

Levofoxin® 5 mg/ml 5 mg/ml, solution for intravenous infusion Levofoxacin

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Info leaflet

1. What Levofoxin 5mg/ml is and what it is used for
2. Before you take Levofoxin 5mg/ml
3. How you take Levofoxin 5mg/ml
4. Possible side effects
5. How to store Levofoxin 5mg/ml
6. Further information

1. Serious side effects

- If you have Levofoxin 5mg/ml 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 include blood in it, possibly with stomach cramps and a high temperature.
- These could be signs of a severe bowel problem.
- If you have 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'.
- Not known (frequency cannot be estimated from the available data)
- 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 having Levofoxin 5mg/ml.

2. What Levofoxin 5mg/ml is and what it is used for

- The name of your medicine is Levofoxin 5mg/ml solution for intravenous infusion.
- Levofoxin 5mg/ml solution for intravenous infusion contains a medicine called levofoxacin.
- Levofoxacin is a 'quinolone' antibiotic. It works by killing the bacteria that cause infections in your body.
- Levofoxin 5mg/ml solution for intravenous infusion can be used to treat infections of the:
- Lungs, in people with pneumonia.
- Urinary tract, including your kidneys or bladder.
- Skin in people with skin infections.
- Prostate gland, where you have a long lasting infection.
- In some special situations, Levofoxin 5mg/ml solution for intravenous infusion may be used to prevent the chances of getting a pneumonia disease named anthrax or worsening of the disease after you are exposed to anthrax causing bacteria.

3. Before you take Levofoxin 5mg/ml

- Do not take Levofoxin 5mg/ml:
- If you are allergic to levofoxacin, any other quinolone antibiotic such as, moxifloxacin, ciprofloxacin or ofloxacin or any of the other ingredients of this medicine (listed in section 6)
- If you have an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.
- If you have ever had epilepsy.
- If you have Levofoxin 5mg/ml with your tendons such as tendons that was related to treatment with a quinolone antibiotic. A tendon is the cord that joins your muscle to your skeleton.
- If you are a child or a growing teenager.
- If you are pregnant, might become pregnant, or think you may be pregnant.
- If you are breast-feeding.
- 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 Levofoxin 5mg/ml

4. Take special care with Levofoxin 5mg/ml

- If you are 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 Levofoxin 5mg/ml")
- You have ever had low 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 Levofoxin 5mg/ml")
- You are diabetic
- You have ever had liver problems
- You have myasthenia gravis.
- If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given Levofoxin 5mg/ml.

5. Using other medicines, herbal or dietary supplement

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Levofoxin 5mg/ml can affect the way some other medicines work. Also some medicines can affect Levofoxin 5mg/ml.
- 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 Levofoxin 5mg/ml:
- 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.

6. Theophylline - used for treating problems

- You are more likely to have a fit (seizure) if taken with Levofoxin 5mg/ml.
- 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 Levofoxin 5mg/ml.
- You may be more likely to have a seizure if you take theophylline with Levofoxin 5mg/ml.
- 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), heart failure (diuretics such as furosemide, bumetanide and frusemide), for psychiatric disorders (antipsychotics), and for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and clarithromycin).
- You may be more likely to get side effects if you take Levofoxin 5mg/ml with:
- Cimetidine - used for your heart.
- Your doctor may want to use a lower dose, if you have kidney problems.
- Cimetidine - used for ulcers and heartburn. Your doctor may want to use a lower dose, if you have kidney problems.
- Tell your doctor if any of the above applies to you.

7. Urinary tests for opiate

- Urine tests may show 'false-positive' results for strong painkillers called 'opiates' in people having Levofoxin 5mg/ml.
- If your doctor has prescribed a urine test, tell your doctor you are having Levofoxin 5mg/ml.
- False-negative tests
- This medicine may cause 'false-negative' results for some laboratory tests that search for the bacteria that cause tuberculosis.

8. Pregnancy and breast-feeding

- Do not have this medicine if:
- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast-feed
- You are taking and using nifedipine
- 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 try to carry out any work that requires a high level of attention.

9. Important information about some of the ingredients of levofoxin 5 mg/ml

- Levofoxin 5mg/ml solution for intravenous infusion contains sodium
- Sodium chloride 540 mg/ml and sodium peroxide 500 mg levofoxacin. This should be taken into consideration by patients on a controlled sodium diet.

10. How you take Levofoxin 5mg/ml

- Levofoxin 5mg/ml solution for intravenous 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 Levofoxin 5mg/ml solution for intravenous infusion, the infusion time should be 60 minutes or more
- This infusion time should be closely monitored.
- 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 Levofoxin 5mg/ml solution for intravenous infusion is given
- If you are not sure why you are being given Levofoxin 5mg/ml or have any questions about how much Levofoxin 5mg/ml is being given to you, speak to your doctor, nurse or pharmacist.
- Your doctor will decide on how much Levofoxin 5mg/ml you should have and the dose will depend on the type of infection you have and whether the infection is in your body
- The length of your treatment will depend on how serious your infection is

Adults and the elderly

- Adults (18 years and over) receive 500 mg once each day
- Infusion of urinary tract, including your kidneys or bladder: 500 mg once each day
- Infusion of urinary tract, including your kidneys or bladder: 500 mg once each day
- Infusion of skin and underneath the skin, including muscles: 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 Teenagers
- This medicine must not be given to children or teenagers
- 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 are not protected from the sun.
- Make sure you use a high factor sun cream
- Always wear a hat and clothes which cover your arms and legs
- Avoid sun beds

a. If you take more Levofoxin 5mg/ml solution for intravenous infusion 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 Levofoxin 5mg/ml may cause the following effects to happen:
- Watery diarrhoea (severe) which may include blood in it, less conscious, having tremor and heart problems - leading to uneven heart beats as well as feeling sick (nausea).
- If you forgot to take Levofoxin 5mg/ml solution for intravenous infusion
- 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 taking Levofoxin 5mg/ml solution for intravenous infusion
- Your doctor or nurse will continue giving you Levofoxin 5mg/ml, even if you feel better.
- If it is stopped too soon, the infection may return, 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.

5. 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 Levofoxin 5mg/ml 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)
- Watery diarrhoea which may include blood in it, possibly with stomach cramps and a high temperature. These could be signs of a severe bowel problem.
- If you have 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'.
- Not known (frequency cannot be estimated from the available data)
- 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 having Levofoxin 5mg/ml, consult an eye specialist immediately.

Tell your doctor if you notice any of the following serious 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
- Changes in the way your blood sugar levels or 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 way your blood sugar levels or enzymes in your blood
- Feeling stressed (anxiety), feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling (vertigo)
- Shortness of breath (dyspnoea)
- Changes in the way your stomach is feeling, feeling full, 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, feeling problems, feeling restless (agitation), abnormal dreams or nightmares.
- Tingling feeling in your hands and feet (paresthesia)
- Problems with your hearing (otitis) 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 kidneys work and occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis
- Fever
- Not known (frequency cannot be estimated from the available data)
- Lowering in red blood cells (anaemia): this can make the skin pale or yellow due to damage of the red blood cells
- Pain, including pain in the back, chest and extremities
- 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)
- 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 your senses 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
- Unusually fast heart rate (tachycardia)-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 reaction

- 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 mouth and throat (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 without blurred vision (Idiopathic intracranial hypertension)
- If any of the side effects gets serious or lasts longer than a few days, tell your doctor or pharmacist.
- How to store Levofoxin 5mg/ml
- Keep this medicine out of the reach and sight of children.
- Store below 30°C and keep away from light.
- Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP.
- The expiry date refers to the last day of that month.
- The expiry date of Levofoxin 5mg/ml solution is not a clear yellowish liquid and has particles on it.
- Do not throw away any medicines via wastewater or household waste. Ask your nurse or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- Shelf life: 36 months

6. Further information

- What 'Levofoxin 5mg/ml' contains:
- The active substance is levofoxacin hemihydrate 512 mg (500 mg as base);
- The other ingredients are sodium chloride, sodium hydroxide, hydrochloric acid and water for injection.
- What 'Levofoxin 5mg/ml' looks like and contents of the pack:
- Levofoxin 5mg/ml solution for intravenous infusion is available in glass presentation
- Levofoxin 5mg/ml solution for intravenous infusion is a slightly yellowish liquid.
- It is presented in glass bottle
- The 100 ml bottle is available in packs of 1
- ES: LABOALTOLEVA 2017-2020 S.A.
- Route de Tunis - KM 7 - BP 206 - 8300 Nabeul - Tunisie
- Tel: (216) 72 23 50 06 / Fax: (216) 72 23 51 06
- e-mail: marketing@levofoxin.com
- For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.
- Soleira Trading Establishment
- (Medical equipment & pharmaceuticals)
- P.O. Box 1421, Riyadh 11421 - Kingdom of Saudi Arabia
- Tel: 00 966 1 46 46 955 / Fax: 00 966 1 46 34 362

d. This leaflet was last approved in "August 2014"; version number " 00 "

e. To register our leaflet:

f. Saudi Arabia:

g. Other GCC states:

Please contact the relevant competent authority.

f. Council of Arab Health Ministers

- This is a Medication
- Medication is a product which affects your health and its consumption carries a dangerous for you.
- Follow strictly the doctor's prescription and the method of use of the medicine.
- The doctor and the pharmacist are experts in medicine in benefits and risks.
- Do not be concerned or interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medications out of reach of children.
- KEEP AVOIDING OUT OF THE REACH OF CHILDREN.
- Council of Arab Health Ministers
- Union of Arab Pharmacists

This patient information leaflet is approved by the Saudi Food and Drug Authority

