Approved Patient Information Leaflet for Medicines for Human Use:

CIPROFLOXACIN 250/500/750 mg AUSTELL tablets

SCHEDULING STATUS

S4

CIPROFLOXACIN 250 mg AUSTELL film-coated tablets

CIPROFLOXACIN 500 mg AUSTELL film-coated tablets

CIPROFLOXACIN 750 mg AUSTELL film-coated tablets

Ciprofloxacin

Sugar free

Read all of this leaflet carefully before you start taking CIPROFLOXACIN 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.
- CIPROFLOXACIN AUSTELL 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 CIPROFLOXACIN AUSTELL is and what it is used for

2. What you need to know before you take CIPROFLOXACIN AUSTELL

3. How to take CIPROFLOXACIN AUSTELL

4. Possible side effects

5. How to store CIPROFLOXACIN AUSTELL

6. Contents of the pack and other information

1. What CIPROFLOXACIN AUSTELL is and what it is used for

CIPROFLOXACIN AUSTELL contains the active substance ciprofloxacin. CIPROFLOXACIN AUSTELL an antibiotic belonging to the fluoroquinolone family.

CIPROFLOXACIN AUSTELL is used in adults to treat severe and/or complicated bacterial infection of the lungs, bladder, gut (diarrhoea), bone, or skin and soft tissues where other antimicrobials used for similar infections were considered not to be an appropriate treatment option, have failed, cannot be used or are not tolerated. lt is also used to prevent you getting an infection caused by a bacterium called Neisseria meningitidis.

2. What you need to know before you take CIPROFLOXACIN AUSTELL

Do not take CIPROFLOXACIN AUSTELL:

- if you are allergic (hypersensitive) to ciprofloxacin, any other quinolone medicines, or any of the other ingredients of this medicine (listed in section 6),
- if you are taking tizanidine, a medicine used to treat muscle spasms,
- if you are pregnant and breastfeeding your baby,
- **if you or your child are younger than 18 years,**
- 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 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 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 myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis)",
- 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,
- if you have mitral valve and or/aortic valve regurgitation (a heart condition where the mitral and/or aortic valve does not close properly).

Warnings and precautions

- **Take special care with CIPROFLOXACIN AUSTELL** if you have ever had kidney problems, because your treatment might need adjustment,
- if you have a history of tendon problems during previous treatment with antibiotics such as CIPROFLOXACIN AUSTELL,
- if you are currently taking other medicines that can reduce your blood potassium levels,
- 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 CIPROFLOXACIN AUSTELL),
- 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, CIPROFLOXACIN AUSTELL can cause acute kidney injury (see Do not take CIPROFLOXACIN AUSTELL),
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be

exacerbated (see Do not take CIPROFLOXACIN AUSTELL),

- CIPROFLOXACIN AUSTELL may interfere with the interpretation of diagnostic culture tests for tuberculosis,
- if you have a severe, sudden allergic reaction (an anaphylactic reaction/shock, angio-oedema e.g. tightness in the chest, feeling dizzy, sick or faint, or experiencing dizziness when standing up.) If this happens, stop taking CIPROFLOXACIN AUSTELL and contact your doctor immediately,
- if you have pain and swelling in the joints and tendonitis, especially if you are elderly and on corticosteroid treatment. If you experience any inflammation or swelling, stop taking CIPROFLOXACIN AUSTELL immediately. Avoid any unnecessary exercise, as this may cause tendon rupture.
- if you are epileptic or suffer from other neurological conditions, you might experience side effects associated with the central nervous system. If this happens, stop taking CIPROFLOXACIN AUSTELL immediately, and contact your doctor,
- if you experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or muscle weakness. If this happens, stop taking CIPROFLOXACIN AUSTELL and contact your doctor immediately,
- if you develop diarrhoea while you are on antibiotic treatment or post treatment. If it becomes severe or persistent, and you notice blood in your stool, stop taking CIPROFLOXACIN AUSTELL immediately and contact your doctor,
- if you are taking blood or urinary samples, inform the doctor or laboratory staff,
- CIPROFLOXACIN AUSTELL may cause liver damage. Symptoms of this include loss of appetite, jaundice (yellowing of the skin), dark urine, itching or tenderness of the stomach. If any of these occur, stop CIPROFLOXACIN AUSTELL treatment and inform your doctor,
- CIPROFLOXACIN AUSTELL may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience symptoms such as fever and

serious deterioration of your general condition, or fever with local infection symptoms such as a sore throat/pharynx/mouth or urinary problems, inform your doctor immediately,

- if you or a family member is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD), inform your doctor, since you since you may experience a risk of anaemia with CIPROFLOXACIN AUSTELL,
- skin sensitivity to sunlight or ultraviolet (UV) light. If this occurs, avoid exposure to strong sunlight or artificial UV light such as sunbeds,
- if you experience psychiatric reactions the first time you take CIPROFLOXACIN AUSTELL. If you suffer from depression or psychosis, your symptoms may become worse under treatment with CIPROFLOXACIN AUSTELL. In rare cases, depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, contact your doctor immediately.
- CIPROFLOXACIN AUSTELL may cause disturbances in blood sugar, including both a decrease in blood sugar below normal levels (hypoglycaemia) and an increase in blood sugar above normal levels (hyperglycaemia). Disturbances in blood sugar occurred usually in elderly diabetic patients, receiving concomitant treatment with oral antidiabetic medicines that lower blood sugar (e.g. glibenclamide) or with insulin. Loss of consciousness due to severe reduction in blood sugar (hypoglycaemic coma) has been reported. If you suffer from diabetes, your blood sugar should be carefully monitored,
- if your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- if you notice any severe skin reactions, as you could have developed a severe disorder, such as Stevens Johnson syndrome (a skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth), toxic epidermal necrolysis (a serious condition with blistering of the skin) or drug reaction with eosinophilia and systemic symptoms (a medicine reaction that causes rash, fever, facial swelling, inflammation of internal organs,

hematologic abnormalities and systemic illness), any of which could be life-threatening or fatal.

Children and adolescents

Do not use CIPROFLOXACIN AUSTELL you are under 18 years old (see Do Not Take CIPROFLOXACIN AUSTELL).

Other medicines and CIPROFLOXACIN AUSTELL

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The following medicines are known to interact with CIPROFLOXACIN AUSTELL. Using CIPROFLOXACIN AUSTELL together with these medicines can influence the therapeutic effect of these medicines. It can also increase the probability of experiencing side effects.

Tell your doctor if you are taking:

- tizanidine (for muscle spasticity in multiple sclerosis),
- other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics,
- if you are on treatment with ACE inhibitors/angiotensin receptor blockers (ARBs) used to control your blood pressure, ask your doctor if you are not sure,
- concomitant use of fluoroquinolones and ACE inhibitors/angiotensin receptor blockers may precipitate acute kidney injury,
- medicines used to treat diabetes, such as oral antidiabetic tablets (e.g. glibenclamide) or insulin,

- medicines that can increase ability to get seizures such theophylline, nonsteroidal anti-inflammatory drugs (NSAIDs), medicines used to stop your blood from clotting such as vitamin K antagonists (e.g. warfarin, acenocoumarol, phenprocoumon or fluindione) or other oral anti-coagulants (to thin the blood),
- probenecid (for gout),
- methotrexate (for certain types of cancer, psoriasis, rheumatoid arthritis),
- theophylline (for breathing problems),
- olanzapine, clozapine (antipsychotics),
- ropinirole (for Parkinson's disease),
- phenytoin (for epilepsy),
- metoclopramide (for nausea and vomiting),
- cyclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation),
- zolpidem (for sleep disorders).

CIPROFLOXACIN AUSTELL may increase the levels of the following medicines in your blood:

- xanthine derived products such as pentoxifylline (for circulatory disorders),
- caffeine,
- duloxetine (for depression, diabetic nerve damage or incontinence),
- lidocaine (for heart conditions or anaesthetic use),
- sildenafil (e.g. for erectile dysfunction),
- agomelatine (for depression).

Some medicines reduce the effect of CIPROFLOXACIN AUSTELL.

Tell your doctor if you take or wish to take:

- antacids,

- omeprazole,
- mineral supplements (e.g. calcium, magnesium, aluminium, iron),
- highly buffered medicine (e.g. didanosine tablets),
- sucralfate,
- a polymeric phosphate binder (e.g. sevelamer or lanthanum carbonate),
- medicines or supplements containing calcium, magnesium, aluminium or iron.

If these preparations are essential, take CIPROFLOXACIN AUSTELL about two hours before or no sooner than four hours after them.

CIPROFLOXACIN AUSTELL with food and drink

Unless you take CIPROFLOXACIN AUSTELL during meals, do not eat or drink any dairy products (such as milk, yoghurt or calcium-rich orange juice) or drinks with added calcium when you take the tablets, as they may affect the absorption of the active substance.

Pregnancy and breastfeeding

You should not use CIPROFLOXACIN AUSTELL during pregnancy or when 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 taking CIPROFLOXACIN AUSTELL.

Driving and using machines

The ability to drive a motor vehicle or operate machinery may be impaired by CIPROFLOXACIN AUSTELL tablets. CIPROFLOXACIN AUSTELL may make you feel less alert. Some neurological adverse events can occur. Therefore, make sure you know how you react to CIPROFLOXACIN

AUSTELL before driving a vehicle or operating machinery.

3. How to take CIPROFLOXACIN AUSTELL

Do not share medicines prescribed for you with any other person.

Always take CIPROFLOXACIN AUSTELL exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

In the treatment of infections caused by Pseudomonas aeruginosa, an aminoglycoside must be administered concomitantly.

The usual dosage range is 250 – 750 mg twice daily. The duration of treatment depends upon the severity of the infection, clinical response and bacteriological cultures.

Severe and or complicated infections of the lower respiratory tract:

750 mg twice daily.

In cystic fibrosis patients: 750 mg twice daily. The low body mass of these patients should, however, be taken into consideration when determining dosage (7,5 to 15 mg/kg/day).

Severe and/or complicated infections of the urinary tract:

500 mg twice daily.

Severe and/or complicated infections of the skin:

750 mg twice daily.

Severe and/or complicated infectious diarrhoea: 500 mg twice daily.

Severe and/or complicated bone infections:

750 mg twice daily.

Treatment may be required for 4 – 6 weeks or longer.

Elderly patients should be treated with the lowest possible dose. Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

Your doctor will tell you how long your treatment with CIPROFLOXACIN AUSTELL will last. This will depend on the type of infection you have and how bad it is.

- Swallow the tablets with plenty of fluid. Do not chew the tablets because they do not taste nice.
- Do try to take the tablets at around the same time every day.
- You can take the tablets at mealtimes or between meals. Any calcium you take as part of a meal will not seriously affect uptake. However, do not take CIPROFLOXACIN AUSTELL tablets with dairy products such as milk or yoghurt or with fortified fruit juices (e.g. calcium-fortified orange juice).

Do not stop taking this medication without discussing it with your doctor.
If you have the impression that CIPROFLOXACIN AUSTELL is too strong or too weak, tell your doctor or pharmacist.

If you take more CIPROFLOXACIN AUSTELL than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CIPROFLOXACIN AUSTELL
If you forget to take a dose, take it as soon as you remember it. If it is almost time for the next dose, wait until then. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CIPROFLOXACIN AUSTELL It is important that you finish the course of treatment even if you begin to feel better after a few days. If you stop taking this medicine too soon, your infection may not be completely cured and the symptoms of the infection may return or

get worse. You might also develop resistance to the antibiotic.

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

4. Possible side effects

CIPROFLOXACIN AUSTELL can have side effects

Not all side effects reported for CIPROFLOXACIN AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

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

- severe sudden allergic reactions (swelling of the face, lips, tongue, throat and airways (breathing tubes), difficult breathing, blueness of the skin, low blood pressure, heart failure and can result in death,
- a serious life-threatening skin rash, usually in the form of blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes such as genitals which may progress to widespread blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis),
- seizure,
- sudden severe pain in your chest, abdomen (tummy) or back,
- muscle weakness, inflammation of the tendons which could lead to rupture of the tendon, particularly affecting the large tendon at the back of the ankle (Achilles tendon),
- unusual feelings of pain, burning tingling, numbness or muscle weakness in the extremities (neuropathy),

- a drug reaction that causes rash, fever, inflammation of internal organs, haematologic abnormalities and systemic illness (DRESS Drug Reaction with Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis),
- yellowing of the skin and eyes, dark urine, loss of appetite, itching, tender stomach and tiredness which may be symptoms of liver problems, jaundice (cholestatic icterus), hepatitis, or death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure,
- kidney failure, blood or crystals in the urine.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea,
- diarrhoea (running stomach).

Less frequent side effects:

- vomiting (throwing up),
- dyspepsia (indigestion),
- stomach pain,
- flatulence (wind),
- changes to the blood count (haemolytic anaemia, leukopenia, leukocytosis, neutropenia, anaemia), a drop in a type of white blood cells (agranulocytosis), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal, bone-marrow depression which may also be fatal,
- allergic reaction, swelling (oedema), or rapid swelling of the skin and mucous membranes

(angio-oedema) and allergic reaction called serum sickness-like reaction,

- general feeling of weakness and myalgia (muscle pain in back, chest, body), muscle cramps, inflammation of the tendons,
- syndrome associated with impaired water excretion and low levels of sodium (SIADH),
- decreased appetite, increased blood sugar (hyperglycaemia) which can cause you feeling thirsty and passing water more often than usual or decreased blood sugar (hypoglycaemia) which can cause you feeling weak or irritable, sweating and/or trembling, hypoglycaemic coma,
- hyperactivity, feeling of being agitated, confusion, anxiety, abnormal dreams, depression (feeling of sadness or thinking of suicide), psychotic reactions, feeling of happiness and sadness,
- headache, dizziness, sleep disorders, taste disorders,
- disturbances in vision, double vision, colour vision,
- hearing problems, like tinnitus (ringing in ear) and temporary loss of hearing,
- inflammation of the bowel (colitis) linked to antibiotic use (can be fatal in very rare cases),
- changes in the way your heart beats, rapid heartbeat (tachycardia), abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart),
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors, or giddiness,
- worsening of the symptoms of myasthenia gravis,
- sensitivity to light,
- fungal superinfections,
- a high concentration of eosinophils, a type of white blood cell,
- increased amounts of certain substances in the blood (transaminases and/or bilirubin),
- rash, itching, or hives,

- poor kidney function usually seen with less urine than is normal for you,
- crystalluria (crystals found in urine), kidney failure, infection in the kidneys, blood in the urine, urinary tract inflammation,
- expansion of blood vessels (vasodilation), low blood pressure (hypotension) which can cause you feeling faint, light-headed or dizzy, or fainting,
- shortness of breath, including asthmatic symptoms,
- increased levels of the enzyme amylase, transaminases, alkaline phosphatase,
- liver problems, hepatitis (inflammation of the liver), liver necrosis (sign of liver failure),
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure and pseudotumor cerebri),
- inflammation of the wall of the blood vessels (vasculitis),
- severe abdominal pain (pancreatitis),
- small, pin-point bleeding under the skin (petechiae); various skin eruptions or rashes,
- influence on blood clotting (in patients treated with Vitamin K antagonists),
- asthenia (feeling of abnormal weakness or lack of energy), fever, sweating.

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CIPROFLOXACIN AUSTELL.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store CIPROFLOXACIN AUSTELL

- Store at or below 25ºC. Protect from light.
- Store in the original package.
- Do not use after the expiry date stated on the carton.
- Store all medicines out of reach of children.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CIPROFLOXACIN AUSTELL contains

- The active substance is ciprofloxacin

Each CIPROFLOXACIN 250 mg AUSTELL film-coated tablet contains 250 mg of ciprofloxacin (as hydrochloride).

Each CIPROFLOXACIN 500 mg AUSTELL film-coated tablet contains 500 mg of ciprofloxacin (as hydrochloride).

Each CIPROFLOXACIN 750 mg AUSTELL film-coated tablet contains 750 mg of ciprofloxacin (as hydrochloride).

- **The other ingredients are**

Tablets core

colloidal silicon dioxide,

magnesium stearate,

maize starch,

microcrystalline cellulose,

sodium starch glycollate.

Film-coating

hydroxyl propyl methyl cellulose,

polyethylene glycol,

purified talc,

titanium dioxide.

Sugar free.

What CIPROFLOXACIN AUSTELL looks like and contents of the pack

CIPROFLOXACIN 250 mg AUSTELL:

White to creamish white, circular biconvex film-coated tablets with ‘CPR 250’ embossed on one side and `BL’ embossed on other side.

Blister pack (Clear PVC film & Printed Aluminium foil) of 1 x 10’s, 1 x 14’s, 10 x 10’s.

White HDPE Securipack of 100 tablets.

CIPROFLOXACIN 500 mg AUSTELL:

White to creamish white, capsule shaped biconvex film-coated tablets marked ‘BL’ on one side and ‘CPR 500’ on the other side.

Blister pack (Clear PVC film & Printed Aluminium foil) of 1 x 10’s, 10 x 10’s.

White HDPE Securipack of 100 tablets.

CIPROFLOXACIN 750 mg AUSTELL:

White to creamish white capsule shaped film-coated tablets with ‘CPR 750’ embossed on one side and ‘BL’ embossed on other side.

Blister pack (Clear PVC film & Printed Aluminium foil) of 1 x 10’s, 10 x 10’s.

White HDPE Securipack of 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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CIPROFLOXACIN 750 mg AUSTELL: 37/20.1.1/0354

Access to the corresponding Professional Information and Afrikaans Patient Information Leaflet

Professional Information and Afrikaans Patient Information Leaflet for this medicine is available on the following URL:

https://austell.co.za/product-info/

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