

## Package leaflet: information for the user

### Levofloxacin Normon 5 mg/mL solution for infusion

**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, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

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

#### **1. What Levofloxacin Normon 5 mg/mL solution for infusion is and what it is used for**

The name of this medicine is Levofloxacin Normon 5 mg/mL solution for infusion. Levofloxacin Normon 5 mg/mL solution for infusion contains an active ingredient called levofloxacin, which belongs to a group of medicines called antibiotics. Levofloxacin is a quinolone antibiotic that works by killing the bacteria that causes infections in your body.

**Antibiotics are used to treat bacterial infections and do not serve to treat viral infections such as flu or catarrh.**

**It is important that you follow the instructions related to doses, dosage interval and duration of treatment indicated by your doctor.**

**Do not store or reuse this medicine. If once treatment is completed you have antibiotic left, bring it back to the pharmacy for its correct disposal. Medicines should not be disposed of via wastewater or household waste.**

#### **Levofloxacin Normon 5 mg/mL solution for infusion may 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 Normon 5 mg/mL solution for infusion may be used to lessen the chances of getting a pulmonary disease called anthrax, or the worsening of the disease if you have been exposed to the bacteria causing anthrax.

#### **2. What you need to know before you use Levofloxacin Normon 5 mg/mL solution for infusion**

##### **Do not use this medicine and talk to your doctor 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.
- 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 growing adolescent.
- 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 using Levofloxacin Normon.

## **Warnings and precautions**

### **Talk to your doctor before taking this medicine**

If you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone, you should not take fluoroquinolone/quinolone antibacterial medicines, including Levofloxacin Normon 5 mg/mL solution for infusion. If this applies to you, you should tell your doctor as soon as possible.

### **Ask your doctor, nurse or pharmacist for advice before using this medicine if:**

- You are 60 years of age or older.
- You are using corticosteroids, sometimes called steroids (see section ‘Other medicines and Levofloxacin Normon’).
- 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 (G6PD) deficiency’, as 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 Normon 5 mg/mL solution for infusion”).
- You are diabetic.
- You have ever had liver problems.
- You have myasthenia gravis.
- You have been diagnosed with an expansion or “lump” of the blood vessels (aortic aneurysm or aneurysm of a large peripheral vessel).
- You have had a previous episode of aortic dissection (tear in the wall of the aorta).
- 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 disorders (e.g., connective tissue disorders such as Marfan’s syndrome or Ehlers-Danlos syndrome, Turner syndrome, Sjögren’s syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behçet’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 peeling skin, blisters 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 using Levofloxacin Normon.

### **During treatment with this medicine**

- If you feel sudden, severe pain in your abdomen or back, which can be symptoms of aortic aneurysm

and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.

- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

**Pain and swelling in the joints and inflammation or rupture of tendons** may occur rarely. The 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. Tendon inflammation and rupture may occur within 48 hours of starting treatment and have even been reported up to several months after discontinuation of treatment with Levofloxacin Normon 5 mg/mL solution for infusion. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Levofloxacin Normon 5 mg/mL solution for infusion, 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 Normon 5 mg/mL solution for infusion and inform your doctor immediately in order to prevent the development of a potentially irreversible condition.**

**Prolonged, disabling and potentially irreversible serious side effects.**

Fluoroquinolone or quinolone antibacterial medicines, including Levofloxacin Normon 5 mg/mL solution for infusion, 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 Normon 5 mg/mL solution for infusion, 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.

**Serious skin reactions**

Serious skin rashes, including Stevens–Johnson syndrome, toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported.

- SJS/TEN may initially appear on the trunk as reddish target-shaped spots or circular spots often with blisters in the centre. Ulcers on the mouth, throat, nose, genitals and eyes (red or swollen eyes) may also appear. These severe skin rashes are often preceded by fever and/or flu-like symptoms. These rashes may be fatal or develop into to a generalized peeling of the skin and to life-threatening complications.
- DRESS appears initially as flu-like symptoms and a rash on the face, then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a severe rash or any of these skin symptoms, stop taking levofloxacin and contact your doctor or seek medical attention immediately.

**Other medicines and Levofloxacin Normon 5 mg/mL 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 Normon can affect the way some other medicines work. Also some medicines can affect the way that Levofloxacin Normon 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 taking Levofloxacin Normon 5 mg/mL solution for infusion:**

- 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 Normon 5 mg/mL solution for infusion.
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used for pain and inflammation such as acetylsalicylic acid, ibuprofen, fenbufen, ketorolac, indomethacin. You are more likely to have a fit (seizure) if taken with Levofloxacin Normon.
- 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 Normon. 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 Normon. If your doctor has prescribed a urine test, tell your doctor that you have been given Levofloxacin Normon.

### **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 use 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 Normon 5 mg/mL solution for infusion contains sodium**

This medicine contains 354 mg sodium (main component of cooking/table salt) per 100 mL. This is equivalent to 17.7% of the recommended maximum daily dietary intake of sodium for an adult.

## **3. How to use Levofloxacin Normon 5mg/mL solution for infusion**

### **How to use Levofloxacin Normon 5mg/mL solution for infusion**

- Levofloxacin Normon 5 mg/mL 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 intravenous infusion).
- For 500 mg Levofloxacin Normon 5 mg/mL 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 Normon 5 mg/mL solution for infusion is given**

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

- Your doctor will decide on how much Levofloxacin Normon 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 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 elderly patients with kidney problems**

Your doctor may need to give you a lower dose.

### **Children and adolescents**

This medicine must not be given to children or adolescents.

### **Protect your skin from sunlight**

Keep out of direct sunlight (even if it is cloudy outside) while having this medicine and for two days after you stop having it, as 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 UVA lamps.

### **If you use more Levofloxacin Normon 5mg/mL 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 receiving this medicine.

Having too much Levofloxacin Normon 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).

In case of overdose or accidental ingestion, contact your doctor or pharmacist at once or go to the nearest hospital, indicating the medicine and the amount received.

### **If you forget to use Levofloxacin Normon 5 mg/mL 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 do think you have missed a dose, tell your doctor or nurse.

### **If you stop treatment with Levofloxacin Normon 5 mg/mL solution for infusion**

Your doctor or nurse will continue giving you Levofloxacin Normon, 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 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 Normon and tell a doctor or nurse or go to hospital straight away if you notice the following side effect:**

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

- If you have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

**Stop having Levofloxacin Normon 5 mg/mL solution for infusion and tell a doctor or nurse straight away if you notice any of the following serious side effects, as you may need urgent medical treatment:**

**Rare** (may affect up to 1 in 1,000 people).

- Watery diarrhea 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).
- Generalized rash, high body temperature, elevated liver enzymes, blood abnormalities (eosinophilia), enlarged lymph nodes and other concerned organs of the body (drug reaction with eosinophilia and systemic symptoms 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).

- 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.
- Severe skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis. These may appear on the trunk as reddish target-shaped spots or circular spots often with blisters in the centre, peeling of the skin, ulcers in the mouth, throat, nose, genitals and eyes and may be preceded by fever and flu-like symptoms. See also section 2.
- Loss of appetite, skin and eyes becoming yellow in color, dark-colored 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 taking Levofloxacin Normon, 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, dizziness.
- Feeling sick (nausea, vomiting) and diarrhea.
- 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).
- Breathing difficulties (dyspnea).
- 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 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 (hypoglycemia). 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 (paresthesia).
- 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.
- Clearly delimited erythematous spots with/or without blisters that develop within a few hours of levofloxacin administration and are cured with post-inflammatory residual hyperpigmentation; usually repeated at the same site of the skin or mucous membrane after subsequent exposure to levofloxacin.

**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 (hyperglycemia) or lowering of your blood sugar levels leading to coma (hypoglycemic 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 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.
- Inflammation of the pancreas (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 of the mouth (stomatitis).
- Muscle rupture and muscle destruction (rhabdomyolysis).
- Joint redness and swelling (arthritis).
- Pain, including pain of the back, chest and limbs.
- 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.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2.

### **Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

## **5. How to store Levofloxacin Normon 5 mg/mL solution for infusion**

Keep out of the sight and reach of children.

Store below 25 °C.

Store in the original package in order to protect from light. No protection from light is required during the infusion.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not use Levofloxacin Normon 5 mg/mL solution for infusion if the solution is not clear, is not greenish yellow and/or presents particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines and packs you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Levofloxacin Normon 5 mg/mL solution for infusion contains**

The active substance is levofloxacin.

Levofloxacin Normon 5 mg/mL solution for infusion is available in a 100 mL plastic bag with a plastic outer bag. One mL of the solution for infusion contains 5 mg of levofloxacin.

The other ingredients are: sodium chloride, hydrochloric acid or sodium hydroxide and water for injection.

### **What Levofloxacin Normon 5 mg/mL solution for infusion looks like and contents of the pack**

Levofloxacin Normon 5 mg/mL solution for infusion is a clear solution, greenish-yellow, without particles. It is presented in:

Plastic bag: the 100 mL bag with plastic outer bag is available in packs of 1 and 20 units.

Not all pack sizes are marketed in all countries.

**Marketing Authorization Holder and Manufacturer**

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This package leaflet does not include all information about your medicine. If you have any further questions or you are not sure, ask your doctor or pharmacist.

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