Approved Patient Information Leaflet for Medicines for Human Use:

LEVOFLOXACIN IV 5 mg/mL AUSTELL

SCHEDULING STATUS: S4

LEVOFLOXACIN IV AUSTELL 5 mg/mL Solution for infusion

Levofloxacin hemihydrate

Sugar free

Read all of this leaflet carefully before you are given LEVOFLOXACIN IV 5 mg/mL AUSTELL.

- 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 IV 5 mg/mL AUSTELL is and what it is used for
2. What you need to know before you take use LEVOFLOXACIN IV 5 mg/mL AUSTELL
3. How to take use LEVOFLOXACIN IV 5 mg/mL AUSTELL
4. Possible side effects
5. How to store LEVOFLOXACIN IV 5 mg/mL AUSTELL
6. Contents of the pack and other information

1. WHAT LEVOFLOXACIN IV 5 mg/mL AUSTELL is and what it is used for

The name of your medicine is LEVOFLOXACIN IV 5 mg/mL AUSTELL Solution for Infusion and it 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. It is used to treat certain bacterial infections in the body.

2. What you need to know before you are given LEVOFLOXACIN IV 5 mg/mL AUSTELL

Do not take LEVOFLOXACIN IV 5 mg/mL AUSTELL:

LEVOFLOXACIN IV 5 mg/mL AUSTELL should not be administered to you:

- if you are hypersensitive (allergic) to levofloxacin, other quinolones or any of the other ingredients of LEVOFLOXACIN IV 5 mg/mL AUSTELL listed in section 6
- if you have ever had epilepsy
- **if you or your child are younger than 18 years**
- if you are pregnant, might become pregnant, or think you might be pregnant
- if you are breastfeeding
- if you have ever had tendon (ligament) problems related to treatment with a fluoroquinolone antibiotic
- if you have moderate to severe kidney problems and are on treatment for high blood pressure with medicines called ACE inhibitors/angiotensin receptor blockers. Ask your doctor if you are unsure
- if you have a damaged mitral and/or aortic heart valve which cannot close properly.

You should not be given LEVOFLOXACIN IV 5 mg/mL AUSTELL 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 IV 5 mg/mL AUSTELL solution for infusion.

Warnings and precautions

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.

Special care should be taken with LEVOFLOXACIN IV 5 mg/mL AUSTELL:

- if you are using corticosteroids, sometimes called steroids (see Other Medicines and LEVOFLOXACIN IV 5 mg/mL AUSTELL)
- if you have ever had a fit (seizure) (see Do Not Take LEVOFLOXACIN IV 5 mg/mL AUSTELL)

- if you have had damage to your brain due to a stroke or other brain injury (see Do Not Take LEVOFLOXACIN IV 5 mg/mL AUSTELL)
- if you have kidney problems as the doctor may need to adjust the dose of LEVOFLOXACIN IV 5 mg/mL AUSTELL
- if you have a condition known as 'glucose 6-phosphate dehydrogenase (G6PD) deficiency'. You are more likely to have serious problems with your blood when taking LEVOFLOXACIN IV 5 mg/mL AUSTELL
- if you are currently taking other medicines that can reduce your blood potassium levels (see Other Medicines and LEVOFLOXACIN IV 5 mg/mL AUSTELL)
- if you have ever had mental health problems such as history of psychosis (seeing, hearing or believing things that are not real) or any psychiatric disease such as schizophrenia or a depressive disorder
- if you have a family history of aortic aneurysm or aortic dissection or other risk factors or existing predisposing conditions (e.g. connective tissue disorders such as Marfan Syndrome, Vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure or known atherosclerosis (see Do Not Take LEVOFLOXACIN IV 5 mg/mL AUSTELL). If you develop sudden abdominal, chest or back pain, seek help immediately at the casualty department at your nearest hospital
- if you have ever had heart problems, 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 Other Medicines and LEVOFLOXACIN IV 5 mg/mL AUSTELL)
- 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 are diabetic consult your doctor before taking LEVOFLOXACIN IV 5 mg/mL AUSTELL. LEVOFLOXACIN IV 5 mg/mL AUSTELL may cause disturbances in your blood sugar level, especially if you are elderly and treated with oral medicines or insulin to lower your blood sugar. Your doctor may wish to monitor your blood sugar during your treatment with LEVOFLOXACIN IV 5 mg/mL AUSTELL
- if you have ever had liver problems or if you have an underlying disease such as sepsis. If you develop yellow skin or eyes, or if you have pain in your abdomen or dark urine, contact your doctor immediately
- if you have myasthenia gravis (type of muscle weakness), you should not be treated with LEVOFLOXACIN IV 5 mg/mL AUSTELL as it may worsen the disease
- LEVOFLOXACIN IV 5 mg/mL AUSTELL may interfere with the interpretation of diagnostic culture tests for tuberculosis
- 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 that you have been given LEVOFLOXACIN IV 5 mg/mL AUSTELL.
- if you suffer from porphyria (this is a disease which is usually hereditary and affects the skin and/or the nervous system), inform your doctor before being given LEVOFLOXACIN IV 5 mg/mL AUSTELL.
- if you develop symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms inform your doctor immediately as you will need to be treated to avoid irreversible damage.

Fluoroquinolone / quinolone antibacterial medicines, including levofloxacin, such as in LEVOFLOXACIN IV 5 mg/mL AUSTELL have been associated with side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Inflammation and ruptures of tendons may occur within the first 48 hours of treatment with LEVOFLOXACIN IV 5 mg / mL AUSTELL and even up to several months after stopping LEVOFLOXACIN IV 5 mg / mL AUSTELL 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 IV 5 mg / mL AUSTELL, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture. Pain and swelling in the joints and inflammation or rupture of tendons may occur. 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.

Children and adolescents

LEVOFLOXACIN IV 5 mg/mL AUSTELL must not be given to children and adolescents under the age of 18 years.

Other medicines and LEVOFLOXACIN IV 5 mg/mL AUSTELL

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

This is because LEVOFLOXACIN IV 5 mg/mL AUSTELL solution for infusion can affect the way some other medicines work. Also, some medicines can affect the way that LEVOFLOXACIN IV 5 mg/mL AUSTELL solution for infusion works.

Medicines which may affect the way that LEVOFLOXACIN IV 5 mg/mL AUSTELL works:

Tell your doctor if you are taking any of the following medicines:

- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or rupture of your tendons.
- 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, fenbufen, ketobrufen, indomethacin. You are more likely to have a fit (seizure) if taken with levofloxacin.
- Probenecid - used for gout and cimetidine - used for ulcers and heartburn. Special care should be taken when taking either of these medicines with levofloxacin. If you have kidney problems, your doctor may want to give you a lower dose.
- If you are on treatment with ACE inhibitors/angiotensin receptor blockers used to control your blood pressure. Ask your doctor if you are not sure.

Effect of levofloxacin such as in LEVOFLOXACIN IV 5 mg/mL AUSTELL on other medicines:

Tell your doctor if you are taking any of the following 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.
- 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 (antiarrthythmics 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).
- Medicines that you are taking for diabetes such as insulin, glibenclamide, glimepride, metformin or others. You may need to test your blood sugar more often.

Pregnancy and breastfeeding

You should not use LEVOFLOXACIN IV 5 mg/mL AUSTELL during pregnancy or when breastfeeding your baby. LEVOFLOXACIN IV 5 mg/mL AUSTELL may cause damage to the cartilage of weight bearing joints of the 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 taking LEVOFLOXACIN IV 5 mg/mL AUSTELL.

Driving and using machines

You may get side effects after being given this medicine, LEVOFLOXACIN IV 5 mg/mL AUSTELL may make you feel dizzy, sleepy, have 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, and therefore your ability to drive and operate machines.

It is not always possible to predict to what extent LEVOFLOXACIN IV 5 mg/mL AUSTELL may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which LEVOFLOXACIN IV 5 mg/mL AUSTELL affects you.

LEVOFLOXACIN IV 5 mg/mL AUSTELL contains sodium

LEVOFLOXACIN IV 5 mg/mL AUSTELL contains 15,4 mmoL (354,2 mg) sodium per 100 mL dose. This should be taken into consideration by patients on a controlled sodium diet.

3. How to take use LEVOFLOXACIN IV 5 mg/mL AUSTELL

Carefully follow all instructions given to you by your doctor, nurse or pharmacist. Check with your doctor, nurse or pharmacist if you are not sure.

You will not be expected to give yourself LEVOFLOXACIN IV 5 mg/mL AUSTELL. It will be given to you by a person who is qualified to do so.

LEVOFLOXACIN IV 5 mg/mL AUSTELL will be given to you as an infusion into a large vein over a period of time. Your heart rate and blood pressure will be monitored during the infusion.

- Your doctor will decide on how much levofloxacin you should have

- The dose will depend on the type of infection you have, where the infection is in your body and also your kidney function
- The length of your treatment will depend on how serious your infection is.

Your doctor will tell you how long your treatment with LEVOFLOXACIN IV 5 mg/mL AUSTELL will last. If you have the impression that the effect of LEVOFLOXACIN IV 5 mg/mL AUSTELL is too strong or too weak, tell your doctor or pharmacist.

If you are given more LEVOFLOXACIN IV 5 mg/mL AUSTELL than you should

Since a health care provider will administer LEVOFLOXACIN IV 5 mg/mL AUSTELL, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take LEVOFLOXACIN IV 5 mg/mL AUSTELL

Since a health care provider will administer LEVOFLOXACIN IV 5 mg/mL AUSTELL, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

LEVOFLOXACIN IV 5 mg/mL AUSTELL can have side effects.

Not all side effects reported for LEVOFLOXACIN IV 5mg/mL AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving LEVOFLOXACIN IV 5 mg/mL AUSTELL, please consult your health care provider for advice.

If any of the following happens, while you are receiving LEVOFLOXACIN IV 5 mg/mL AUSTELL or after receiving LEVOFLOXACIN IV 5 mg/mL AUSTELL, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, tongue, throat and airways (breathing tubes), difficulty breathing, blueness of the skin, low blood pressure, heart failure and can result in death
- Rash or itching

These are all very serious side effects. If you have them, you may have had a serious reaction to LEVOFLOXACIN IV 5 mg/mL AUSTELL. You may need urgent medical attention or hospitalisation.

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’
- Severe skin rashes which may include blistering or peeling of the skin around your lips, eyes, mouth, nose and genitals
- 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
- Sudden severe pain in your chest, abdomen (tummy) or back
- Heart palpitations, chest pain, fatigue, or shortness of breath. These can be signs of aortic or mitral valve regurgitation (when the valves of the heart are not closing properly)

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

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking LEVOFLOXACIN IV 5 mg/mL AUSTELL, your doctor will consult an eye specialist immediately.

Tell your doctor 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:

- 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
- 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
- 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)
- 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).

Frequency not known side effects:

- 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 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
- 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, 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)
- Loss of memory.

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 your doctor or 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 IV 5 mg/mL AUSTELL.

5. HOW TO STORE LEVOFLOXACIN IV 5 mg/mL AUSTELL

Your doctor, pharmacist or healthcare professional knows how to store LEVOFLOXACIN IV 5 mg/mL AUSTELL The doctor or nurse who is administering LEVOFLOXACIN IV 5 mg/mL AUSTELL to you, will make sure that the medicine is not used after the expiry date printed on the vial.

- Store all medicines out of reach of children.
- Store at or below 25 °C.

They will also reconstitute LEVOFLOXACIN IV 5 mg/mL AUSTELL and visually inspect the solution before giving it to you. Only clear solution without particles will be used.

- From a microbiological point of view, LEVOFLOXACIN IV 5 mg/mL AUSTELL should be used immediately.
- If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.
- LEVOFLOXACIN IV 5 mg/mL AUSTELL is for single use only.
- Do not use LEVOFLOXACIN IV 5 mg/mL AUSTELL 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 LEVOFLOXACIN IV 5 mg/mL AUSTELL is cloudy or discoloured. Normally it is clear and greenish-yellow in colour.
- Compatibility of LEVOFLOXACIN IV 5 mg/mL AUSTELL with other infusion solutions: Chemical and physical in use stability has been demonstrated for 72 hours at 25 °C in 0,9 % sodium chloride solution, 5 % dextrose solution and 5 % dextrose in lactated Ringer’s solution, and 24 hours at 2 to 8 °C in combined solutions for parenteral nutrition.

6. Contents of the pack and other information

What LEVOFLOXACIN IV 5 mg/mL AUSTELL contains

The active substance is levofloxacin (as hemihydrate).

1 mL of solution contains 5 mg of levofloxacin

The other ingredients are sodium chloride, hydrochloric acid 10 %, sodium hydroxide 0,1N and water for injections.

What LEVOFLOXACIN IV 5 mg/mL AUSTELL looks like and contents of the pack

LEVOFLOXACIN IV 5 mg/mL AUSTELL is a clear, odourless, light yellow to greenish solution.

LEVOFLOXACIN IV 5 mg/mL AUSTELL is supplied in a 100 mL vial (Type I, glass) with either chlorobutyl or bromobutyl rubber stopper and blue, polypropylene flip-off cap.

Each vial contains 5 mg per mL of LEVOFLOXACIN IV 5 mg/mL AUSTELL

Each carton contains 1 or 12 vials.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Austell Laboratories (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

This leaflet was last revised in

11 May 2021

REGISTRATION APPLICATION NUMBER

50/20.1.1/0162