

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Levofloxacin 5mg/ml solution for infusion

levofloxacin

**Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### WHAT IS IN THIS LEAFLET

1. What Levofloxacin solution for infusion is and what it is used for
2. What you need to know before you use Levofloxacin solution for infusion
3. How Levofloxacin solution for infusion is used
4. Possible side effects
5. How to store Levofloxacin solution for infusion
6. Contents of the pack and other information

### 1. WHAT LEVOFLOXACIN SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

The name of your medicine is Levofloxacin solution for infusion. Levofloxacin solution for 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 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, Levofloxacin solution for 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 USE LEVOFLOXACIN SOLUTION FOR INFUSION

#### 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.

#### Do not use this medicine:

- 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
- If you have ever had epilepsy
- If 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
- 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 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 solution for infusion.

#### Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Levofloxacin solution for infusion if:

- You are 60 years of age or older
- You are using corticosteroids, sometimes called steroids (see "Other medicines and Levofloxacin solution for infusion")
- 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 Levofloxacin solution for infusion)
- 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 a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).
- You are diabetic
- You have ever had liver problems
- You have myasthenia gravis

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.

#### 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 Levofloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Levofloxacin, 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 Levofloxacin and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

#### Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including Levofloxacin, 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 Levofloxacin, 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.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given Levofloxacin solution for infusion.

#### Other medicines and Levofloxacin solution for infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Levofloxacin solution for infusion can affect the way some other medicines work. Also some medicines can affect the way Levofloxacin solution for infusion 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 Levofloxacin solution for infusion:**

- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or breakage 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 solution for infusion
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used for pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with Levofloxacin solution for infusion
- 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 Levofloxacin solution for infusion. 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 taking Levofloxacin. If your doctor is due to take a urine test, tell them 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 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 taking 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 solution for infusion contains sodium

Levofloxacin contains 8.1mmol of sodium in 50ml. This information should be taken into consideration in patients in a salt controlled diet.

Levofloxacin contains 16.2mmol of sodium in 100ml. This information should be taken into consideration in patients in a salt controlled diet.

### 3. HOW TO USE LEVOFLOXACIN SOLUTION FOR INFUSION

#### How Levofloxacin solution for infusion is given

- Levofloxacin 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 250 mg Levofloxacin solution for infusion, the infusion time should be 30 minutes or more
- For 500 mg Levofloxacin 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 Levofloxacin solution for infusion is given

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

- 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 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.

#### Use in children and adolescents:

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 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 use more Levofloxacin solution for 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 forget to use Levofloxacin solution for 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 think you might have missed a dose inform your doctor or nurse.

#### If you stop using Levofloxacin solution for 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 product, 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 affects are normally mild to moderate and often disappear after a short time.

#### Stop having Levofloxacin solution for infusion and tell a doctor or nurse straight away if you notice the following side effects:

##### 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

##### 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)

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

- Burning, tingling, pain or numbness. These may be signs of something called 'neuropathy'



**The following information is intended for medical or healthcare professionals only:**

## Levofloxacin 5mg/ml solution for infusion

levofloxacin

#### Therapeutic indications

Levofloxacin solution for infusion is indicated in adults for the treatment of the following infections (see sections 4.4 and 5.1)

- Community-acquired pneumonia.
- Complicated skin and soft tissue infections.

For previously indicated infections, Levofloxacin should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.

For community-acquired pneumonia Levofloxacin solution for infusion should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections.

- Acute pyelonephritis and complicated urinary tract infections (see section 4.4)
- Chronic bacterial prostatitis
- Inhalation Anthrax: post-exposure prophylaxis and curative treatment (see section 4.4).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

#### Posology and method of administration

Levofloxacin solution for infusion is administered by slow intravenous infusion once or twice daily. The dosage depends on the type and severity of the infection and the susceptibility of the presumed causative pathogen. Treatment with Levofloxacin after initial use of the intravenous preparation may be completed with an appropriate oral presentation according to the SPC for the film-coated tablets and as considered appropriate for the individual patient. Given the bioequivalence of the parenteral and oral forms, the same dosage can be used.

#### Posology

The following dose recommendations can be given for Levofloxacin solution for infusion:

**Dosage in patients with normal renal function** (creatinine clearance> 50 ml/min)

Indication	Daily dose regimen (according to severity)	Total duration of treatment (according to severity)
Community-acquired pneumonia	500 mg once or twice daily	7 – 14 days
Acute pyelonephritis	500 mg once daily	7 – 10 days
Complicated urinary tract infections	500 mg once daily	7 – 14 days
Chronic bacterial prostatitis	500mg once daily	28 days
Complicated skin and soft tissue infections	500 mg once or twice daily	7 – 14 days
Inhalation anthrax	500mg once daily	8 weeks

Treatment duration includes intravenous plus oral treatment. The time to switch from intravenous to oral treatment depends on the clinical situation but is normally 2 to 4 days.

**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
- 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 the vein

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking Levofloxacin solution for infusion, 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 the 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 1000 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

**Not known** (frequency cannot be estimated from the available data):

- 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 vision, inflammation of the eye (uveitis)
- Impairment or loss of hearing
- 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)

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.

**Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in:

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE LEVOFLOXACIN SOLUTION FOR INFUSION

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date, which is stated on the outer package and bag after EXP. The expiry date refers to the last day of the month.

Keep the bag in the outer package in order to protect from light.

Store below 25°C

Do not use Levofloxacin solution for infusion if the solution is not clear, if the solution is not green to yellow and/or if it is not free from particles.

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.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Levofloxacin solution for infusion contains**

- The active substance is levofloxacin
- Each ml of solution for infusion contains 5 mg of levofloxacin (as hemihydrate)
- The other ingredients are: sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections

**What Levofloxacin Solution for infusion looks like and contents of the pack**

**Plastic bags:**

Polypropylene bag containing 50 ml of solution for infusion with a twist-off-port:

Packs: 1 bag of 50 ml or 10 bags of 50 ml

Polypropylene bag containing 100 ml of solution for infusion with a twist-off-port:

Packs: 1 bag of 100 ml or 10 bags of 100 ml

## Marketing Authorisation Holder and Manufacturer

Hikma Farmacêutica (Portugal), S.A.  
Estrada do Rio da M6, nº 8, 8A – 8B  
Fervença, 2705 – 906 Terrugem SNT  
Portugal  
Tel: +351 21 960 84 10  
Fax: +351 21 961 51 02  
e-mail: [portugalgeral@hikma.com](mailto:portugalgeral@hikma.com)

**Distributed by:**

Consilient Health (UK) Ltd.  
No.1 Church Road, Richmond upon Thames,  
Surrey, TW9 2QE

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Austria:	Levofloxacin Hikma 5 mg/ml Infusionslösung
Germany:	Levofloxacin Hikma 5 mg/ml Infusionslösung
Ireland:	Levofloxacin 5mg/ml solution for infusion
Italy:	Levofloxacin Hikma 5 mg/ml Soluzione per infusione
Netherlands:	Levofloxacin Hikma 5 mg/ml, oplossing voor infusie
Portugal:	Levofloxacin Hikma
United Kingdom:	Levofloxacin 5mg/ml solution for infusion

**This leaflet was last revised in June 2020.**



P0962

**hikma.**



## Special populations

**Impaired renal function** (creatinine clearance  $\leq 50$  ml/min)

	Dose regimen		
	250 mg/24 h	500 mg/24 h	500 mg/12 h
<b>Creatinine clearance</b>	<i>first dose:</i> 250 mg	<i>first dose:</i> 500 mg	<i>first dose:</i> 500 mg
50 - 20 ml/min	<i>then:</i> 125 mg/24 h	<i>then:</i> 250 mg/24 h	<i>then:</i> 250 mg/12 h
19 - 10 ml/min	<i>then:</i> 125 mg/48 h	<i>then:</i> 125 mg/24 h	<i>then:</i> 125 mg/12 h
< 10 ml/min (including haemodialysis and CAPD) <sup>1</sup>	<i>then:</i> 125 mg/48 h	<i>then:</i> 125 mg/24 h	<i>then:</i> 125 mg/24 h

<sup>1</sup> No additional doses are required after haemodialysis or continuous ambulatory peritoneal dialysis (CAPD).

## Impaired liver function

No adjustment of dosage is required since levofloxacin is not metabolised to any relevant extent by the liver and is mainly excreted by the kidneys.

## Elderly population

No adjustment of dosage is required in the elderly, other than that imposed by consideration of renal function (See section 4.4 "Tendinitis, tendon rupture" and QT interval prolongation).

## Paediatric population

Levofloxacin is contraindicated in children and growing adolescents (see section 4.3).

## Method of administration

Levofloxacin solution for infusion is only intended for slow intravenous infusion; it is administered once or twice daily. The infusion time must be at least 30 minutes for 250 mg or 60 minutes for 500 mg Levofloxacin solution for infusion (see section 4.4).

## List of excipients

Sodium chloride  
Sodium hydroxide (for pH adjustment)  
Hydrochloric acid (for pH adjustment)  
Water for injections.

## Incompatibilities

Levofloxacin should not be mixed with heparin or alkaline solutions (e.g. sodium hydrogen carbonate).

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

## Special precautions for storage

Keep the bag in the outer package in order to protect from light.

Store below 25°C

Inspect visually prior to use.

Only clear solutions without particles should be used.