Package Leaflet : Information for the Patient

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# Levofloxacin Infusion IP (500 mg/100 ml)

**AMERICAN**
**LEVOXICAN IV**
Infusion

**Composition :**
**Each 100 ml Contains :**
Levofloxacin Hemihydrate IP
Equivalent to Levofloxacin 500 mg
Water for Injections IP q.s.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet
1. What Levofloxacin infusion is and what it is used for
2. What you need to know before you are given Levofloxacin infusion.
3. How Levofloxacin infusion is given.
4. Possible side effects
5. How to store Levofloxacin infusion

1. What Levofloxacin infusion is and what it is used for
Levofloxacin infusion 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.
Levofloxacin 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, Levofloxacin infusion 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 Levofloxacin infusion
- Do not have this medicine and tell your doctor if:
- you are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin 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 problems 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 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 Levofloxacin.
Warnings and precautions Before taking this medicine
You should not take fluoroquinolone/quinolone antibacterial medicines, including Levofloxacin, if
you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible. Talk to your doctor, nurse or pharmacist before you are given Levofloxacin if:
- you are 60 years of age or older
- you are using corticosteroids, sometimes called steroids (see section "Other medicines and Levofloxacin")
- 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 a family history of prolonged QT interval (seen on ECG, electrical recording of the heart), salt imbalance in the blood (especially low level of potassium or magnesium in the blood), a very slow heart rhythm (called 'bradycardia'), a weak heart (heart failure), a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes 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, Sjogren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Bechet'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.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given Levofloxacin.
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 hat and clothes which cover your arms and legs
- Avoid sun beds

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

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. Levofloxacin infusion contains sodium
This medicine contains 177 mg sodium (main component of cooking/table salt) in each 50 ml vial. This is equivalent to 8.85% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 354 mg sodium (main component of cooking/table salt) in each 100 ml vial.
This is equivalent to 17.7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Levofloxacin infusion is given
Your doctor will explain to you exactly how much Levofloxacin you will be given as well as how often and for how long.
- Levofloxacin 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 Levofloxacin 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.

Use in adults and elderly
The recommended dose is:
- 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

Use in adults and elderly with kidney problems
Your doctor may need to give you a lower dose.
Use in children and adolescents
This medicine must not be given to children or adolescents.
If you have more Levofloxacin 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 Levofloxacin 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 Levofloxacin 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 having Levofloxacin infusion
Your doctor or nurse will continue giving you Levofloxacin, 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 Levofloxacin and tell a doctor or nurse straight away if you notice any of the following serious side effects:
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
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system)
- Fits (convulsions)
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- 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)
- You have an allergic reaction. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue
- Burning, tingling, pain, or numbness. These may be signs of something called 'neuropathy'

Frequency unknown (frequency cannot be estimated from the available data)
- 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
- 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
- Abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)

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

5. Dosage
Dosage : As directed by the Physician.
6. How to store Levofloxacin infusion
Storage: Store at a temperature not exceeding 30°C.
Do not freeze. Protect from light.
Keep the medicine out of reach of children.

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