Approved Patient Information Leaflet for Medicines for Human Use: OFLOXACIN 200/400 mg tablets AUSTELL

SCHEDULING STATUS

S4

OFLOXACIN 200 mg AUSTELL

OFLOXACIN 400 mg AUSTELL

Ofloxacin

Sugar free

Read all of this leaflet carefully before you start taking OFLOXACIN AUSTELL:

- Keep this leaflet. You may need to read it again.
- Do not share OFLOXACIN AUSTELL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

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

3. How to take OFLOXACIN AUSTELL

4. Possible side effects

5. How to store OFLOXACIN AUSTELL

6. Contents of the pack and other information

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

OFLOXACIN AUSTELL contains the active substance ofloxacin OFLOXACIN AUSTELL is an antibiotic belonging to the fluoroquinolone family.

OFLOXACIN AUSTELL is used in adults for the treatment of certain infections caused by bacteria where other antimicrobials are considered not to be an appropriate treatment option, have failed, are contraindicated or not tolerated:

. It is most commonly used to treat infections of the:

- Chest or lungs,
- Urinary tract infections (bladder and kidney infections),
- Genital tract infections in men and women (e.g. gonorrhoea, urethritis, cervicitis, a sexually transmitted disease),
- Preventing the growth of certain organisms or microbes in patients with neutropenia (patients with low white blood cells).

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

Do not take OFLOXACIN AUSTELL:

- if you are allergic (hypersensitive) to OFLOXACIN AUSTELL or other quinolone medicines, or any of the other ingredients of this medicine (listed in section 6),
- if you ever had a serious allergic reaction while taking OFLOXACIN AUSTELL,
- if you are pregnant or breastfeeding,
- if you have epilepsy or a history of convulsions,
- if you have existing lesions in the brain, which makes you more prone to getting seizures (e.g. after an injury to the brain or stroke),
- if you or your child are younger than 18 years old,
- if you have a history of tendon disorders e.g. swelling of the tendons (called tendinitis) which can affect areas such as the wrist or the achilles tendon,
- 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 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 mitral valve/aortic regurgitation (a condition where the mitral or aortic valve of the heart does not close properly, which allows blood to flow back into the heart),
- if you are on treatment for high blood pressure with medicines called ACE inhibitors/angiotensin receptor blockers (ARBs) e.g. ramipril, lisinopril.

Warnings and precautions

Take special care with OFLOXACIN AUSTELL:

- Before driving or operating potentially dangerous machinery, determine how this medication affects you,
- if you have problems with your joints,
- if you have continuous diarrhoea, which may be a sign of pseudomembranous colitis (swelling and inflammation of the colon caused by a bacteria *C difficile*). If this happens, stop OFLOXACIN AUSTELL immediately and go to your doctor,
- if you have pain and swelling in the joints and inflammation and rupture of the tendons. Your risk is increased if you are old, have kidney problems, if you had an organ transplant and treated with corticosteroids. At the first sign of this, stop taking OFLOXACIN AUSTELL and speak to your doctor.
- if you have a condition known as myasthenia gravis (a disorder causing pain and weakness in the muscle),
- if you think you have tuberculosis (a type of lung disease), taking OFLOXACIN AUSTELL may provide you with a false-negative result,
- if you have reduced kidney or liver function,

- if you have porphyria (a build up of a chemical called porphyrin in the blood), as OFLOXACIN AUSTELL may trigger an attack,
- if you have a problem with the valves of your heart (mitral or aortic valve). Your doctor may have to do an ECG (electrocardiogram) and perform a thorough investigation,
- if you are taking a group of medicines called ACE inhibitors/angiotensin receptor blockers e.g. lisinopril, ramipril, as this may case acute kidney injury especially if you have kidney problems or are old,
- if you have been diagnosed with an enlargement or 'bulge' of a large blood vessel (aortic aneurysm or large vessel aneurysm),
- if you have experienced an episode of aortic dissection (a tear in the wall of the aorta),
- 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, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).

Children and adolescents

Do not take OFLOXACIN AUSTELL if you are below the age of 18 years.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking OFLOXACIN AUSTELL tablets.

Other medicines and OFLOXACIN AUSTELL

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

The following medicines may affect how OFLOXACIN AUSTELL works**:**

- antacids containing aluminium hydroxide, sucralfate, magnesium hydroxide and aluminium phosphate,
- calcium, iron, zinc supplements,
- theophylline (used for seizures),
- blood thinning medicines e.g. warfarin,
- anti-diabetes medications e.g. glibenclamide,
- probenecid (used for gout),
- cimetidine (used for reflux),
- furosemide (water tablet),
- methotrexate (used for cancer),
- medicines used for high blood pressure such as ACE inhibitors or ARB's e.g. lisinopril, ramipril, losartan.

OFLOXACIN AUSTELL with food and drink

OFLOXACIN AUSTELL can be taken with or without food. OFLOXACIN AUSTELL should be swallowed whole with a glass of water.

Pregnancy and breastfeeding

The safety and efficacy of OFLOXACIN AUSTELL in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking OFLOXACIN AUSTELL.

Driving and using machines

The ability to drive a motor vehicle or operate machinery may be impaired by OFLOXACIN AUSTELL tablets**.** OFLOXACIN AUSTELL may cause drowsiness or dizziness. Before driving or operating potentially dangerous machinery, determine how this medicine affects you.

3. How to take OFLOXACIN AUSTELL

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

Always take OFLOXACIN AUSTELL exactly as your doctor has instructed you to. Check with your doctor or pharmacist if you are unsure.
The usual recommended adult dose is 200 mg to 400 mg ofloxacin twice daily.

Your doctor will explain to you exactly how OFLOXACIN AUSTELL you will have to take as well as how often and for how long. This will depend on the type of infection you have and how bad it is.
Your doctor will tell you how long your treatment OFLOXACIN AUSTELL will last.

If you have the impression that the effect of OFLOXACIN AUSTELL is too strong or too weak, tell your doctor or pharmacist.

Kidney or liver problems

Tell your doctor if you have any kidney or liver problems, you may be given a lower dose.

If you take more OFLOXACIN AUSTELL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you stop taking OFLOXACIN AUSTELL

Keep on taking OFLOXACIN AUSTELL until your doctor tells you to stop. If you stop, your infection may get worse again.

4. Possible side effects

OFLOXACIN AUSTELL can have side effects.

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

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

Severe sudden allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- overgrowth of microorganisms and fungal infection,
- blood disorders such as anaemia, low white blood cell count, destruction of red blood cells, low neutrophil count, low blood cells, increase in eosinophils in blood, low platelet level,
- allergic reactions, which may cause low blood pressure, burning in the eyes, cough, swelling of the skin including the face, tongue, difficulty with breathing,
- eating disorder (anorexia),
- agitation, restlessness, inability to sleep, sleep disorders, hallucinations,
- anxiousness, confusion, nightmares, depression,
- dizziness, headache, weakness, nightmares, sleepiness, drowsiness, inability to smell and taste, tingling sensation in fingers and toes (paraesthesia), unsteady posture, disturbances in muscle coordination,
- eye irritation, blurred vision, double vision, abnormal colour vision,
- feeling of spinning (vertigo), ringing in the ears (tinnitus), loss of hearing,
- increase in heart rate,
- drop in blood pressure,
- cough, infection of the nose and throat, shortness of breath, tightness of chest,
- stomach pain, diarrhoea, nausea, vomiting, loss of appetite, inflammation of the digestive tract, cholestatic jaundice (the flow of bile from or to the liver stops),
- increased liver enzymes, increased blood bilirubin, infection of the liver,
- hypersensitivity reactions, itchiness, hives, photosensitivity, hot flushes, increased sweating,
- skin disorders such as rash, erythema multiforme, toxic epidermal necrolysis which may include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals,

- bursting of small blood vessels (vascular purpura), inflammation of the blood vessel walls, petechiae (small round, brown-purple spots under the skin), blisters, papules (small raised tender bumps on skin),
- inflammation of the tendons, pain in joints and muscles, inflammation and rupture of the tendon (e.g. Achilles tendon),
- crystals in the urine, increase in serum creatinine, acute kidney failure,
- anaphylactic reaction and shock, angioedema (swelling under the skin),
- weakness and numbness from nerve damage (peripheral neuropathy), fits/seizures,
- pseudomembranous colitis (inflammation of the large intestine),
- disturbances of the senses of taste and smell.

Side effects with frequency not known:

- agranulocytosis (severe reduction in white blood cells),
- depression of the bone marrow,
- increase or decrease in blood sugar levels,
- mental psychosis, feeling of suicide, nervousness,
- tremor, uncontrolled muscle movement, loss of taste of the tongue (ageusia), loss of consciousness, increase in pressure in the skull (pseudotumor cerebri),
- uveitis (inflammation of the middle layer of the eye),
- reduced hearing,
- irregular heart beat, ventricular tachycardia (torsades de pointes), prolongation of the QT interval of the ECG,
- inflammation of the lung tissue (pneumonitis),
- shortness of breath,
- indigestion, feeling of bloatedness, constipation, inflammation of the pancreas,
- severe liver damage, liver failure,
- severe skin rash (Stevens Johnsons syndrome),
- stomatitis (swelling and sores on the inside of the mouth),

- exfoliative dermatitis (redness and peeling of the skin over large areas of the body),
- rhabdomyolysis (breakdown of muscle tissue),
- myopathy resulting in muscle weakness, tear of the muscle, tear of the ligaments, arthritis,
- acute interstitial nephritis, which is a condition that causes renal failure,
- porphyria (release of porphyrins into the blood),
- asthenia (weakness or lack of energy),
- fever,
- pain in the back, chest, extremities

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. This includes any possible side effects not listed in this leaflet. 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 OFLOXACIN AUSTELL.

5. How to store OFLOXACIN AUSTELL

- Store all medicines out of reach of children.
- Store at or below 25 °C in a dry place.
- Protect from light.
- Store in the original package.
- Do not use after the expiry date stated on the blister or carton

- 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 OFLOXACIN AUSTELL contains

The active substance is ofloxacin

Each OFLOXACIN 200 mg AUSTELL film-coated tablet contains 200 mg ofloxacin.

Each OFLOXACIN 400 mg AUSTELL film-coated tablet contains 400 mg of ofloxacin.

The other ingredients are:

Tablet core:

Hydroxypropyl cellulose,

Magnesium stearate,

Microcrystalline cellulose,

Purified water,

Sodium starch glycollate (type-a),

Tablet coating:

Opadry -1-7000-White (Hypromellose 2910, Macrogol 400, Titanium dioxide)

Purified water

What OFLOXACIN AUSTELL looks like and contents of the pack

OFLOXACIN 200 mg AUSTELL:

White, capsule shaped, biconvex, film coated tablets, scored on both sides.

The tablets are packed in clear PVC/PVDC-Aluminium foil Blister packs containing 6 or 10 tablets, in a blue outer cardboard carton.

OFLOXACIN 400 mg AUSTELL:

White, capsule shaped, biconvex, film coated tablets, scored on both sides.

The tablets are packed in clear PVC/PVDC-Aluminium foil Blister packs containing 10 tablets in a blue outer cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: +27860287835

This leaflet was last revised in

Date of registration: 07 July 2006

Date of revision: 15 November 2022

Registration number

OFLOXACIN 200 mg AUSTELL: A39/20.1.1/0149

OFLOXACIN 200 mg AUSTELL: A39/20.1.1/0150