

LEVOFLOX 5 mg/ml, solution for infusion

Levofloxacin

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 refer to it. You may not need all of this information. You may also need to take other medicines. You may have questions about your illness or the 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. See section 4.

What is this leaflet?

- 1. What you need to know before you take LEVOFLOX 5 mg/ml, solution for infusion?
- 2. What you need to know before you take LEVOFLOX 5 mg/ml, solution for infusion?
- 3. How to take LEVOFLOX 5 mg/ml, solution for infusion?
- 4. Possible side effects?

5. How to store LEVOFLOX 5 mg/ml, solution for infusion?

6. Content of the package and other information

1. **WHAT IS LEVOFLOX 5 mg/ml, solution for infusion AND IN WHICH CASE IS IT USED?**
Levofloxacin is an antibiotic belonging to the quinolones, fluorquinolones family. ATC code: J01MAA12
The name of your medicine is LEVOFLOX 5 mg/ml solution for infusion.
LEVOFLOX 5 mg/ml contains an active substance called levofloxacin. It belongs to a group of medicines called quinolones. Levofloxacin is used for "quenching" or "killing" the bacteria that causes infections in your body. LEVOFLOX 5 mg/ml can be used to treat infections of the:

- sinuses, in multiple abscesses
- prostate, when you have an infection that lasts.

In special situations, LEVOFLOX 5 mg/ml can be used to reduce the chances of getting a lung disease called anthrax.

Signs of an allergic reaction include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.

2. **WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEVOFLOX 5 mg/ml, solution for infusion?**
Never take LEVOFLOX 5 mg/ml, solution for infusion if:

- You are allergic to levofloxacin, to other quinolone antibiotics such as moxifloxacin, ciprofloxacin or ofloxacin, or to any of the other components of this medicine (listed in section 6).
- Signs of an allergic reaction include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
- You have ever had epileptic seizures.
- You have ever had a problem with your tendons, such as tendonitis, which was related to treatment with an antibiotic of the quinolone family. The tendon is the structure by which a muscle fits into a bone.
- You are a growing child or adolescent.
- You are pregnant or possibly pregnant, or you think you may be pregnant.
- You are breastfeeding.

3. **How to take LEVOFLOX 5 mg/ml, solution for infusion**
Take the medicine exactly as if any of the above apply to you. If you are not sure, talk to your doctor, nurse or nurse before taking LEVOFLOX 5 mg/ml solution for infusion

4. **Before taking this medicine**
You should not take antibiotics of the fluorquinolone / quinolone family, including this medicine, if you have had a serious fever with a sinusitis or sinusitis, on the buttocks or red, thick, sharp-tipped, round or circular patches often with blisters in their center. Tell your doctor as soon as possible.

5. **When to take the medicine**
You should not take other medicines or substances before taking LEVOFLOX 5 mg/ml solution for infusion if:

- You are taking corticosteroids, sometimes called steroids (see section - Other medicines and LEVOFLOX 5 mg/ml, solution for infusion) - serious risks.
- You have had a transplant.
- You have had a problem with epileptic seizures (convulsions).
- You have brain damage due to stroke or other brain injury.
- You have had kidney problems.
- You are taking a medicine called "glicose-6-phosphate dehydrogenase deficiency". You are more likely to have serious blood problems when receiving this medicine.

6. **What you have ever had and mental health problems**
• You have ever had heart problems: you will be careful with this medication if you are born with or have a family history of heart disease, or if you have had a heart problem, such as coronary artery disease, high blood pressure or known atherosclerosis. (especially low levels of potassium or magnesium in the blood), if you have a very slow heartbeat (called "bradycardia"), if you have a weakened heart (heart failure), if you have had a history of heart attack (myocardial infarction), if you are a woman, or if you are taking any of the above-mentioned medicines which may cause certain ECs (see section - Other medicines and LEVOFLOX 5 mg/ml, solution for infusion).

• You are allergic to any of the following medicines:
• You have ever had liver problems.
• You have an enlarged prostate.
• You have an enlarged or "swollen" large blood vessel (aortic aneurysm or peripheral aneurysm of a large vessel).
• You have ever had a previous episode of aortic dissection (a tear in the aortic wall).
• You have a family history of aortic aneurysm or aortic dissection or other connective tissue disorders (for example, connective tissue disorders such as Marfan syndrome or vascular Ehlers-Danlos syndrome, or vascular systems such as Takayasu arteritis).

• You have ever developed a severe rash, severe skin peeling, blisters and/or sores in the mouth after taking levofloxacin.
• You have ever had a problem with your tendons, such as tendonitis, which was related to treatment with an antibiotic of the quinolone family. The tendon is the structure by which a muscle fits into a bone.

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• Make sure you are using a sunscreen with a high sun protection factor.
• Always wear a hat and clothes that cover your arms and legs.
• Avoid sunbathing.
• If you take more LEVOFLOX 5 mg/ml solution for infusion than you should
Your doctor or nurse will usually give you too much medicine. Your doctor and nurse will monitor your condition for improvement, and ask you to take medicine given to you. Do not hesitate to ask questions if you are not sure why you are taking medicine.

One excessive dose of Levofloxacin 5 mg/ml solution for infusion may cause the following effects: seizures (convulsions), confusion, dizziness, decreased consciousness, tremors and heart problems - causing irregular heartbeat as well as feeling unwell (nausea).

What you need to take LEVOFLOX 5 mg/ml solution for infusion
Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that the medicine will not be given to you as prescribed. If you are unable to take your medicine, contact your doctor or pharmacist to get your medicine.

If you stop taking LEVOFLOX 5 mg/ml solution for infusion
Your doctor or nurse will continue to give you LEVOFLOX 5 mg/ml solution for infusion even if you feel better. If stopped too soon, you may develop a relapse of your infection. After a few days of treatment with this medicine, your doctor may decide to give you the tablet form of this medicine to complete your treatment cycle. You may have a problem with your tendons, such as tendonitis, which was related to treatment with an antibiotic of the quinolone family. The tendon is the structure by which a muscle fits into a bone.

4. **POSSIBLE SIDE EFFECTS?**
Most of the side effects are mild and do not last long. However, some side effects are serious and some are life-threatening. These effects are normally mild or moderate and often go away within a short time.
Stop LEVOFLOX 5 mg/ml solution for infusion and tell a doctor or nurse immediately if you notice the following side effects:

Very rare (may affect up to 1 in 10 000 people)
• You are having an allergic reaction. The signs may include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
Stop LEVOFLOX 5 mg/ml solution for infusion and tell a doctor or nurse immediately if you notice any of the following serious side effects - you may need urgent medical treatment:

Rare (may affect up to 1 in 100 people)
• You are having an allergic reaction. The signs may include: a rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
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