

## PACKAGE LEAFLET: Information for the user

### LEVOSMART

Film-coated tablets – 500 mg

(Levofloxacin hemihydrate)

**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.

#### **What is in this leaflet:**

1. What Levosmart is and what it is used for
2. Before you take Levosmart
3. How to take Levosmart
4. Possible side effects
5. How to store Levosmart
6. Content of the pack and other information

#### **1. WHAT LEVOSMART IS AND WHAT IT IS USED FOR**

Levosmart film-coated tablets contain an active substance known as levofloxacin. This belongs to a group of drugs called antibiotics. Levofloxacin is a quinolone antibiotic. It works by eliminating bacteria that cause infections in your body.

#### **Levosmart is indicated 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, in case you have a long lasting infection;
- skin and subcutaneous tissue, including muscles; this is sometimes called 'soft tissue'.

In some special situations, Levosmart 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. BEFORE YOU TAKE LEVOSMART**

### **Do not take this medicine 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 excipients of this medicine (listed in section 6); signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue;
- have ever had epilepsy;
- 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;
- are a child or a growing adolescent;
- are pregnant, might become pregnant or think you may be pregnant;
- are breastfeeding.

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 Levosmart.

### **Take special care with Levosmart**

#### **Before taking this medicine:**

You should not take fluoroquinolone / quinolone antibacterial medicines, including Levosmart, 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 if you:**

- are 60 years of age or older;
- are using corticosteroids, sometimes called steroids (see section “Other medicines and Levosmart”);
- have ever had a fit (seizure);
- have had damage to your brain due to a stroke or other brain injury;
- have kidney problems;
- have something known as ‘glucose-6-phosphate dehydrogenase deficiency’; you are more likely to have serious problems with your blood when taking this medicine;
- have ever had mental health problems;
- 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 Levosmart”);
- are diabetic;
- have ever had liver problems;
- have myasthenia gravis;
- have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm);
- have experienced a previous episode of aortic dissection (a tear in the aorta wall);
- you have been diagnosed with leaking heart valves (heart valve regurgitation).
- have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or Ehlers-Danlos syndrome, Turner syndrome, Sjögren’s syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]);

- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking levofloxacin.

### **Serious skin reactions**

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) 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.

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

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

### **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 Levosmart therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Levosmart, 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 Levosmart and contact your doctor immediately in order to prevent the development of potentially irreversible condition.

- If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

#### 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 Levosmart, 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 medicines and Levosmart**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Levosmart can affect the way some other medicines work. Also some medicines can affect the way Levosmart works.

**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 Levosmart:**

- 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 Levosmart;
- 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 Levosmart;
- 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; your doctor may want to give you a lower dose if you have kidney problems;
- cimetidine – used for stomach ache and ulcers. The doctor may prescribe a lower dose, if you have renal impairment.

**Do not take Levosmart tablets at the same time as the following medicines. This is because it can affect the way Levosmart tablets work:**

- iron tablets (for anemia), zinc supplements, magnesium or aluminium - containing antacids (for acid or heartburn), didanosine or sucralfate (for stomach ulcers). See Section 3 "How to take Levosmart".

### **Urine tests for opiates**

Urine tests may show 'false-positive' results for strong painkillers called ' opiates' in people taking Levosmart. If your doctor has prescribed a urine test, tell your doctor you are taking Levosmart.

## **Tuberculosis tests**

This medicine may cause “false-negative” results for some laboratory tests that search for the bacteria that cause tuberculosis.

## **Pregnancy and breastfeeding**

Do not take this medicine if you:

- are pregnant, might become pregnant or think you may be pregnant;
- are breastfeeding or planning to breastfeed.

## **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.

## **3. HOW TO TAKE LEVOSMART**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablets may be taken during meals or at any time between meals.

**If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate,** do not take these medicines at the same time as Levosmart. Take them at least 2 hours before or after Levosmart.

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 elderly**

### **Sinuses infection**

- one tablet of Levosmart 500 mg, once each day.

**Lungs infection, in people with long-term breathing problems**

- one tablet of Levosmart 500 mg, once each day.

**Pneumonia**

- one tablet of Levosmart 500 mg, once or twice each day.

**Infection of urinary tract, including your kidneys or bladder**

- $\frac{1}{2}$  or one tablet of Levosmart 500 mg, each day.

**Prostate gland infection**

- one tablet of Levosmart 500 mg, once each day.

**Infection of skin and subcutaneous tissue, including muscles**

- one tablet of Levosmart 500 mg, once or twice each day.

**Adults and elderly with kidney problems**

Your doctor may need to give you a lower dose.

**Children and adolescents**

This medicine must not be taken by children or adolescents.

**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 take more Levosmart 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. In this way 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 Levosmart**

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 Levosmart**

Do not stop taking Levosmart 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 medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

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 Levosmart and see a doctor or go to a hospital straight away if you notice the following side effects:**

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

- you have an allergic reaction. The signs may include: rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue.

**Stop taking Levosmart and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**

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

- watery diarrhoea which may have blood in it, possibly with stomach cramps and 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);
- seeing and hearing things that do not exist (hallucinations, paranoia), change of opinions and thoughts (psychotic reactions), including risks of suicidal thoughts or actions;
- feeling depressive, mental problems, restlessness feeling (agitation), abnormal dreams or nightmares;
- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis.

These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. See also section 2.

- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). See also section 2.
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH).

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

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

**Others:**

- 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 Levosmart, 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 problems (increased bilirubin) or kidney problems (increased creatinine);
- 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;
- sharply demarcated, erythematous patches with/without blistering that develop within hours of administration of levofloxacin and heals with postinflammatory residual hyperpigmentation; it usually recurs at the same site of the skin or mucous membrane upon subsequent exposure to levofloxacin;
- memory insufficiency.

#### **Other effects:**

- lowering of 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 (hypoglycaemic 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, inflammation of the eye;
- hearing 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).

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.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **5. HOW TO STORE LEVOSMART**

Keep this medicine out of the sight and reach of children!

Do not store above 25°C! Keep the tablets in the original package in a dry place.

Do not use this medicine after the expiry date, which is stated on the package.

## **6. CONTENT OF THE PACK AND OTHER INFORMATION**

### **What Levosmart 500 mg film-coated tablets contain**

**The active substance** is levofloxacin hemihydrate.

Each film-coated tablet contains 512.5 mg levofloxacin hemihydrate equivalent to 500 mg levofloxacin.

**The excipients** are:

*Tablet core:* microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate, magnesium stearate;

*Film coating:* polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, yellow iron oxide, red iron oxide, black iron oxide.

### **Content of the pack**

Box with 10 film-coated tablets.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

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Tiranë, Shqipëri.

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