

Patient Information Leaflet LEVOFLOXACIN 250 / 500 BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LEVOFLOXACIN 250 BIOTECH solution for infusion

LEVOFLOXACIN 500 BIOTECH solution for infusion

Levofloxacin hemihydrate

Sugar free

Read all of this leaflet carefully before you start using LEVOFLOXACIN BIOTECH:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

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

1. What LEVOFLOXACIN BIOTECH is and what it is used for

LEVOFLOXACIN BIOTECH 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 causes infections in your body.

LEVOFLOXACIN BIOTECH may be used to treat the following:

- Infection of the sinuses (sinusitis).
- Infections of the lungs (chronic bronchitis or pneumonitis).
- Infection of prostate gland, where you have a long-lasting infection.
- Urinary tract infections, including your kidneys or bladder.
- Infections of the skin and underneath the skin, including muscles. This is sometimes called 'soft tissue'.
- Infections in the stomach (intra-abdominal infections).

2. What you need to know before you use LEVOFLOXACIN BIOTECH

Do not use LEVOFLOXACIN BIOTECH if:

- You are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or ofloxacin, or any of the other ingredients of LEVOFLOXACIN BIOTECH (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 convulsion.
- 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 might be pregnant.
- You are breastfeeding.
- Your heart's mitral valve or aortic valve doesn't close tightly, allowing blood to flow backward in your heart.

- You are on treatment for high blood pressure with medicines called angiotensin converting enzyme (ACE) inhibitors/angiotensin receptor blockers (ARBs).

Warnings and precautions:

You should not take fluoroquinolone/quinolone antibacterial medicines, including receiving 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.

Talk to your doctor, nurse or pharmacist before you receive LEVOFLOXACIN BIOTECH:

- If you are 60 years of age or older.
- If you are using corticosteroids, sometimes called steroids.
- If you have ever had a fit (seizure).
- If you have had damage to your brain due to a stroke or other brain injury.
- If you have kidney problems.
- If you have something known as glucose 6-phosphate dehydrogenase (G6PD) deficiency (a rare hereditary disease). You are more likely to have serious problems with your blood when receiving LEVOFLOXACIN BIOTECH.
- If you have ever had mental health problems.
- If you have ever had heart problems: caution should be taken when using this kind of medicine, if you were born with or any member of your family has had (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 "Taking other medicines").
- If you have been diagnosed with an enlargement or bulge of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- If you have experienced a previous episode of aortic dissection (a tear in the aorta wall).

- If 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).
- If you are diabetic.
- If you have ever had liver problems.
- If you have myasthenia gravis.
- If you feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.
- Caution should be taken while taking medicine from the group ACE inhibitors/ARBs (types of antihypertensive medicines) and fluoroquinolone, including levofloxacin, as there is risk of acute kidney injury with concomitant use of both medicine groups.

You should not take fluoroquinolone/quinolone antibacterial medicines, including levofloxacin, if your heart's mitral valve or aortic valve doesn't close tightly. A thorough cardiovascular examination including electrocardiogram should be performed before consuming fluoroquinolone/quinolone class of medicines.

Take special care with LEVOFLOXACIN BIOTECH:

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, receive daily doses of 1 000 mg levofloxacin 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 BIOTECH 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 BIOTECH 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.

Other medicines and LEVOFLOXACIN BIOTECH:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because LEVOFLOXACIN BIOTECH can affect the way some other medicines work. Also some medicines can affect the way that LEVOFLOXACIN BIOTECH 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 using LEVOFLOXACIN BIOTECH.

- ACE inhibitors/ARBs used to control your blood pressure (see section “Do not use LEVOFLOXACIN BIOTECH”).
- 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 BIOTECH
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (used for pain and inflammation) such as aspirin, ibuprofen, fenbufen, ketobrufen, indomethacin. You are more likely to have a fit (seizure) if taken with LEVOFLOXACIN BIOTECH
- 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 (antidysrhythmics 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 BIOTECH. 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 BIOTECH. If your doctor has prescribed a urine test, tell your doctor that you have been given LEVOFLOXACIN BIOTECH.

Tuberculosis tests:

Levofloxacin may cause false negative results for some tests used in laboratory to search for the bacteria causing tuberculosis.

Pregnancy and breastfeeding:

You should not receive LEVOFLOXACIN BIOTECH when you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving LEVOFLOXACIN BIOTECH.

Driving and using machines:

You may get side effects after being given LEVOFLOXACIN BIOTECH, 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 BIOTECH contains sodium:

LEVOFLOXACIN 250 BIOTECH contains 7,7 mmol (177 mg) sodium per 50 mL solution for infusion.

LEVOFLOXACIN 500 BIOTECH contains 15,4 mmol (354 mg) sodium per 100 mL solution for infusion.

This should be taken into consideration if you are on a controlled sodium diet.

3. How to use LEVOFLOXACIN BIOTECH

LEVOFLOXACIN BIOTECH 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 LEVOFLOXACIN 250 BIOTECH, the infusion time should be 30 minutes or more.
- For LEVOFLOXACIN 500 BIOTECH, 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 BIOTECH is given:

If you are not sure why you are being given LEVOFLOXACIN BIOTECH or have any questions about how much LEVOFLOXACIN BIOTECH 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 the elderly:

Sinusitis: 500 mg once daily for 10 days

Acute exacerbation of chronic bronchitis: 500 mg once daily for 5 - 10 days

Pneumonia: 500 mg once or twice daily for 10 - 14 days

Prostatitis: 500 mg once a day for 28 days.

Complicated urinary tract infections and acute pyelonephritis: 250 mg once daily for 10 days

Uncomplicated urinary tract infections in women: 250 mg once daily for 3 days

Complicated skin and skin structure infections: 500 mg twice daily for 10 - 14 days

Intra-abdominal infections: 500 mg once daily in combination with an antibiotic with anaerobic coverage for 10 - 14 days.

Above indications when bacteraemia or septicaemia is present: 500 mg twice daily for 10 - 14 days.

If you have kidney problems:

Your doctor may need to give you a lower dose.

If you are elderly or have liver problems:

Your doctor does not need to adjust the dose.

Protect your skin from sunlight:

Keep out of direct sunlight while using LEVOFLOXACIN BIOTECH and for 2 days after stopping. 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 hat and clothes which cover your arms and legs.
- Avoid sun beds.

If you receive more LEVOFLOXACIN BIOTECH 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.

Receiving too much LEVOFLOXACIN BIOTECH 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 LEVOFLOXACIN BIOTECH:

Since a health care provider will have instructions on when to give you this medicine, it is unlikely that

you will not be given LEVOFLOXACIN BIOTECH as it has been prescribed. However, if you do think you have missed a dose, tell your health care provider.

If you stop receiving LEVOFLOXACIN BIOTECH:

Your health care provider will continue giving you LEVOFLOXACIN BIOTECH, even if you feel better. If it is stopped too soon, your condition may get worse or the bacteria may become resistant to LEVOFLOXACIN BIOTECH. After a few days treatment with the solution for infusion, your doctor may decide to switch you to a tablet form of levofloxacin to complete your course of treatment.

4. Possible side effects

LEVOFLOXACIN BIOTECH can have side effects.

Not all side effects reported for LEVOFLOXACIN BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving LEVOFLOXACIN BIOTECH, please consult your health care professional for advice.

If any of the following happens, stop administration of LEVOFLOXACIN BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms.

These are all very serious side effects. If you have them, you may have had a serious reaction to LEVOFLOXACIN BIOTECH. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice

any of the following:

- 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).
- Burning, tingling, pain, or numbness. These may be signs of something called neuropathy.
- 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.
- Persistent headache with or without blurred vision (benign intracranial hypertension).
- Increase of your blood sugar levels (hyperglycaemia) or lowering of your blood sugar levels (hypoglycaemia) leading to coma (hypoglycaemic coma). 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.
- Unusual fast beating of your heart (tachycardia).
- 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).
- Shortness of breath (dyspnoea) or difficulty breathing or wheezing (bronchospasm).
- If your eyesight becomes impaired or if you have any other eye disturbances whilst taking LEVOFLOXACIN BIOTECH, consult an eye specialist immediately.
- Pancreatitis, inflammation of the liver (hepatitis).
- Changes in the way your kidney works and occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis.
- Muscle weakness. This is important in people with myasthenia gravis (a disease of the nervous

system).

- Muscle rupture and muscle destruction (rhabdomyolysis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

Frequent side effects:

- 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.

Less frequent side effects:

- Infection by fungi named Candida (yeast infections) and resistance of certain microorganisms.
- Changes in the number of white blood cells (leukopenia, eosinophilia, neutropenia, agranulocytosis). This may result in fever, sore throat and a general feeling of being unwell that does not go away.
- Bruising and bleeding easily due to a lowering in the number of blood platelets (thrombocytopenia).
- Loss of appetite (anorexia).
- Feeling stressed (anxiety), feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling (vertigo).
- Feeling depressed, mental problems, feeling restless (agitation), abnormal dreams or nightmares.
- Changes in the way things smell or taste, loss of smell or taste (parosmia, anosmia, dysgeusia, ageusia).
- Tingly feeling in your hands and feet (paraesthesia).
- Problems with eyesight (blurred vision) or temporary loss of vision.

- Problems with your hearing (tinnitus), impairment or loss of hearing.
- Low blood pressure (hypotension).
- Loss of appetite, stomach upset or indigestion (dyspepsia), pain in your stomach area, feeling bloated (flatulence) or constipation.
- Blood tests may show unusual results due to liver (bilirubin increased) or kidney (creatinine increased) problems.
- Itching and skin rash, severe itching or hives (urticaria), sweating too much (hyperhidrosis).
- Joint pain or muscle pain.

Side effect of unknown frequency:

- Lowering in red blood cells (anaemia): 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).
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).
- Temporary loss of consciousness or posture (syncope).
- Problems moving and walking (dyskinesia, extrapyramidal disorders).
- Joint redness and swelling (arthritis).
- Inflammation of the vessels that carry blood around your body due to an allergic reaction (vasculitis).
- Inflammation of the tissue inside the mouth (stomatitis).
- Pain, including pain in the back, chest and extremities.
- Attacks of porphyria in people who already have porphyria (a metabolic disease).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LEVOFLOXACIN BIOTECH.

5. How to store LEVOFLOXACIN BIOTECH

Store at or below 25 °C.

Keep container in the outer carton to protect from light.

Do not use after expiry date stated on the carton.

Any unused solution must be discarded.

Do not dispose of unused medicine in drains or sewerage systems; return them to your doctor or pharmacist.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What LEVOFLOXACIN BIOTECH contains:

The active substance levofloxacin hemihydrate.

LEVOFLOXACIN 250 BIOTECH: Each 50 mL vial contains levofloxacin hemihydrate equivalent to 250 mg levofloxacin.

LEVOFLOXACIN 500 BIOTECH: Each 100 mL vial contains levofloxacin hemihydrate equivalent to 500 mg levofloxacin.

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

What LEVOFLOXACIN BIOTECH looks like and contents of the pack:

Yellow to greenish yellow clear solution, practically free from particles.

LEVOFLOXACIN 250 BIOTECH is packed in 50 mL colourless glass vial with grey aluminium chlorobutyl rubber stopper and aluminium cap with polypropylene flip off seal and into a cardboard carton.

LEVOFLOXACIN 500 BIOTECH is packed in 100 mL colourless glass vial with grey aluminium chlorobutyl rubber stopper and aluminium cap with polypropylene flip off seal and into a cardboard

Biotech Laboratories (Pty) Ltd
Levofloxacin 250 / 500 Biotech
Solution for infusion
Each vial containing 250 / 500 mg levofloxacin as levofloxacin hemihydrate

carton.

Holder of certificate of registration:

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