



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

LEVOC IV INFUSION

Levofloxacin 500mg/100ml

are taking other medicines that result in abnormal ECG changes (see section "Other medicines and levofloxacin").

- 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 levofloxacin

Read all of this leaflet carefully before you start using this medicine. - Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your health care provider. - 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Levoc IV Infusion is and what it is used for
2. Before you take Levoc IV Infusion
3. How to take Levoc IV Infusion
4. Possible side effects
5. How to store Levoc IV Infusion
6. Further information

1. WHAT LEVOC IV INFUSION IS AND WHAT IT IS USED FOR Levoc IV 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 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 may be used to reduce the chances of getting a lung disease named anthrax or worsening of the disease after you are exposed to the bacteria causing anthrax

2. BEFORE YOU USE LEVOC IV INFUSION

Do not use Levoc IV Infusion if:

- You are allergic (hypersensitive) to levofloxacin or any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or ofloxacin or any of the other ingredients of Levoc IV Infusion. 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 breast-feeding

Do not use 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

Caution with Levoc IV Infusion

• Before treatment with Levoc IV Infusion, talk to your health care provider 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 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 a female or elderly or you

Taking other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because levofloxacin can affect the way some other medicines work. Also, some medicines can affect the way levofloxacin works.

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 levofloxacin: - 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 Levofloxacin.
- 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 Levofloxacin.
- Cyclosporin - used after organ transplants. You may be more likely to get the side effects of cyclosporin.
- 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 Levofloxacin. 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 levofloxacin. If your doctor has prescribed a urine test, tell your doctor you are taking levofloxacin.

Tuberculosis tests

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

Pregnancy and breast-feeding

Do not take 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 experience 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 TO TAKE LEVOC IV INFUSION

- Levofloxacin 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, 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



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

LEVOC IV INFUSION

Levofloxacin 500mg/100ml

antibiotic. If your blood pressure drops noticeably while you are being given the infusion, it will be stopped straight away.

How much Levofloxacin is given?

- If you are not sure why you are being given levofloxacin or have any questions about how much levofloxacin is being given to you, speak to your health care provider.
- Your doctor will decide on how much levofloxacin 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 the urinary tract, including your kidneys or bladder: 500 mg once daily
- Prostate gland infection: 500 mg once daily
- Infection of the 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 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 hat and clothes which cover your arms and legs • Avoid sun beds

If you take more Levoc IV 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.
- Taking 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 forget to take Levoc IV 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 Levoc IV 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 of 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 product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Levoc IV Infusion can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEVOC IV INFUSION

Keep all medicines out of the reach of children.

Store below 30°C, in a dry place.

Do not use Levoc IV Infusion after the expiry date 'Exp. Date' which is stated on the label. The expiry date refers to the last day of that month.

Do not use Levoc IV Infusion if you notice leaking or visible particles in the product or if the solution is unclear or discoloured.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Levoc IV Infusion contains:

- The active pharmaceutical ingredient is Levofloxacin

What Levoc IV Infusion looks like and contents of the pack:

- Levoc IV Infusion is a solution with no visible particles.
- It comes in 100ml solution for infusion in an LDPE, placed in an outer carton with insert.

Supplier and Manufacturer

Fidson Healthcare Plc.
Km. 38, Lagos-Abokuta Expressway,
Sango Ota, Ogun State
+234 807 700 8888
www.fidson.com
customer@fidson.com

[PMN0520-0820-01]