LEAFLET: INFORMATION FOR THE USER

LEVOFLOXACIN NORMON 5 mg/ml SOLUTION FOR INTRAVENOUS INFUSION

Read all this leaflet carefully before you start taking this medicinal product.
- Keep this leaflet, as you may need to read it again.
- If you have any doubts, consult your doctor or pharmacist.
- This medicinal product has been prescribed to you and should not be given to other people, even if they have the same symptoms, as it may harm them.
- If you think any of the side effects you suffer are severe or if you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

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1. WHAT LEVOFLOXACIN NORMON 5 mg/ml SOLUTION FOR INTRAVENOUS INFUSION IS AND WHAT IT IS USED FOR

LEVOFLOXACIN NORMON belongs to a group of drugs known as fluoroquinolones, a type of antibacterial (antibiotic) with bactericide activity.

This drug is only used in adults, and always on prescription, for the treatment of the following bacterial infections when caused by sensitive microorganisms:
- Community-acquired pneumonia.
- Complicated (difficult to treat) infections of the urinary tract, including pyelonephritis (infection of the kidneys).
- Chronic bacterial prostatitis (inflammation of the prostate caused by bacteria).
- Skin and soft tissue infections.

2. BEFORE USING LEVOFLOXACIN NORMON 5 mg/ml SOLUTION FOR INTRAVENOUS INFUSION

• Do not use LEVOFLOXACIN NORMON 5 mg/ml:
- If you are allergic (hypersensitive) to levofloxacin or any of the other components of this drug.
- If you suffer from epilepsy or a disease of the nervous system that can cause convulsions (such as head traumas, cerebrovascular accident, etc.).
- If you suffer or have suffered from tendon (part of the muscle) disorders (e.g. tendonitis, which is inflammation of the tendons) related to taking drugs in the fluoroquinolone (antibiotic) family. This is due to the risk of presenting similar problems with LEVOFLOXACIN NORMON, including ruptured tendons.
- If you are pregnant, think you may be so or if you are breastfeeding, as LEVOFLOXACIN NORMON may affect the infant.

LEVOFLOXACIN NORMON 5 mg/ml Solution for Intravenous Infusion is indicated for adults and should not be administered to children or adolescents in periods of growth, due to the risk of producing lesions in growing bone cartilage.

In case of doubt, consult your doctor or pharmacist.

• Take special care with LEVOFLOXACIN NORMON 5 mg/ml:
- If you have previously suffered a brain injury (such as cerebrovascular accident or a severe brain injury), as the risk of convulsions (seizures) may increase if you receive treatment with LEVOFLOXACIN NORMON (you should not get LEVOFLOXACIN NORMON if you suffer from epilepsy). Make sure that your doctor knows your medical history to give you suitable advice.
- Do not expose yourself to strong sunlight for long periods and do not use sun lamps or sun beds while being treated with LEVOFLOXACIN NORMON, as some people may be more sensitive to light during treatment with LEVOFLOXACIN NORMON (sunburn reactions).
- If severe, persistent diarrhoea with or without blood appears during or after treatment with LEVOFLOXACIN NORMON, tell your doctor immediately as this may be a sign of severe intestinal inflammation (pseudomembranous colitis) which can occur after antibiotic treatment and may require stopping administration of the medication or starting specific treatment.
- On rare occasions, LEVOFLOXACIN NORMON can cause pain and inflammation of tendons (tendonitis) which frequently affects the Achilles tendon, leading to rupture of the tendon, especially in elderly patients or patients who are on treatment with corticosteroids (cortisone and similar drugs). If any problems with tendons appear during or after treatment with levofloxacin, rest the affected limb to avoid tendon injury and immediately consult your doctor as it may be necessary to stop treatment.
- If you suffer from an abnormality of the enzyme called glucose-6-phosphate dehydrogenase (G6-PD) (a rare hereditary disease), as you may be predisposed to destruction of red blood cells (haemolysis) when treated with antibiotic drugs of the quinolone family; therefore levofloxacin should be used with caution in these patients.

• Use of other drugs with LEVOFLOXACIN NORMON 5 mg/ml:

Let your doctor or pharmacist know if you are using or have recently used any other medicinal products, even those acquired without medical prescription.

It is not recommended to use LEVOFLOXACIN NORMON at the same time as other drugs such as:
- Theophyline (drug used to treat respiratory problems).
- Fenbufen or similar non-steroidal anti-inflammatory drugs (which are used for pain and inflammation) as the convulsive threshold may decrease, increasing the risk of inducing convulsive seizures.

Vitamin K antagonists:

If you are taking oral anticoagulant drugs (vitamin K antagonists, such as warfarin), inform your doctor, who will monitor clotting tests for the possibility of an increase in the effects of anticoagulants.

• Pregnancy

Consult your doctor or pharmacist before using any medicinal product.

If you are pregnant, or think you might be, do not use LEVOFLOXACIN NORMON without first consulting your doctor, as the safety of using LEVOFLOXACIN NORMON during pregnancy has not been studied.

• Breastfeeding

Consult your doctor or pharmacist before using any medicinal product.

If you are breastfeeding, do not use LEVOFLOXACIN NORMON as it is excreted in breast milk.

• Driving and operating machinery

Due to the possibility of suffering side effects such as dizziness, somnolence or sight disorders, LEVOFLOXACIN NORMON can reduce the capacity to carry out certain tasks, such as driving or handling machinery.

• Use in children

Growing children and adolescents should not use LEVOFLOXACIN NORMON due to the risk of producing lesions to joint cartilage.

• Use in the elderly

LEVOFLOXACIN NORMON may cause pain or inflammation of the tendons.

• Patients with reduced renal activity (renal insufficiency)

Lower doses may be required than with normal renal activity.

• Important information on some of the components of LEVOFLOXACIN NORMON 5 mg/ml SOLUTION FOR INTRAVENOUS INFUSION: This drug contains 354 mg of sodium per 100 ml, which should be taken into consideration with patients on low sodium diets.

3. HOW TO USE LEVOFLOXACIN NORMON 5 mg/ml SOLUTION FOR INTRAVENOUS INFUSION

This drug is administered by infusion.

The normal dose is:

Patients with normal kidney function (creatinine clearance > 50 ml/min):

Indication	Daily Dose (depending on severity)
Community-acquired pneumonia	500 mg once or twice daily
Complicated urinary tract infections, including pyelonephritis	250 mg[1] once a day
Chronic bacterial prostatitis	500 mg once a day
Skin and soft tissue infections	500 mg twice daily

[1]: In the case of severe infection, an increase in dose should be considered.

Elderly patients and patients with impaired hepatic function (liver) (but normal kidney function) should receive the same dose as normal adults.

Dosage in patients with renal insufficiency (creatinine clearance ≤ 50 ml/min):

If kidney function is lower than normal, your doctor will reduce the dose of LEVOFLOXACIN NORMON 5 mg/ml Solution for Intravenous Infusion in the following way:

	250 mg/24 h	**500 mg/24 h**	**500 mg/12 h**
Creatinine clearance	Initial dose 250 mg	Initial dose 500 mg	Initial dose 500 mg
50-20 ml/min	Then: 125 mg/24 h	Then: 250 mg/24 h	Then: 250 mg/12 h
19-10 ml/min	Then: 125 mg/48 h	Then: 125 mg/24 h	Then: 125 mg/12 h
< 10 ml/min (including haemodialysis and CAPD)[1]	Then: 125 mg/48 h	Then: 125 mg/24 h	Then: 125 mg/24 h

[1]: Additional doses after haemodialysis or continuous ambulatory peritoneal dialysis (CAPD) are not required.

Length of treatment:

The length of treatment is determined by the clinical status and response to treatment. As with all antibacterial agents, treatment with LEVOFLOXACIN NORMON should be continued for a minimum of 2 to 3 days after body temperature has returned to normal and symptoms have disappeared.

• If you get more LEVOFLOXACIN NORMON 5 mg/ml than you should:

Your doctor or nurse will ensure that you receive the correct intravenous dose. An accidental overdose could lead to symptoms in the central nervous system, such as confusion, dizziness, alteration to consciousness and seizures and heart disorders, which could cause abnormal heart rate. In case of overdose, the treatment will depend on the symptoms. Levofloxacin is not eliminated from the body by dialysis. There is no specific antidote.

In the event of overdose or accidental ingestion, contact the Toxicology Information Service.

4. POSSIBLE SIDE EFFECTS

Like all medicines, LEVOFLOXACIN NORMON can have side effects, although not everyone suffers from them.

Cardiac disorders: *Rare (at least 1 per 10,000 patients):* abnormal drop in blood pressure (hypotension), abnormally fast heartbeat (tachycardia). *Very rare (less that 1 per 10,000 patients):* circulatory collapse (anaphylactic shock). *Isolated cases:* heart disorders that can possibly lead to abnormal heart rate.

Blood disorders: *Infrequent (at least 1 per 1,000 patients):* increase or decrease in white corpuscle count. *Rare (at least 1 per 10,000 patients):* decrease in platelet count in blood, leading to a tendency to bruise and bleed easily. *Very rare (less that 1 per 10,000 patients):* sharp drop in white corpuscle count (agranulocytosis), which produces symptoms of recurring or persistent fever, sore throat and a feeling of getting worse. *Isolated cases:* severe drop in red blood cell count due to breakage of cells (haemolytic anaemia), drop in blood cells (pancytopenia).

Nervous system disorders: *Infrequent (at least 1 per 1,000 patients):* headache, dizziness, somnolence, sleep disorders. *Rare (at least 1 per 10,000 patients):* pins and needles in hands and feet (paraesthesia), trembling, restlessness (agitation), anxiety, depression, psychotic reactions, fits (seizures) and confusion. *Very rare (less that 1 per 10,000 patients):* sight and hearing disorders, taste and smell disorders, clumsiness (swelling), psychiatric problems including hallucinations and changes of mood. It may also cause movement disorders including difficulties with gait.

Gastrointestinal disorders: *Frequent (at least 1 per 100 patients):* nausea, diarrhoea. *Infrequent (at least 1 per 1,000 patients):* loss of appetite (anorexia), gastric disorders (dyspepsia), vomiting, abdominal pain. *Rare (at least 1 per 10,000 patients):* diarrhoea with blood which in very rare cases may indicate enterocolitis (inflammation of the colon with diarrhoea), including pseudomembranous colitis. *Very rare (less than 1 per 10,000 patients):* sharp drop in blood sugar levels (hypoglycaemia), which may be important in diabetic patients who are being treated with hypoglaecemic drugs.

Renal and urinary disorders: *Very uncommon (at least 1 in 1,000 patients):* abnormal values in blood tests due to kidney problems. *Very common (at least 1 in 10,000 patients):* Kidney function problems and, occasionally, renal failure that may result from renal inflammation of an allergic type (interstitial nephritis).

Skin disorders and subcutaneous tissue: *Frequent (at least 1 per 100 patients):* itching and rash. *Rare (at least 1 per 10,000 patients):* general allergic reactions (anaphylactic/anaphylactoid reactions) which can occasionally occur minutes or hours after the first dose, with symptoms that may be wheals, irritation or itching on the skin (rash) and difficulty in breathing which may become severe (dyspnoea/bronchospasm). *Very rare (less that 1 per 10,000 patients):* sudden drop in blood pressure or shock, allergic skin reactions such as photosensitivity (allergic reaction to sunlight and ultraviolet light). *Isolated cases:* severe, blistering reactions of the skin and mucous membranes (Stevens-Johnson syndrome), appearance of multiple, large blisters (toxic epidermal necrolysis or Lyell's syndrome) and exudative erythaema multiforme.

Muscle, bone and tendon disorders: *Rare (at least 1 per 10,000 patients):* pain and inflammation of the tendons (tendonitis) (e.g. Achilles tendon), joint and muscle pain. *Very rare (at least 1 per 10,000 patients):* ruptured tendon (e.g. the Achilles tendon). This adverse reaction may occur within 48 hours of starting treatment and may occur in both extremities. Muscle weakness, which may be particularly notable in patients with myasthenia gravis (a rare disease of the nervous system). *Isolated cases:* muscle disorders with muscle cell lesions (rhabdomyolysis).

Hepatobiliary disorders: *Frequent (at least 1 per 100 patients):* increase in hepatic enzyme levels in blood. *Infrequent (at least 1 per 1,000 patients):* abnormal analysis values due to kidney or liver problems. *Very rare (less that 1 per 10,000 patients):* inflammation of the liver.

Other reactions: *Infrequent (at least 1 per 1,000 patients):* general weakness. *Very rare:* fever, allergic inflammation of the minor blood vessels or pulmonary allergic reactions.

Some drugs in the family to which LEVOFLOXACIN NORMON belongs may induce attacks of porphyria in patients with porphyria (very rare metabolic disease). Thus, this may also occur with LEVOFLOXACIN NORMON.

Any antibacterial treatment that eliminates certain germs may lead to imbalance in the microorganisms (bacteria / fungi) that are normally found in humans. Consequently, the number of other bacteria or fungi may increase, which in rare cases may require treatment.

If you think any of the side effects you suffer are severe or if you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE LEVOFLOXACIN NORMON 5 mg/ml SOLUTION FOR INTRAVENOUS INFUSION

Keep LEVOFLOXACIN NORMON out of the reach and sight of children.

Your doctor or nurse will ensure that LEVOFLOXACIN NORMON is stored correctly.

Bottles: Store below 30ºC. Keep the bottle in the outer packaging in order to protect it from light.

Bags: Store below 25ºC. Protect from humidity. Keep the bag in the outer packaging in order to protect it from light.

Expiry: do not use LEVOFLOXACIN NORMON after the expiry date shown on the packaging after EXP. The expiry date is the last day of the indicated month.

Medicinal products should not be poured down the drain or thrown into the rubbish. Ask a pharmacist how to dispose of packaging and medicinal products you do not need. This will help to protect the environment.

Throw away if you observe any alterations either in the container of the liquid.

6. ADDITIONAL INFORMATION

Composition of LEVOFLOXACIN NORMON 5 mg/ml SOLUTION FOR INTRAVENOUS INFUSION

The drug substance is levofloxacin. Each 100 ml of solution contains levofloxacin hemihydrate, equivalent to 500 mg of levofloxacin.

The other components (excipients) are: sodium chloride, hydrochloric acid or sodium hydroxide and water for injection.

Product appearance and contents of the package:

LEVOFLOXACIN NORMON 5 mg/ml is a yellow-greenish solution. Each packet contains 1 transparent glass bottle of 100 ml or a 1/ 20 plastic bags of 100 ml with a plastic outer bag.

Marketing authorization holder and manufacturer:

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

This information is intended for medical or healthcare professionals only:

LEVOFLOXACIN NORMON 5 mg/ml solution for intravenous infusion is a product prepared for use which should only be administered by slow intravenous infusion. Infusion time for 500 mg (100 ml) ***should not be less than 60 minutes*** (1 hour).

PRECAUTIONS:

Infusion Time

Observe the infusion time of at least 60 minutes per 500 mg of LEVOFLOXACIN NORMON (100 ml of solution for infusion). It is known that during infusion with ofloxacin, tachycardia and temporary drop in blood pressure may occur. In rare cases, circulatory collapse may occur as a result of a sharp drop in blood pressure. If there is a marked drop in blood pressure during infusion with levofloxacin (l-isomer ofloxacin), infusion should be stopped immediately.

Until its use, the bottle of LEVOFLOXACIN NORMON should be kept in its outer packaging to protect it from light. No protection from light is required for the infusion period or three days after removal from its exterior packaging if kept under indoor lighting conditions.

Until its use, the bag of LEVOFLOXACIN NORMON should be kept in its outer bag in order to protect it from light. No protection from light is required for the infusion period. After perforating the rubber cap, the solution should be used immediately (within 3 hours) to prevent possible bacterial contamination.

LEVOFLOXACIN NORMON should not be mixed with certain solutions (e.g. sodium bicarbonate) or heparin.

LEVOFLOXACIN NORMON may be administered alone or with one of the following solutions: 0.9% sodium chloride solution, USP; 5% glucose, USP; 2.5% glucose in Ringer solution; combination solutions for parenteral nutrition (amino acids, carbohydrates, electrolytes). The validity period of the product in the different solutions is a maximum of 8 hours at 25ºC.

OTHER PRESENTATIONS

LEVOFLOXACIN NORMON 500 mg Film-coated tablets.