

Levodopa®
5 mg/ml , solution for intravenous infusion
Lefvofloxacin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- If you need more time 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. See section 4.

What is in this leaflet:

1. What Levodopa 5 mg/ml solution for intravenous infusion is and what it is used for
2. What you need to know before you take Levodopa 5 mg/ml solution for intravenous infusion
3. How Levodopa 5 mg/ml solution for intravenous infusion is given
4. Possible side effects
5. How to store Levodopa 5 mg/ml solution for intravenous infusion
6. Contents of the pack and other information

1. What Levodopa 5 mg/ml solution for intravenous infusion is and what it is used for
The name of your medicine is Levodopa 5 mg/ml solution for intravenous infusion.
Levodopa 5 mg/ml solution for intravenous infusion contains a medicine called levofloxacin.
Levodopa is a 'quinolone' antibiotic. It works by killing the bacteria that cause infections in your body.

Levodopa 5 mg/ml solution for intravenous 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 soft tissues of the skin, including muscles. This is sometimes called 'soft tissue'.
 - In some special situations, Levodopa solution for intravenous 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 take Levodopa 5 mg/ml solution for intravenous infusion**
Do not take Levodopa 5 mg/ml solution for intravenous infusion 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)
 - You have had an allergic reaction including: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
 - You have ever had epilepsy
 - Skin and soft tissue infections 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 adolescent
 - You are pregnant, might become pregnant, or think you may be pregnant
 - You are breast-feeding

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist as you are given Levodopa 5 mg/ml solution for intravenous infusion.

Warnings and Precautions

Talk to your doctor, nurse or pharmacist before taking Levodopa 5 mg/ml solution for intravenous infusion if:

- You are 60 years of age or older
- You are using corticosteroids, sometimes called steroids (see section "Other medicines and Levodopa 5 mg/ml solution for intravenous 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 (G6PD) 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 heart disease, lowering in the level of potassium or magnesium in the blood, have a very slow heart rhythm (called or elderly) or you are taking other medicines that result in abnormal ECG changes (see section "Other medicines and Levodopa 5 mg/ml solution for intravenous 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 dissection or aortic dissection or other 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 cholesterol, 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.
If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given Levodopa 5 mg/ml solution for intravenous infusion.

Other medicines and Levodopa 5 mg/ml solution for intravenous infusion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Levodopa 5 mg/ml solution for intravenous infusion can affect the way some other medicines work. Also some medicines can affect the way Levodopa 5 mg/ml solution for intravenous infusion works.

Medicines and Levodopa 5 mg/ml solution for intravenous infusion

- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation if you take these medicines.
- 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, fenfen, ketoprofen, indomethacin. You are more likely to have a fit (seizure) if taken with levofloxacin.
- Ciprofloxacin – used after organ transplants. You may be more likely to get the side effects of ciprofloxacin.
- Metoclopramide – used for 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 ('tetracycline' antibiotics such as erythromycin, azithromycin and clarithromycin).
- Probenecid – used for gout. Special care should be taken when taking this medicine with levofloxacin. Your doctor may want to use a lower dose, if you have kidney problems.
- Cimetidine – used for ulcers and heartburn. Special care should be taken when taking this medicine with levofloxacin.

Your doctor may want to use a lower dose, if you have kidney problems.

Urine tests for opiates

Urine tests may show 'false-positive' results for strong painkillers called 'opiates' in people taking levofloxacin. If your doctor has prescribed a urine test, tell your doctor you are having levofloxacin.

Tuberculosis tests

This medicine may cause 'false negative' results for some laboratory tests that search for the bacteria that cause 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 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.

Levodopa 5 mg/ml solution for intravenous infusion contains sodium chloride

This medicinal product contains 840 mg of sodium chloride per dose of 500 mg levofloxacin (100 ml). This should be taken into consideration by patients on a controlled sodium diet.

How Levodopa 5 mg/ml solution for intravenous infusion is given

How Levodopa 5 mg/ml solution for intravenous infusion is given

- Levodopa 5 mg/ml solution for intravenous 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)
- Your doctor will decide the dose of intravenous 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 Levodopa 5 mg/ml solution for intravenous infusion 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 doctor 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 the elderly

- Pneumonia: 500 mg once or twice each day
- Infection of urinary tract, including your kidneys or bladder: 500 mg once each day
- Prostate gland infection: 500 mg once each day
- Infection of skin and soft tissues, including muscles: 500 mg once or twice each day.

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 having the 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

You have received Levodopa 5 mg/ml solution for intravenous 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 is 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 miss a dose of Levodopa 5 mg/ml solution for intravenous 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 having Levodopa 5 mg/ml solution for intravenous infusion

Your doctor or nurse will continue giving you Levodopa 5 mg/ml solution for intravenous infusion, even if you feel better. If it stopped too soon, the infection may return, 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 medicine, ask your doctor, nurse, or pharmacist.

4. Possible side effects

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 Levodopa 5 mg/ml solution for intravenous infusion and tell a doctor or nurse straight away if you notice the following side effect:

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

your lips, face, throat, or tongue.

Stop having Levodopa 5 mg/ml solution for intravenous infusion and tell a doctor or nurse straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

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'

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 genitalia

• Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen). These may be signs of liver problems which may include a fatal failure of the liver.

If you have any of the above side effects, or if you have any other eye disturbances whilst having Levodopa 5 mg/ml solution for intravenous infusion, consult an eye specialist immediately.

Tell your doctor if any of the following side effects get 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 a 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 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)

• Increased immune response (hypersensitivity)

• Lowering of your blood sugar levels (hypoglycaemia). This is important for people who have diabetes.

• Seeing or hearing things that are not there (hallucinations, paraesthesia), 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.

• Double vision (diplopia) or blurred vision

• 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 (arthralgia-like like shock)

• Increase of your blood sugar levels (hyperglycaemia) or lowering of your blood sugar levels leading to coma (hypoglycaemia) coma). This is important for people who have diabetes.

• Changes in the way things smell, loss of smell (anosmia), loss of taste (ageusia)

• Problems moving and walking (dyskinesia, extrapyramidal disorders)

• Loss of consciousness or loss of consciousness (syncope)

• Temporary loss of vision

• Impairment or loss of hearing

• Abnormal 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

• 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)

• Muscle rupture and muscle destruction (rhabdomyolysis)

• Joint redness and swelling (arthritis)

• Pain, swelling and redness 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)

Reporting of side effects

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

Saudi Arabia:

The National Poison Information and Drug Safety Centre (NPC)

• Fax: +966 - 11 205 7662

• Call NPC at +966 - 11 - 2038222, Ext: 2317 - 2356 - 2340.

• Reporting hotline: 19999

• Email: npc.druginfo@sdpa.gov.sa

• Website: www.sdpa.gov.sa/npc

• Other GCC states:

1. Please contact the relevant competent authority.

5-How to store Levodopa 5 mg/ml solution for intravenous infusion

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

Store below 30°C and keep away from light.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP.

The expiry date refers to the last day of that month.

Do not use Levodopa if you notice that the solution is not a clear yellowish limpid liquid and has particles on it.

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.

Shelf life: 36 months

6 - Contents of the pack and other information

What Levodopa 5 mg/ml solution for intravenous infusion contains:

The active substance is levofloxacin hemihydrate 512 mg (500 mg as base);

One ml of solution for intravenous infusion contains 5 mg of Levofloxacin.

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

What Levodopa 5 mg/ml solution for intravenous infusion looks like and contents of the pack:

Levodopa solution for intravenous infusion is available in one presentation.

Levodopa 5mg/ml solution for intravenous infusion is a slightly yellowish limpid liquid.

It is presented in glass bottle.

Pack size:

The 100 ml bottle: 1 bottle per box.

Marketing Authorisation Holder and Manufacturer:

LES LABORATOIRES MEDIS-S.A.

Route de Tunis- KM 7 - BP 206 - 8000 Nabed - Tunisie

Tel: (216) 72 23 50 06 / Fax: (216) 72 23 51 06

E-mail: marketing.ventes@medis.com.tn

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

Salehija Trading Establishment

(Medical equipment & pharmaceuticals)

P.O.Box: 991, Riyadh 11421 - Kingdom of Saudi Arabia

Tel: 00 966 1 46 46 955 / Fax: 00 966 1 46 34 362

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Instructions issued by Council of Arab Health Ministers

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- The doctor and the pharmacist are experts in medicine in bettering your health.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicines out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

This presentation information leaflet is approved by the Saudi Food and Drug Authority



