or have suffered in the past, from liver problems.
- you have a disease that causes severe muscle weakness (myasthenia gravis).
- you have nervous system problems (peripheral neuropathy).
- you have been diagnosed with an enlargement or bulge of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- you have previously had an aortic dissection (a tear in the aorta wall).
- you have been diagnosed with leaky heart valves (heart valve regurgitation).
- you have a family history of aortic aneurysm or aortic dissection or a congenital heart valve disease or other risk factors or predisposing conditions (e.g., connective tissue disorders such as Marfan syndrome, Ehlers-Danlos syndrome, Turner's syndrome, Sjogren syndrome [an inflammatory autoimmune disease] or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, or known atherosclerosis or rheumatoid arthritis or endocarditis).
- you have ever developed a severe skin rash or peeling, blistering and/or mouth sores after taking Levofloxacin.

Serious skin reactions

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported with the use of levofloxacin.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- A red and scaly widespread rash with bumps under the skin (including the skin folds, chest, abdomen [including stomach], back and arms) and blisters, accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis – AGEP).

If you develop a serious rash or another of these skin symptoms, stop taking **Levo** and contact your doctor or seek medical attention immediately.

Do not take fluoroquinolone/quinolone antibacterials, including **Levo**, if you experienced in the past any serious side effect when taking quinolone or fluoroquinolone. In such case, inform the doctor as soon as possible.

When you are taking the medicine:

- if you experience sudden and severe pains in your stomach, chest or back, which can be symptoms of aortic aneurysm and dissection (tear) – **proceed to an emergency room immediately**. Your risk may be higher if you are being treated with systemic corticosteroids.
- if you start to experience a sudden burst in shortness of breath, especially when you lie flat in your bed, or if you notice swelling of the ankles, legs or stomach, or new onset of heart palpitations (a sensation of rapid or irregular heart rate) – **inform the doctor immediately**.
- if you begin to experience sudden and involuntary jerks, muscle spasms or muscle contractions – **refer to the doctor immediately** since these may be signs of myoclonus. The doctor may need to stop the treatment with **Levo** and begin appropriate treatment.
- if you feel nauseous, generally unwell, severe discomfort or persistent or worsening pain in the stomach area or vomiting – **refer to a doctor immediately** as this may be a sign of inflammation of the pancreas (acute pancreatitis).
- if you experience fatigue, pallor, bruising, uncontrolled bleeding, fever, sore throat and a serious deterioration in your general condition, or a feeling that your resistance to infections may be reduced – **refer to the doctor immediately** since these may be signs of blood disturbances. Your doctor may need to monitor your blood with blood counts. In case of unusual blood counts, the doctor may need to stop the treatment.

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 **Levo** therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking **Levo**, 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 legs and feet or hands and arms. If this happens, stop taking **Levo** and inform the 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 **Levo**, 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 **Levo**, contact the doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.

Medicines from the fluoroquinolone family, including **Levo**, may cause worsening of the symptoms of myasthenia gravis, such as worsening of muscle weakness or breathing problems – **if you experience these effects, refer to the doctor immediately.**

If you are not sure if any of the above warnings apply to you, refer to the doctor or pharmacist before taking **Levo**.

Children and adolescents

The medicine is not intended for children and adolescents.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because **Levo** may affect the activity of other medicines and other medicines may affect the activity of **Levo**.

In particular, inform the doctor or pharmacist if you are taking the following medicines, since the combination with Levo can increase the chance of onset of side effects:

- corticosteroids, sometimes called steroids – used to treat inflammations. You may be at higher risk for inflammation and/or tendon rupture.

- warfarin – used for blood thinning. You may be at higher risk for bleeding. Your doctor may have to refer you to routine blood tests, to check your blood clotting capacity.
- theophylline – used for treating breathing problems. You may have a higher chance of suffering from a seizure when taken in combination with **Levo**.
- non-steroidal anti-inflammatory drugs – used for pain and inflammatory conditions, e.g., aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You are at higher risk of seizures when taken together with **Levo**.
- ciclosporin – for use after organ transplants. You may be at a higher risk of suffering from the side effects of ciclosporin.
- medicines that affect the way the heart beats, including medicines for the treatment of abnormal heart rate (antiarrhythmics, such as: quinidine, hydroquinidine, disopyramide, sotalol, dofetilide, ibutilide and amiodarone), medicines to treat depression (tricyclic antidepressants, such as: amitriptyline and imipramine), medicines to treat psychiatric disorders (antipsychotics), medicines to treat bacterial infections (macrolide antibiotics, such as: erythromycin, azithromycin, and clarithromycin).
- probenecid – for treatment of gout. Your doctor may prescribe you a lower dosage if you have kidney problems.
- cimetidine – for treatment of heartburn and ulcers in the digestive system. Your doctor may prescribe you a lower dosage if you have kidney problems.

Tell your doctor if any of the above conditions apply to you.

Do not take Levo tablets at the same time as the following medicines, as this may affect the way Levo works:

Iron tablets (for treatment of anemia), zinc supplements, antacids containing magnesium or aluminum (given for heartburn), didanosine, sucralfate (for gastric ulcers) (see in section 3 “If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate”).

Urine tests for opiates

While using **Levo**, urine tests may show false-positive results for strong pain killers called opiates. If your doctor has referred you for a urine test, tell the doctor that you are taking **Levo**.

Tuberculosis tests

While using **Levo**, certain laboratory tests for detecting the bacteria that cause tuberculosis may show false-negative results.

Sugar tests

Diabetic patients being treated with oral anti-diabetes preparations or insulin must monitor their blood sugar levels.

Use of the medicine and food

The medicine can be taken with a meal or at any time between meals.

Pregnancy and breastfeeding

Do not use **Levo** if:

you are pregnant, may become pregnant or think you are pregnant.

you are breastfeeding or plan to breastfeed.

Driving and using machinery

You may suffer from side effects after taking this medicine, including feelings of dizziness, sleepiness, spinning sensation (vertigo) or vision changes. Some of these side effects may affect your ability to concentrate and on your response rate. If this happens, do not drive or engage in any activity that requires a high level of attention.

Important information about some of the ingredients of the medicine

This medicine contains less than 1 mmol sodium (23 mg) per tablet, namely, it is considered “sodium-free”.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor’s instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and the treatment regimen will be determined by the doctor only.

The dosage depends on the type of infection that you have and on its location in the body. The duration of treatment will be determined by the severity of the infection.

If you feel that the effect of the medicine is too weak or too strong, do not change the dosage on your own, rather, ask your doctor about it.

The usual dosage is generally:

Pneumonia: one **Levo** tablet, once or twice a day.

Urinary tract infections: one **Levo** tablet, once a day.

Infection of the skin or nearby tissues, muscle infection: one **Levo** tablet, once or twice a day.

Elderly patients or patients with kidney diseases

The doctor may prescribe a lower dosage for you.

Do not exceed the recommended dose.

Do not give the medicine to children or adolescents.

Swallow the medicine with a glass of water.

If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate, do not take these medicines at the same time as Levo. Wait an interval of at least two hours before or after taking **Levo**.

Protect your skin from the sun

Avoid direct exposure to the sun throughout the course of treatment with this medicine and for two additional days after you stop taking it. This is because your skin will become more sensitive to the sun and burns, tingling or severe blisters may occur if you do not take the following precautionary measures:

- make sure you are using sunscreen with a high sun protection factor.
- always wear a hat and clothes that cover your arms and legs.
- avoid using tanning beds.

If you accidentally take a higher dosage

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you, so that the doctor will know what you took.

With an overdose, you may suffer from the following side effects: seizures, sense of confusion, dizziness, reduced consciousness, trembling and heart problems – which lead to irregular pulse, nausea or burning sensation in the stomach.

If you forgot to take the medicine at the required time, take the medicine as soon as you remember, unless it is almost time for the next dose. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

If you stop taking the medicine

Do not stop taking the medicine only because you feel better. It is important that you complete the treatment prescribed for you by the doctor. If you stop treatment too early, the infection may recur, your condition may worsen or the bacteria may develop resistance to the medicine.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Levo** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

These side effects are generally mild or moderate and often disappear after a short time.

Discontinue use of Levo and refer to a doctor or proceed to a hospital immediately if you suffer from the following side effects:

Very rare side effects – effects that occur in less than 1 user in 10,000:

- An allergic reaction. Signs can include: rash, breathing or swallowing problems, swelling of your lips, face, throat or tongue.

Discontinue use of Levo and immediately refer to a doctor if you notice any of the following severe effects – you may need urgent medical attention:

Rare side effects – effects that occur in 1-10 in 10,000 users:

- Watery diarrhea, which may be bloody, may be accompanied by abdominal cramps and high fever. These may be signs of a severe intestinal problem.
- Pain or inflammation in the tendons or ligaments, which can lead to their rupture. The Achilles tendon is affected most often.
- Seizures.

- Seeing or hearing things that do not exist (hallucinations, paranoia).
- Feeling depressed, mental problems, feeling of restlessness, strange dreams or nightmares.
- Reduced blood sugar levels (hypoglycemia) or reduced blood sugar levels that lead to coma (hypoglycemic coma). This information is important for people who have diabetes.

Very rare side effects – effects that occur in less than 1 user in 10,000:

- Burning sensation, tingling, pain or numbness. These may be symptoms of neuropathy.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Severe skin rashes, including Stevens Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). These can manifest on the body as reddish target-like patches or circular patches, often with blisters in their center, skin peeling, ulcer in the mouth, throat, nose, genitals, and eyes and may be preceded by fever and flu-like symptoms (see in section 2 “Serious skin reactions”).
- A red and scaly widespread rash with bumps under the skin (including the skin folds, chest, abdomen [including stomach], back and arms) and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis – AGEP). See in section 2 “Serious skin reactions”.
- Loss of appetite, yellowing of the skin and eyes, dark-colored urine, itching or tenderness of the abdomen; these may be signs of liver problems that may include fatal liver failure.
- A change in your opinion and thoughts (psychotic reactions) with risk of suicidal thoughts and actions and panic attacks.
- Nausea, general unwell feeling, discomfort or pain in the stomach area or vomiting. These may be signs of inflammation of the pancreas (acute pancreatitis) (See section 2 “Before using the medicine”).
- Burning nerve pain (neuralgia).

If your vision is impaired or if you are suffering from any eye disturbances during the course of treatment with **Levo**, consult the eye doctor immediately.

Very rare cases of long lasting side effects (up to months or years) or permanent side effects, 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), fatigue, memory and concentration impairment, mental health effects (which may include sleep disorders, anxiety, panic attacks, depression and suicidal ideation), 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.

Report on cases of enlargement or weakening of the aortic wall or tears in the aortic wall (aneurysm and dissection), which may burst and be fatal, and on leaky heart valves in patients taking fluoroquinolone (see section 2 “Before using the medicine”).

Consult the doctor if any of the following side effects worsens or persists for more than a few days:

Common side effects – effects that occur in 1-10 in 100 users:

- Sleeping problems.
- Headache, feeling of dizziness.
- Nausea, vomiting and diarrhea.
- Increase in the level of certain liver enzymes in the blood.

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- Changes in the number of bacteria or other fungi, infection by a fungus called Candida, which may require treatment.
- Changes in the number of white blood cells in blood test results (leucopenia, eosinophilia).
- Feeling of tension (anxiety), confusion, nervousness, sleepiness, tremor, a spinning sensation (vertigo).
- Shortness of breath (dyspnea).
- Changes in sense of taste, loss of appetite, irritable bowel syndrome or indigestion, pain in the abdominal area, abdominal bloating (wind), or constipation.
- Itching and skin rash, severe itch or hives (urticaria), excessive sweating.
- Joint or muscle pain.
- Abnormal blood test results may occur due to problems with the liver (increased bilirubin) or kidney (increased creatinine).
- General weakness.

Rare side effects – effects that occur in 1-10 in 10,000 users:

- Bruising and bleeding easily due to a drop in blood platelet counts (thrombocytopenia).
- A low level of white blood cells (neutropenia).
- Increased reaction of the immune system (hypersensitivity).
- Tingling sensation in the hands and soles of the feet (paresthesia).
- Hearing problems (tinnitus) and vision problems (blurred vision).
- Unusually fast heart beat (tachycardia) or hypotension.
- Muscle weakness – especially important in myasthenia gravis patients (a rare disease of the nervous system).
- Changes in kidney function and sometimes kidney failure that may occur as a result of an allergic reaction of the kidney, called interstitial nephritis.
- Fever.
- Erythema patches with distinct borders with/without blisters, that develop within hours of taking levofloxacin and heal with residual hyperpigmentation after the inflammation; this usually recurs in the same area of the skin or mucous membrane after re-exposure to levofloxacin.
- Memory impairment.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Decrease in red blood cells (anemia), which can cause yellowing or paleness of the skin due to damage to red blood cells, a decrease in the number of all blood cell types (pancytopenia).

- The bone marrow stops producing new blood cells. This may cause tiredness, reduced ability to fight infections and uncontrolled bleeding (bone marrow failure).
- Fever, sore throat and generalized sick feeling that does not pass. May be caused by a reduced number of white blood cells (agranulocytosis).
- Loss of blood circulation (anaphylactic-like shock reaction).
- Increase of your blood sugar levels (hyperglycemia). This information is important for patients with diabetes.
- Changes in sense of smell, loss of sense of smell or taste.
- Feelings of great excitement, euphoria, nervousness or enthusiasm (mania).
- Movement and walking problems (dyskinesia, extrapyramidal disturbances).
- Temporary loss of consciousness or stability (fainting).
- Temporary loss of vision, eye inflammation.
- Impaired or loss of hearing.
- Abnormally rapid heart rate, life-threatening irregular heart rhythm, including cardiac arrest, changes in the heart rhythm (called “QT interval prolongation”, seen in an ECG test, a recording of the electrical activity of the heart).
- Breathing difficulties or wheezing (bronchospasm).
- Pulmonary allergic reactions.
- Pancreatitis.
- Hepatitis.
- Increased sensitivity of the skin to sunlight and to ultraviolet light, hyperpigmented areas on the skin (hyperpigmentation).
- Allergic inflammatory reaction of the blood vessels (vasculitis).
- Inflammation of the oral mucosa (stomatitis).
- Muscle tears and muscle destruction (rhabdomyolysis).
- Redness and swelling of the joints (arthritis).
- Pain, including pain in the back, chest and limbs.
- Sudden and uncontrolled “jerks”, muscle spasms or muscle contractions (myoclonus).
- Porphyria attack in patients with porphyria (a very rare metabolic disease).
- Persistent headache, with or without blurred vision (benign increase in intracranial pressure).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link <https://sideeffects.health.gov.il>. Additionally, you can report to “Unipharm Ltd.”.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

- Storage conditions: store below 25°C and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose; Crospovidone; Hydroxypropyl methylcellulose; Coating blend white (Hypromellose; Titanium dioxide; Polyethylene glycol); Sodium stearyl fumarate; Colloidal silicon dioxide; Coating blend yellow (Hypromellose; Titanium dioxide; D&C yellow #10 aluminum lake; Macrogol/PEG 400; Erythrosine aluminum lake; FD&C blue #2/indigo carmine aluminum lake).

What the medicine looks like and the contents of the package:

Levo is packaged in trays (blister) inserted into a carton package. **Levo** comes in package sizes of 5, 7, 10, 12 and 14 tablets. Not all package sizes may be marketed.

Levo are oblong, capsule-shaped, yellow film-coated tablets with break line on one side.

Registration holder and address: Unipharm Ltd., P.O.Box 16545, Tel Aviv, 6116401.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Levo: 129 35 30746 02

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