Approved Patient Information Leaflet for Medicines for Human Use:
AVOXA 400 mg film coated tablets

SCHEDULING STATUS **S4**

AVOXA 400 mg Film-coated tablets

Moxifloxacin

Contains sugar (175,70 mg mannitol)

Read all of this leaflet carefully before you start using AVOXA:

- 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.
- AVOXA 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 AVOXA is and what it is used for

AVOXA contains moxifloxacin, which belongs to a group of medicines called antibiotics.

AVOXA is used for the treatment of a bacterial infection of the sinuses, airways, lungs, skin and skin tissues, 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.

AVOXA is only available on your doctor's prescription. Before prescribing the medicine, your doctor may want to determine which organism has infected you.

2. What you need to know before you take AVOXA

Do not use AVOXA:

- if you are hypersensitive (allergic) to moxifloxacin, other quinolones or any of the ingredients of AVOXA (listed in section 6),
- if you have serious liver disease,
- 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 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 a salt imbalance (such as low potassium concentration) in the 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 are pregnant or may become pregnant, or if you breastfeed your baby,
- if you or your child are younger than the age of 18 years,

- if you have moderate to severe impairment of your kidney function and are treated with ACE inhibitors/ angiotensin receptor blockers,
- if you have a damaged mitral and/or aortic valve which cannot close properly,
- if you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis).

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or professional healthcare provider.

Warnings and precautions

Take special care with AVOXA

- If you or any of your family members have a history of heart disease. AVOXA can cause changes in your heart's ECG, particularly in female or elderly patients or patients taking certain other medicines that lower blood potassium levels.
- 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.
- If you are allergic to the active ingredient or any of the inactive ingredients of AVOXA. Discontinue AVOXA at the first sign of a skin rash or other signs (tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing) indicative of an allergic reaction (an anaphylactic reaction/shock due to hypersensitivity).
- If you have severe liver disease.
- AVOXA may cause a rapid and severe inflammation of the liver which could lead to life-threatening liver failure (including fatal cases). Please tell your doctor before you continue treatment if you develop signs such as rapidly feeling unwell and/or being sick associated with yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed.

- If you are currently suffering from, or have ever had, mental health problems, depression, suicide thoughts or suicide attempts, inform your doctor about this, before taking AVOXA.
- If you suffer from epilepsy or a condition which makes you likely to have convulsions talk to your doctor before taking AVOXA.
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), inform your doctor about this, before taking AVOXA, as it may worsen the symptoms of your disease.
- If you have a kidney disease that prevents you from getting adequate fluids in your body; dehydration may increase the risk of kidney failure.
- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), tell your doctor, who will decide if AVOXA is suitable for you.
- If you have a complicated infection of the female upper genital tract (e.g. associated with an abscess of the fallopian tubes and ovaries or of the pelvis), for which your doctor considers an intravenous treatment necessary, treatment with AVOXA tablets is not appropriate. For the treatment of mild to moderate infections of the female upper genital tract your doctor should prescribe another antibiotic in addition to AVOXA. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.
- If you suffer from diabetes, especially if you are elderly and treated with oral medicines or insulin to lower your blood sugar, as your blood sugar levels will need to be monitored carefully.
- If you have moderate to severe impairment of your kidney function, or if 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. Your kidney function will be checked before and during treatment if you are receiving fluoroquinolone antibiotics, such as AVOXA, with ACE inhibitors/ angiotensin receptor blocker to control your blood pressure.
- If you have a damaged mitral and/or aortic heart valve which cannot close properly.
- AVOXA may cause a Stevens-Johnson syndrome, which is a serious illness with skin reaction or blistering and/or peeling of the skin, eyelids, genitals and mucosal areas of your body. You should contact your doctor immediately and treatment with AVOXA must be stopped.

- If you develop diarrhoea while taking AVOXA you should stop taking AVOXA. In this situation, you should not take medicines that stop or slow down bowel movement.
- AVOXA can cause tendon (ligament) pain, inflammation (tendinitis) or tendon tearing, during treatment and up to several months after discontinuing AVOXA treatment. The Achilles tendon (the heel tendon) is most frequently affected. The risk is of inflammation and tearing of tendons is increased if you are elderly or if you are currently treated with corticosteroids. At the first sign of any pain or inflammation of the tendon, discontinue treatment; rest and refrain from exercise; and tell your doctor immediately. The recovery process of your tendons, muscles and joints may take weeks or months and full recovery to your pre-treatment status may not occur.
- Tell the doctor or laboratory staff that you are taking AVOXA if you have to provide a blood or urine sample.
- Inform your doctor if you are going for a test for Mycobacteria such as a tuberculosis (TB) test, as receiving AVOXA at the same time may interfere with the results of the test.
- Your skin may become sensitive to sunlight or UV light when taking AVOXA. Avoid prolonged exposure to sunlight or do not use tanning beds or any other UV lamp while taking AVOXA.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness in your limbs. If this happens, stop taking AVOXA and contact your doctor immediately. The recovery process of your nerve condition may take weeks or months and full recovery to your pre-treatment condition may not occur.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or healthcare provider about your concerns.

Children and adolescents

The use of AVOXA in children and adolescents below the age of 18 years is contraindicated.

Other medicines and AVOXA

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

Tell your doctor, pharmacist or other healthcare provider if you are using any of the following medicines:

- Medicines that affect your heart rhythm (for example, quinidine, procainamide, amiodarone, sotalol) and other medicines that also cause QTc prolongation.
- Medicines for the heart such as digoxin as additional monitoring of patients is advised.
- Medicines used to control your blood pressure called ACE inhibitors/ angiotensin receptor blockers.
- Medicines (H_2 antagonists) used for ulcers such as ranitidine, as they can affect the way AVOXA works.
- Medicines for mental disorders, including tricyclic antidepressants.
- Other medicines used to treat infections, such as erythromycin.
- Medicines for stomach ulcer/acidity: Certain antacids for indigestion, for example those containing magnesium or aluminium may reduce the action of AVOXA. Do not take antacids 4 hours before or 2 hours after taking AVOXA.
- Mineral supplements: minerals like iron could reduce the action of AVOXA and should be taken at least 4 hours before or 2 hours after you have taken AVOXA.
- Medicines to thin your blood (oral anti-coagulants such as warfarin): inform your doctor as it may be necessary to monitor your blood clotting time.
- Medicines for diabetes, such as glibenclamide, as AVOXA may reduce the concentration of glibenclamide.
- Anti-inflammatory medicines (known as NSAIDs), such as ibuprofen, naproxen sodium and aspirin may increase the risk of stimulation of the central nervous system and may lead to convulsions.

- Taking any medicine containing charcoal at the same time reduces the action of AVOXA. You should not take these medicines together.

AVOXA with food and drink

You can take AVOXA at any time of the day, with or without food. Swallow it whole with plenty of water. Ensure that you also take plenty of fluids during the day.

Pregnancy and breastfeeding

AVOXA should not be used if you are pregnant or breastfeeding.

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 AVOXA.

Driving and using machines

AVOXA may cause dizziness and light-headedness; therefore, first find out how you react to this medicine before you operate a vehicle or machinery or engage in activities requiring mental alertness or coordination.

It is not always possible to predict to what extent AVOXA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AVOXA affects them

AVOXA CONTAINS MANNITOL AND CROSCARMELLOSE SODIUM

AVOXA contains mannitol (a type of sugar) and may have a laxative effect.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet. That is to say essentially “sodium free”.

3. How to take AVOXA

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

Always take AVOXA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

AVOXA tablets are for oral use. **AVOXA should not be used in children and adolescents below the age of 18 years.**

The usual dose is one tablet (400 mg) once daily.

All patient groups, including elderly patients (above 65 years of age), patients with kidney problems and patients with low body weight, may take the same dose.

Your doctor will tell you how long your treatment with AVOXA will last; this will depend on your type of infection and the severity of the infection.

Swallow your tablets whole with a glass of water. It does not matter what time of the day you take your tablets, but you should take it at more or less the same time every day. Take plenty of fluids each day. You may take the tablet with or without food.

AVOXA should be taken exactly as prescribed. Do not change the dose prescribed by your doctor.

Do not stop taking your tablets, even if you are feeling better, unless your doctor tells you to do so. It is important to complete the treatment; otherwise the bacteria causing your infection may become resistant to AVOXA.

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

If you take more AVOXA than you should

If you have accidentally taken too much AVOXA, you may experience nausea, vomiting or diarrhoea or any of the side effects mentioned in section 4 “Possible side effects”.

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

The doctor may want to monitor your ECG. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take AVOXA

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 AVOXA

Talk to your doctor if you want to stop taking AVOXA. If you stop taking AVOXA too soon, your infection may not be completely cured.

4. Possible side effects

AVOXA can have side effects.

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

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

- if you have an allergic reaction (hypersensitivity) with severe itching of the skin with raised lumps; or an allergic reaction resulting in possibly life-threatening shock (difficulty breathing, drop of blood pressure, fast pulse, swelling of the face, lips, tongue, throat and airways (breathing tubes), blueness of the skin, heart failure, and can result in death);
- if you have swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing (angioedema);

- if you experience palpitations, an irregular heartbeat or fainting spells during treatment with AVOXA. Your doctor may wish to perform an ECG to look at your heart rhythm;
- at first sign of tendon inflammation or pain. Tendon rupture may occur even after discontinuation of therapy;
- sudden severe pain in your chest, abdomen (tummy) or back.

These are all very serious side effects. If you have them, you may have had a serious reaction to AVOXA. 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:

- sudden pain, snapping or popping sound, bruising, swelling, tenderness, stiffness, or loss of movement in any of your muscles, ligaments or joints;
- severe diarrhoea, containing blood and/or mucous (antibiotic-associated colitis including pseudomembranous colitis), which in some cases, may develop into complications that are life-threatening;
- confusion, hallucinations, feeling depressed (especially if this leads to thoughts of self-harm, such as suicidal ideations/thoughts, or suicide attempts);
- seizure (convulsions);
- 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.
- jaundice (yellowing of the whites of the eyes or skin, dark urine), inflammation of the liver.
- weakness in muscles, arms or legs;
- urinating less than usual or not at all;
- transient loss of vision;
- numbness, tingling, or unusual pain anywhere in your body;
- changes to the skin and mucous membranes (painful blisters in the mouth/nose or at the penis/vagina), severe skin reaction - fever, sore throat, swelling in your face or tongue, burning

in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling, potentially life-threatening (Stevens-Johnson Syndrome, toxic epidermal necrolysis).

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

Tell your doctor if you notice the following:

Frequent side effects

- Infections caused by resistant bacteria or fungi, e.g. oral and vaginal infections caused by Candida (thrush).
- Headache**,** dizziness.
- Nausea or vomiting, stomach pain, diarrhoea.
- Changes in the electrical activity of the heart (ECG) in patients with less potassium in the blood.
- Increase in transaminase (liver enzymes) which may indicate a problem with your liver.

Less frequent side effects

- Anaemia (low red blood cell count), leukopenia (low white blood cell count), neutropenia (low numbers of special white blood cells – neutrophils), thrombocytopenia (decrease or increase of special cells necessary for blood clotting), thrombocythaemia (increase in platelets in the bone marrow) prolonged prothrombin time or increased INR (decreased blood clotting), agranulocytosis (decreased granulocytes, a type of white blood cell), pancytopenia (decreased red blood cells, white blood cells and platelets).
- Allergic reactions, itching, rash, skin hives, blood eosinophilia (increased eosinophils which is a specialised type of white blood cell), anaphylactic shock, swelling of the voice box (larynx) which can be life threatening.

- Retaining water in the body due to a high level of hormone (SIADH – syndrome of inappropriate antidiuretic hormone secretion).
- Increase blood lipids/fats, increase/decrease in blood sugar, increase in uric acid.
- Feeling anxious, agitated, emotional, restless, or agitated, depression, hallucination, a feeling of self-detachment (not being yourself), psychotic reactions, with thoughts of suicide.
- Tingling sensation (pins and needles) and/or numbness, changes/loss in taste sensation, confusion and disorientation, sleep problems (e.g. sleeplessness or sleepiness), shaking, sensation of dizziness (spinning or falling over), decreased/increased sense of touch or sensation, changes in smell including loss of smell, abnormal dreams, disturbed coordination, convulsions, disturbed concentration, problems with speech, partial or total loss of memory, peripheral/polyneuropathy (damage to the nerves which results in pain, numbness, tingling and muscle weakness)
- Problems with vision (including double or blurred vision), fear of light, temporary loss of vision, inflammation of the middle layer of the eye (uveitis).
- Ringing or noise in the ears, hearing impairment including deafness (usually reversible).
- Changes in the electrical activity of the heart (ECG), palpitations, irregular and fast heartbeat, severe heart rhythm problems, faster heart rate than normal, fainting, abnormal heart rhythms, irregular heartbeat (*Torsade de Pointes*), stopping of heart (cardiac arrest), fainting.
- Dilation of the blood vessels, causing flushing/sweating. high blood pressure, low blood pressure, vasculitis (inflammation of the blood vessels).
- Difficulty in breathing (including asthmatic conditions).
- Loss of appetite, wind and constipation, stomach upset (indigestion or heartburn), inflammation of the stomach, difficulty in swallowing, inflammation of the mouth, antibiotic-associated colitis (severe diarrhoea with blood and/or mucus).
- Disorders of the liver with increase in liver enzymes (bilirubin, LDH, gamma-glutamyl-transferase, blood alkaline phosphatase), jaundice (yellowing of the whites of the eyes or skin),

hepatitis (inflammation of the liver), severe inflammation of the liver (potentially leading to life-threatening liver failure).

- Bullous skin reactions (painful blisters in the mouth/nose or at the penis/vagina), like Stevens-Johnson-Syndrome or Toxic Epidermal Necrolysis, which are potentially life-threatening, Acute generalised exanthematous pustulosis (AGEP) which is a skin eruption and presents with small white or red elevations of the skin.
- Joint pain, muscle pain, muscle stiffness, muscle weakness, muscle cramps or twitching, muscle weakness. Pain and swelling of the tendons (tendinitis), rupture of tendons, worsening of the symptoms of myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), rhabdomyolysis (breakdown of muscle tissue).
- Dehydration, kidney impairment or kidney failure due to dehydration.
- Swelling (of the hands, feet, ankles, lips, mouth or throat), feeling unwell (weakness or tiredness), aches and pains such as back, chest, pelvic pains and pains in the legs and arms, sweating.

Frequency unknown

- Guillain-Barre Syndrome (a condition where your own immune system attacks your nerves causing numbness, weakness and pain).
- Aortic aneurysm (a balloon-like bulge in the aorta) and aortic dissection (a tear in the inner layer of the large blood vessel of the heart), mitral/aortic valve regurgitation (a backflow of blood caused by the failure of the valves to close properly).
- CDAD (C.difficile-associated disease), which is a disruption of the normal balance of flora in the intestine.

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 health care provider. 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 AVOXA.

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 AVOXA

Store in the original packaging at or below 25 °C.

Keep blisters in the carton until required for use.

Protect from moisture.

Do not store your medicine in the bathroom.

Do not use AVOXA after the expiry date printed on the label, container or blister.

Return any expired or unused medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What AVOXA contains

The active substance is moxifloxacin. Each film-coated tablet contains 400 mg of moxifloxacin (as hydrochloride).

The other ingredients are: croscarmellose sodium, isopropropyl alcohol, magnesium stearate, mannitol, microcrystalline cellulose, povidone.

Film coating:

Opadry Pink (iron oxide red, iron oxide yellow, lecithin, polyvinyl alcohol, talc, titanium dioxide, xanthan gum).

What AVOXA looks like and contents of the pack

Dark-pink, biconvex, oblong film-coated tablets

AVOXA tablets are available in packs containing blister strips with 5, 7, 10, 20 and 30 tablets, packed in clear, transparent PVC/PVDC foil sealed with silver aluminium foil, in a 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: +27 11 611 1400 or +27 860 287 835

This leaflet was last revised in

Date of registration: 25 March 2019

Date of revision: 05 February 2025

Registration number

46/20.1.1/0643

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

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

Austell Pharmaceuticals (Pty) Ltd

Tel: +27 11 611 1400 or +27 860 287 835