Approved Patient Information Leaflet

for Medicines for Human Use

AUSTELL MOXIFLOXACIN IV 400 mg/250 mL

SCHEDULING STATUS

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AUSTELL MOXIFLOXACIN IV 400 mg/250 mL solution for infusion

Moxifloxacin

Read all of this leaflet carefully before you are given AUSTELL MOXIFLOXACIN IV

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

What is in this leaflet

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

1. What AUSTELL MOXIFLOXACIN IV is and what it is used for

AUSTELL MOXIFLOXACIN IV is used for the treatment of a 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.

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2. What you need to know before you are given AUSTELL MOXIFLOXACIN IV

AUSTELL MOXIFLOXACIN IV should not be administered to you:

- if you are hypersensitive (allergic) to moxifloxacin, other quinolone antibiotics or any of the other ingredients of AUSTELL MOXIFLOXACIN IV (see the section explaining what AUSTELL MOXIFLOXACIN IV contains),
- if you have severe liver disease,
- if you are pregnant or breastfeeding your baby,
- 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 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 abnormal heart rate or rhythm tracing (ECG) e.g. (prolongation of the “QT time”),
- if you have a salt imbalance (such as low potassium concentration) in your blood which is at present not corrected by treatment,
- if you have heart failure (a “weak” heart),
- if you have a very slow heart rate (bradycardia),
- 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 have other risk factors or existing predisposing conditions),
- if you have severe liver problems,
- if you have moderate to severe impairment of your kidney function and are treated with ACE inhibitors/angiotensin receptor blockers. Ask your doctor if you are not sure,
- if you have mitral valve and or/aortic valve regurgitation (a heart condition where the mitral and/or aortic valve does not close properly),

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- **if you or your child are younger than 18 years.**

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before being given AUSTELL MOXIFLOXACIN IV.

Warnings and precautions

Tell your doctor or healthcare provider before being given AUSTELL MOXIFLOXACIN IV:

- 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 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 'AUSTELL MOXIFLOXACIN IV should not be administered to you'),
- AUSTELL MOXIFLOXACIN IV may interfere with the interpretation of diagnostic culture tests for tuberculosis,
- if you suffer from seizures "fits" or have a condition where you may be likely to have a seizure,
- if you have or have had mental health problems (see 'AUSTELL MOXIFLOXACIN IV should not be administered to you'),
- if you suffer from myasthenia gravis (a disease characterised by abnormal muscle fatigue leading to weakness and paralysis), inform your doctor about this, before receiving AUSTELL MOXIFLOXACIN IV, as it may worsen the symptoms of your disease (see 'AUSTELL MOXIFLOXACIN IV should not be administered to you'),
- if you have moderate to severe impairment of your kidney function, or of you are elderly and are treated with ACE inhibitors/angiotensin receptor blockers to control your blood pressure as this may cause further injury to your kidneys (see 'AUSTELL MOXIFLOXACIN IV should not be administered to you'). Your kidney function will be

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checked before and during treatment if you are receiving fluoroquinolone antibiotics and ACE inhibitors/angiotensin receptor blockers to control your blood pressure,

- if you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), tell your doctor~~,~~
- if you suffer from diabetes, as your blood sugar levels will need to be monitored carefully.

Phototoxic skin reactions have been reported. Therefore, you should avoid excessive sunlight and ultraviolet exposure (e.g. tanning bed) while receiving AUSTELL MOXIFLOXACIN IV. If you develop a skin rash or a sunburn-like reaction, inform your doctor.

Children and adolescents

You should not be given AUSTELL MOXIFLOXACIN IV if you or your child are younger than 18 years (see 'AUSTELL MOXIFLOXACIN IV should not be administered to you').

Other medicines and AUSTELL MOXIFLOXACIN IV

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

If you are taking any medicines containing the following:

- medicines that affect your heart rhythm such as quinidine, procainamide, amiodarone, sotalol,
- medicines used for the treatment of depression such as tricyclic antidepressants (e.g. amitriptyline),
- medicines used to treat psychosis such as haloperidol,
- medicines used to treat infections such as erythromycin,
- medicines used to "thin" your blood such as warfarin: your blood clotting time (INR) must be monitored closely,

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- anti-inflammatory medicines such as ibuprofen or aspirin, these are medicines usually used for pain,
- medicines used to treat diabetes such as glibenclamide or insulin,
- medicines for high blood pressure known as angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) used to control your blood pressure.

Consult your doctor, pharmacist or other healthcare professional as these medicines may interact with AUSTELL MOXIFLOXACIN IV.

AUSTELL MOXIFLOXACIN IV with food and drink

Your doctor or nurse will administer AUSTELL MOXIFLOXACIN IV to you. AUSTELL MOXIFLOXACIN IV can be given to you either before or after a meal.

Pregnancy, breastfeeding and fertility

You should not be given AUSTELL MOXIFLOXACIN IV during pregnancy and when you are 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 healthcare provider for advice before receiving AUSTELL MOXIFLOXACIN IV.

Driving and using machines

AUSTELL MOXIFLOXACIN IV can cause dizziness. Do not drive or operate machinery until you know how AUSTELL MOXIFLOXACIN IV affects you.

AUSTELL MOXIFLOXACIN IV contains sodium

If you are on a controlled salt diet, inform your doctor before being given AUSTELL MOXIFLOXACIN IV.

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3. How to use AUSTELL MOXIFLOXACIN IV

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

Carefully follow all instructions given to you by your doctor, nurse or pharmacist.

You will not be expected to give yourself AUSTELL MOXIFLOXACIN IV. It will be given to you by a person who is qualified to do so.

- This medicine will be given to you through a drip (by infusion into a vein) by a doctor or healthcare provider.
- The duration of your treatment (how long you will receive AUSTELL MOXIFLOXACIN IV for) will be determined by your doctor.

If you have the impression that AUSTELL MOXIFLOXACIN IV is too strong or too weak, tell your doctor or pharmacist.

If you receive more AUSTELL MOXIFLOXACIN IV than you should

Since a healthcare provider will administer AUSTELL MOXIFLOXACIN IV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Treatment of overdosage is usually symptomatic:

- You will be treated in hospital and your progress will be monitored.

If you miss a dose of AUSTELL MOXIFLOXACIN IV

As you will be given this medicine under close supervision, it is unlikely that you will miss a dose. If you feel that you have missed a dose of treatment, tell your doctor or nurse immediately.

If you stop receiving AUSTELL MOXIFLOXACIN IV

If your treatment with AUSTELL MOXIFLOXACIN IV is stopped too soon, the infection may come back or your condition may worsen.

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4. Possible side effects

AUSTELL MOXIFLOXACIN IV can have side effects. Check with your doctor, pharmacist or healthcare provider if any of these side effects persist or become bothersome.

Not all side effects reported for AUSTELL MOXIFLOXACIN IV are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving AUSTELL MOXIFLOXACIN IV, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving AUSTELL MOXIFLOXACIN IV and tell your doctor immediately:

- swelling of the face, lips, tongue, throat and airways (breathing tubes), blueness of the skin, low blood pressure, heart failure and can result in death.

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

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

Frequent side effects:

- if you have low levels of potassium in your blood: heart palpitations (being able to feel your heart beat) or noticing that the rhythm of your heart does not feel normal,
- fungal infections such as oral or vaginal candida infections,
- headache, dizziness,
- nausea (feeling sick), vomiting, pain in the stomach,
- running stomach (diarrhoea),
- injection and infusion site reactions,
- increase in a liver enzyme in the blood (transaminases) and increased in gamma glutamyl-transferase: noticed on a blood test.

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Less frequent side effects*:*

- heart palpitations (being able to feel your heart beat) or noticing that the rhythm of your heart does not feel normal,
- fainting,
- feeling in a sad mood for long periods of time (depression) or having feelings of detachment from reality especially if this leads to thoughts of killing yourself (suicide) or of harming yourself,
- disturbances in your vision (ability to see),
- pain and inflammation (swelling) of your tendons (“sinews”),
- dark urine, yellowing of your skin or the whites of your eyes. These may be signs of a problem with your liver,
- fever (high temperature) and sore throat with a rash, that develops quickly, with itching and peeling or flaking of your skin and possibly blistering of the mouth and the genital and anal regions. Your eyes may also be affected and may be red and swollen. These may be signs of a potentially life-threatening rash,
- feeling dizzy or shaky, sensation of your heart beating fast, sweating, especially if you suffer from diabetes. These may be signs of low blood sugar levels,
- sudden severe pain in your chest, abdomen (tummy) or back,
- pain, burning, tingling sensation and/or numbness in the skin and extremities “pins and needles”,
- low red blood cell counts: you may look pale and feel tired; low white blood cell counts: you may notice that have more infections or flu symptoms than usual; increase or decrease in the blood cells which are necessary for blood clotting,
- hallucinations: seeing or hearing things that are not there,
- loss of memory,
- seizures “fits”,

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- disturbed coordination: noticing an imbalance in your movements especially due to dizziness. If you are elderly, this may lead to falls, Guillain-Barré Syndrome (an autoimmune disorder where immune system attacks healthy cells and causes weakness, numbness, tingling and can cause paralysis),
- tinnitus: ringing or noise in the ears or hearing loss,
- high or low blood pressure,
- difficulty urinating, urinating excessively or if you notice that your urine has changed colour especially if you are an elderly person or are dehydrated,
- dehydration: you may notice that you are extremely thirsty, have a dry mouth, feel dizzy or may faint,
- increase in blood sugar, blood lipids, blood uric acid: noticed on a blood test,
- feeling anxious or agitated,
- a feeling of detachment (not feeling yourself), changes in taste or loss of taste, changes in smell including loss of smell,
- rash, itching and dry skin,
- feeling confused or disorientated, sleep problems, abnormal dreams, shaking, feeling dizzy or the sensation that the room is spinning,
- problems with speech, disturbed concentration,
- loss of appetite, constipation, indigestion, wind, burning sensation in the stomach with pain and bloating (inflammation of the stomach), difficulty swallowing, inflammation of the mouth,
- increase in blood amylase: noticed on a blood test,
- changes in liver function (increase in the liver enzyme, LDH in the blood, increase in other liver enzymes in the blood (alkaline phosphatase): noticed on a blood test,
- increase in blood bilirubin: noticed on a blood test,
- muscle pain, muscle cramps and weakness, inflammation of the joints,
- feeling unwell, pain, sweating, swelling of the hands and/or feet, inflammation of a vein.

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Frequency unknown

- acute generalised exanthematous pustulosis (AGEP), which is a rare skin reaction with pustule formation and a rash,
- rhabdomyolysis, which is a condition where the muscle breaks down and causes muscle pain, weakness and vomiting.

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, pharmacist or nurse. 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 AUSTELL MOXIFLOXACIN IV.

5. How to store AUSTELL MOXIFLOXACIN IV

- Your doctor, nurse or pharmacist knows how to store AUSTELL MOXIFLOXACIN IV. AUSTELL MOXIFLOXACIN IV is not to be refrigerated or frozen.
- The healthcare provider who is administering AUSTELL MOXIFLOXACIN IV to you will make sure that the medicine is not used after the expiry date printed on the label of the bottle. They will also visually inspect the solution before giving it to you and only clear solution without particles will be used.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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6. Contents of the pack and other information

What AUSTELL MOXIFLOXACIN IV contains

- The active substance is moxifloxacin. AUSTELL MOXIFLOXACIN IV contains moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin.
- The other ingredients are: hydrochloric acid (for pH-adjustment), sodium chloride, sodium hydroxide solution (for pH-adjustment), water for injection.

What AUSTELL MOXIFLOXACIN IV looks like and contents of the pack

AUSTELL MOXIFLOXACIN IV is clear yellow solution, free from particles.

AUSTELL MOXIFLOXACIN IV is packaged in an opaque polypropylene bottle oversealed with either a transparent moulded plastic cap, a grey coloured rubber gasket and a pull ring or a twin port cap, which includes the rubber gasket on the inside and two pull rings on the outside.

Bottles are packed in a cardboard box in packs of 1, 5, 10, 12 or 24 bottles. Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

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