

PACKAGE LEAFLET: Information for the user

LEVOSMART

Solution for infusion – 500 mg / 100 ml

(Levofloxacin hemihydrate)

Read all of this leaflet carefully before you are given 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, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse 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. What you need to know before you are given Levosmart
3. How Levosmart is given
4. Possible side effects
5. How to store Levosmart
6. Other information

1. WHAT LEVOSMART IS AND WHAT IT IS USED FOR

Levosmart contains a medicine called levofloxacin. This belongs to a group of medicines called antibiotics. Levofloxacin is a ‘quinolone’ antibiotic. It works by killing the bacteria that cause infections in your body.

Levosmart solution for infusion can be used to treat infections of the:

- lungs, in people with 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’.

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. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN LEVOSMART

Do not have this medicine and tell your doctor if:

- you are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or ofloxacin or 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
- 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, might become pregnant, or think you may be pregnant
- you are breastfeeding.

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given Levosmart.

Warnings and precautions

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, nurse or pharmacist before you have your medicine if:

- you are 60 years of age or older
- you are using corticosteroids, sometimes called steroids (see section "Other medicines and Levosmart")
- 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 Levosmart")
- you are diabetic
- you have ever had liver problems
- you have myasthenia gravis
- you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- you 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)
- you 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, Behçet'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, nurse or pharmacist before being given 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 inform 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 Levosmart, 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. This is because 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, 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. Special care should be taken when taking either of these medicines with Levosmart. If you have kidney problems, your doctor may want to give you a lower dose.

Urine tests for opiates

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

Tuberculosis tests

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

Pregnancy and breastfeeding

Do not have this medicine if:

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

Driving and using machines

You may get side effects after being given 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 LEVOSMART IS GIVEN

How Levosmart solution for infusion is given

- Levosmart solution for infusion is a medicine for use in hospitals.
- It will be given to you by a doctor or nurse as an injection. The injection will be into one of your veins and be given over a period of time (this is called an intravenous infusion).
- For 500 mg Levosmart solution for infusion, the infusion time should be 60 minutes or more.
- Your heart rate and blood pressure should be closely monitored. This is because an unusual fast beating of the heart and a temporary lowering of blood pressure are possible side effects that have been seen during the infusion of a similar antibiotic. If your blood pressure drops noticeably while you are being given the infusion, it will be stopped straight away.

How much Levosmart solution for infusion is given

If you are not sure why you are being given Levosmart or have any questions about how much Levosmart is being given to you, speak to your doctor, nurse or pharmacist.

- Your doctor will decide on how much Levosmart you should have.
- 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.

Adults and the elderly

- Pneumonia: 500 mg once or twice daily
- Infection of urinary tract, including your kidneys or bladder: 500 mg once daily
- Prostate gland infection: 500 mg once daily
- Infection of skin and underneath the skin, including muscles: 500 mg once or twice daily.

Adults and the elderly with kidney problems

Your doctor may need to give you a lower dose.

Children and teenagers

This medicine must not be given to children or teenagers.

Protect your skin from sunlight

Keep out of direct sunlight while having this medicine and for 2 days after you stop having 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 have more Levosmart than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress, and check the medicine you are given. Always ask if you are not sure why you are getting a dose of medicine.

Having too much Levosmart may cause the following effects to 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).

If you miss a dose of Levosmart

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you do think you have missed a dose, tell your doctor or nurse.

If you stop having Levosmart

Your doctor or nurse will continue giving you Levosmart, even if you feel better. If it is stopped too soon, your condition may get worse or the bacteria may become resistant to the medicine. After a few days treatment with the solution for infusion, your doctor may decide to switch you to the tablet form of this medicine to complete your course of treatment.

If you have any further questions on the use of this medicine, ask your doctor, nurse, 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 having Levosmart and tell a doctor or nurse straight away if you notice the following side effect:

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

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

Stop having Levosmart and tell a doctor or nurse 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 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).
- 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'.

Other:

- 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
- Reactions at the site of infusion
- Inflammation of a vein

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.
- 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.

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 (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.
- 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.

If you get any side effects, talk to your doctor, nurse 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.

Keep the bottle in the outer carton in order to protect from light. No protection from light is required during the infusion.

Once the infusion bottle has been opened (rubber stopper perforated) the solution should be used immediately in order to prevent any bacterial contamination.

Do not use this medicine after the expiry date which is stated on the carton and the bottle.

Do not use this medicine if you notice that the solution is not clear and/or has particles in it.

6. OTHER INFORMATION

What Levosmart solution for infusion contains

The active substance is levofloxacin.

One ml of solution for infusion contains 5 mg of levofloxacin (as levofloxacin hemihydrate).

The other ingredients are: sodium chloride, hydrochloric acid and water for injection.

Contents of the pack

Box with a glass bottle of 100 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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