Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL-LEVOFLOXACIN

SCHEDULING STATUS: S4

AUSTELL-LEVOFLOXACIN 250 mg film-coated tablets

AUSTELL-LEVOFLOXACIN 500 mg film-coated tablets

Levofloxacin

Read all of this leaflet carefully before you start taking AUSTELL-LEVOFLOXACIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AUSTELL-LEVOFLOXACIN** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AUSTELL-LEVOFLOXACIN is and what it is used for

2. What you need to know before you take AUSTELL-LEVOFLOXACIN

3. How to take AUSTELL-LEVOFLOXACIN

4. Possible side effects

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6. Contents of the pack and other information

1. What AUSTELL-LEVOFLOXACIN is and what it is used for

AUSTELL-LEVOFLOXACIN contains the active substance levofloxacin. AUSTELL-LEVOFLOXACIN is an antibiotic belonging to the fluoroquinolone family.

AUSTELL-LEVOFLOXACIN is used in adults for the treatment of bacterial infection of the sinuses, airways, lungs (where the infection was contracted outside a hospital), female reproductive organs and severe infections inside the belly (abdomen) where therapy with other appropriate antibiotics have failed, cannot be used or cannot be tolerated.

2. What you need to know before you take AUSTELL-LEVOFLOXACIN

Do not take AUSTELL-LEVOFLOXACIN:

- If you are hypersensitive (allergic) to levofloxacin or any of the other ingredients of AUSTELL-LEVOFLOXACIN (listed in section 6)
- If you are allergic or had a reaction to any fluoroquinolone antibiotic previously
- If you are suffering from epilepsy as the possibility of seizures (fits) is increased
- If you have history of tendon disorders related to fluoroquinolone administration
- If you are pregnant or breastfeeding
- If you are below 18 years as the cartilage of growing bones can be affected.
- If you were born with or have any condition with abnormal heart rhythm whether related to QT time prolongation or not (seen on ECG, electrical recording of the heart)
- If you are taking other medicines that result in an abnormal heart rate and/or rhythm tracing (ECG) e.g. (prolongation of the "QT time")
- If you have been diagnosed with a condition called mitral valve and/aortic valve regurgitation (where the heart’s valve does not close tightly, causing blood to leak backward)

- If you have previously experienced side effects with the use of quinolone/fluoroquinolone antibiotics relating to your joints, muscles, ligaments, nerves, central nervous system (brain), epilepsy or mental health (psychiatric disorder)
- If you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis)"
- If you have an enlargement or bulge, of a large blood vessel (aortic aneurysm) or a previous episode of aortic dissection (a tear in the aortic wall) or a family history of aortic aneurysm/dissection or other risk factors or existing predisposing conditions)
- If you have a family history of aortic aneurysm or aortic dissection or other risk factors
- If you are on treatment for high blood pressure with medicines called ACE inhibitors/angiotensin receptor blockers (ARBs). Ask your doctor if you are unsure.

Warnings and precautions

Take special care with AUSTELL-LEVOFLOXACIN

Tell your doctor before taking AUSTELL-LEVOFLOXACIN

- If you have ever had kidney problems as your treatment may need adjustment
- If you suffer from epilepsy or other neurological conditions
- If you have a history of tendon problems during previous treatment with antibiotics
- If you are diabetic and using oral medicine or insulin, because you may experience a risk of hypoglycaemia with AUSTELL-LEVOFLOXACIN
- If you are currently taking other medicines that can reduce your blood potassium levels
- If you are currently taking medicines for high blood pressure called ACE inhibitors/angiotensin receptor blockers (ARBs) and are elderly or already have impaired kidney function, AUSTELL-LEVOFLOXACIN can cause acute kidney injury (see Do not take AUSTELL-LEVOFLOXACIN)

- If you have been diagnosed with an enlargement or bulge of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm), have experienced a previous episode of aortic dissection (a tear in the aorta wall) or 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) (see Do not take AUSTELL-LEVOFLOXACIN)
- If you have heart problems. Caution should be taken when using AUSTELL-LEVOFLOXACIN, 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 bold), have a very slow heart rhythm (called bradycardia) or abnormal heart rhythms (dysrhythmias), 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, or if you have been diagnosed with a condition called mitral valve and/aortic valve regurgitation (where the heart's valve does not close tightly, causing blood to leak backward) (see section 2: Other medicines and AUSTELL-LEVOFLOXACIN (see Do not take AUSTELL-LEVOFLOXACIN)
- If you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated (see Do not take AUSTELL-LEVOFLOXACIN)
- If you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anaemia with AUSTELL-LEVOFLOXACIN.

For the treatment of some genital tract infections, your doctor can prescribe another antibiotic in addition to levofloxacin. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

Other medicines and AUSTELL-LEVOFLOXACIN

Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines. This is because AUSTELL-LEVOFLOXACIN can affect the way some other medicines work. Also, some medicines can affect the way AUSTELL-LEVOFLOXACIN work.

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 taken with AUSTELL-LEVOFLOXACIN.

- 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. 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 AUSTELL-LEVOFLOXACIN
- Non-steroidal anti-inflammatory drugs (NSAIDS) - used for pain and inflammation such as: aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with AUSTELL-LEVOFLOXACIN
- 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 AUSTELL-LEVOFLOXACIN tablets. If you have kidney problems, your doctor may want to give you a lower dose.

Do not take AUSTELL-LEVOFLOXACIN at the same time as the following medicines. This is because it can affect the way AUSTELL-LEVOFLOXACIN work:

- Iron tablets (for anaemia), zinc supplements, magnesium or aluminium-containing antacids (for acid or heartburn), didanosine, or sucralfate (for stomach ulcers).

Urine tests for opiates:’ Urine tests may show ‘false-positive’ results for strong painkillers called ‘opiates’ in people taking AUSTELL-LEVOFLOXACIN. If your doctor is due to take a urine test, tell them you are taking AUSTELL-LEVOFLOXACIN.

Tuberculosis tests

This medicine may cause “false negative” results for some tests used in laboratory to search for the bacteria causing tuberculosis.

Taking AUSTELL-LEVFLOXACIN with food and drink

Take AUSTELL-LEVOFLOXACIN without regard to meals. Take with water, drink with plenty of water. Taking AUSTELL-LEVOFLOXACIN with orange juice can result in reduced quinolone plasma levels.

Pregnancy and breastfeeding

You must not take AUSTELL-LEVOFLOXACIN if you are pregnant, trying to become pregnant or are breastfeeding.

Driving and using machines

You may get side effects after taking 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.

3. How to take AUSTELL-LEVOFLOXACIN

Always take AUSTELL-LEVOFLOXACIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

AUSTELL-LEVOFLOXACIN tablets should be swallowed whole, without crushing, and with sufficient amount of liquid. They may be taken on an empty stomach or with meals.

Most people need a dose of one or two tablets per day. Patients with kidney problems may need a lower dose.

AUSTELL-LEVOFLOXACIN tablets should be taken two hours before iron salts, antacids and sucralfate administration since reduction of absorption may occur. The duration of treatment depends on the nature and severity of the infection. It is very important to finish your course of tablets as the doctor prescribed.

If you take more AUSTELL-LEVOFLOXACIN than you should

If you accidentally take more tablets than you should, tell a doctor or get other medical advice straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may 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) or having stomach burning.

If you forget to take a dose of AUSTELL-LEVOFLOXACIN

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not double-up the next dose to make up for the missed dose.

If you stop taking AUSTELL-LEVOFLOXACIN.

Do not stop taking AUSTELL-LEVOFLOXACIN just because you feel better. It is important that you complete the course of tablets that your doctor has prescribed for you. If you stop taking the tablets too soon, the infection may return, your condition may get worse or the bacteria may become resistant to the medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Not all side-effects reported for this medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

- Severe sudden allergic reactions (e.g.: face, lips, tongue, throat and airways (breathing tubes), difficult breathing, blueness of the skin, low blood pressure, heart failure and can result in death.
- Sudden severe pain in your chest, abdomen (tummy) or back (see section 2: Warnings and precautions).

- *Gastro-intestinal disturbances:* Nausea, vomiting, diarrhoea, abdominal pain, indigestion and pain in the abdominal area. Bloody diarrhea which may indicate inflammation of the bowel can occur.
- *Central nervous system*: Headache, dizziness and restlessness are among the most common effects. Others include tremors, drowsiness, sleeplessness, nightmares, vision and hearing disorders and more rarely, hallucinations, psychotic reactions, depression and convulsions. Paresthesia (feeling of tingling for example in the hands) and a feeling of numbness have occurred occasionally.
- *Skin*: Allergic reactions such as rash, itchiness, Stevens - Johnson syndrome (severe blistering of the skin and mucous membranes), swelling of the skin and mucous membranes and toxic epidermal necrolysis (Lyell's syndrome). Photosensitivity reactions (skin reactions on exposure to strong sunlight and artificial UV rays) have been reported.
- *Haematological/blood disturbances*: Increase or decrease in the number of white blood cells. Decrease in the number of platelets causing a tendency to bleed or to bruise easily. Very rarely, a severe decrease in the number of white blood cells can occur (agranulocytosis), which can cause fever, sore throat and feeling ill. Anaemia (decrease in red blood cells) can also occur.
- *Psychiatric disorders*: anxiety, depression and psychotic reactions can occur. Very rarely, suicidal thoughts or actions can occur.
- *Cardiovascular system*: increase in heart rate and low blood pressure. Disorders in the heart rhythm or other heart conditions can occur.
- *Muscle, tendon, bones:* tendon rupture (e.g. Achilles tendon) is less frequently observed. If suspected, treatment with AUSTELL-LEVOFLOXACIN must be halted immediately and appropriate treatment (e.g. immobilization) must be initiated. Tendon, joint or muscle pain can also occur. Muscular weakness can particularly affect patients with Myasthenia Gravis (a disease of the nervous system).

- *Liver/kidney:* Increase in blood levels of liver enzymes. Inflammation of the liver and disturbances of kidney function can very rarely occur. Kidney failure which is very rare can be due to an allergic kidney reaction such as interstitial nephritis.
- *Other reactions:* Low blood-glucose levels, especially in diabetics, may occur. Fluroquinolones are known to possibly trigger attacks of porphyria in patients suffering from porphyria. General weakness and allergic lung reactions may occur.

These are very serious side effects. If you have them, you may have had a serious [allergic] reaction to AUSTELL-LEVOFLOXACIN. You may need urgent medical attention or hospitalisation.

5. How to store AUSTELL-LEVOFLOXACIN

Keep this medicine in a dry place below 25°C. Protect from light.

Keep the medicine in its original packaging. Do not transfer the medicine to any other container.

DO NOT USE AFTER THE DATE, WHICH IS STAMPED ON THE PACK.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. Contents of the pack and other information

What AUSTELL-LEVOFLOXACIN contains

The active substance is levofloxacin

Each AUSTELL-LEVOFLOXACIN 250 mg film-coated tablet contains 250 mg of levofloxacin

Each AUSTELL-LEVOFLOXACIN 500 mg film-coated tablet contains 500 mg of levofloxacin

The other ingredients are: Microcrystalline cellulose, hydroxypropyl methyl cellulose, purified

talc, sodium stearyl fumarate, crospovidone, titanium dioxide, polyethylene glycol 400, ferric oxide (red) and ferric oxide (yellow).

What AUSTELL-LEVOFLOXACIN looks like and contents of the pack

AUSTELL-LEVOFLOXACIN 250 mg:

Blister packs of 1 x 3, 1 x 5 and 1 x 10 tablets.

Pink coloured, capsule shaped, biconvex, film coated tablets with a breakline on both the sides.

AUSTELL-LEVOFLOXACIN 500 mg:

Blister packs of 1 x 5 and 1 x 10 tablets.

Pink coloured, capsule shaped, biconvex, film coated tablets with a breakline on both the sides.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

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