Applicant/PHRC: Bayer (Pty) Ltd
Dosage form: Film-coated tablet
Strength: Moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin
Product proprietary name: AVELON

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

AVELON® 400 mg film-coated tablets
Moxifloxacin
Contains sugar (66 mg lactose)

Read all of this leaflet carefully before you start taking AVELON.

- 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.
- AVELON 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 AVELON is and what it is used for
2. What you need to know before you take AVELON
3. How to take AVELON
4. Possible side effects
5. How to store AVELON
6. Contents of the pack and other information

1. What AVELON is and what it is used for

AVELON is used for the treatment of a bacterial infection of the sinuses, airways, lungs (where the infection was contracted outside a hospital), 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.

2. What you need to know before you take AVELON

Do not take AVELON

- If you are hypersensitive (allergic) to moxifloxacin or any of the other ingredients of AVELON (listed in section 6).
- If you have 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 severe liver disease, e.g. liver cirrhosis.
- If you are pregnant or breastfeeding your baby (see section *Pregnancy and breastfeeding*).
- 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)
  - a salt imbalance in the blood (especially low levels of potassium or magnesium in the blood)
  - a very slow heart rhythm (called ‘bradycardia’)
  - a weak heart (heart failure)
  - a history of abnormal heart rhythms

- 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 damaged mitral and/or aortic heart valve which cannot close properly.
- If you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis).
- **If you or your child are younger than 18 years.**
- 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.

Warnings and precautions

Take special care with AVELON

- AVELON can cause certain changes in the ECG (electronic recording of the heart), especially if you are female or if you are elderly.
  If you experience heart palpitations or an irregular heartbeat at any time during treatment, please tell your doctor immediately. If necessary, he/she will then perform an ECG, to determine the pattern of your heartbeat.
- If you are currently taking other medicines that can reduce your blood potassium levels.
- Inform your doctor of any other medications when taken concurrently with AVELON, including over-the-counter/ non-prescription medications.
- AVELON may cause hypersensitivity (allergic) reactions (an anaphylactic reaction/shock), even with the first dose which may be life-threatening or cause life-threatening shock. Discontinue AVELON 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. In these cases, AVELON must be discontinued immediately, and appropriate medical treatment be instituted.
- 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 section *Do not take AVELON*).
- If you have damaged mitral and/or aortic heart valve which cannot close properly
- AVELON 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.
- AVELON can cause a serious illness with skin reaction or blistering and/or peeling of the skin, eyelids, genitals and mucosal areas of your body (Stevens-Johnson syndrome). You should contact your doctor immediately and treatment with AVELON must be stopped.
- Convulsions (fits) have been reported with the use of AVELON, and you should not receive AVELON if you have a history of this condition or continue with treatment if you get fit while taking AVELON. If you have convulsions (fits) while taking this medicine, you should stop taking AVELON and contact your doctor immediately.
- If you develop diarrhoea while taking AVELON you should stop taking AVELON immediately and consult your doctor. In this situation, you should not take medicines that stop or slow down bowel movement (see section *Do not take AVELON*).
- AVELON can cause tendon (ligament) pain, inflammation (tendinitis) or tendon tearing, during treatment and up to several months after discontinuing AVELON 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 (see section *Do not take AVELON*).

- Tell the doctor or laboratory staff that you are taking AVELON if you have to provide a blood or urine sample.
- AVELON may interfere with the interpretation of diagnostic culture tests for tuberculosis.
- Your skin may become sensitive to sunlight or UV light when taking AVELON. Avoid prolonged exposure to sunlight or do not use tanning beds or any other UV lamp while taking AVELON. If a sunburn-like reaction or skin eruptions occur, contact your doctor.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness in your limbs. If this happens, stop taking AVELON 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 (see section *Do not take AVELON*).
- You may experience mental health problems during your first treatment with AVELON. Depression or other mental health problems can progress to thoughts of suicide or suicide attempts. If this happens, stop taking AVELON and contact your doctor immediately (see section *Do not take AVELON*).
- If you suffer from myasthenia gravis (type of muscle weakness) you should not be treated with AVELON as it may worsen your disease (see section *Do not take AVELON*).
- If you have diabetes, consult your doctor before taking AVELON. AVELON may cause disturbances in your blood sugar level, especially if you are elderly and treated with oral medicines or insulin to lower your blood sugar. Your doctor may wish to monitor your blood sugar during your treatment with AVELON.
- 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 (see section *Do not take AVELON*). Your kidney function will be checked before and during treatment if you are receiving fluoroquinolones antibiotics and ACE inhibitors/angiotensin-receptor blockers to control your blood pressure.

Taking other medicines with AVELON

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

- If you are taking AVELON and other medicines that affect your heart, there is an increased risk for altering your heart rate or rhythm. Therefore, you must tell your doctor, if you are taking any of the medicines that belong to the group of anti-dysrhythmics (medicines to treat your heart rhythm abnormalities), antipsychotics (used for schizophrenia), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides)
- You must tell your doctor if you are taking other medicines that can lower your blood potassium levels (e.g. some diuretics, some laxatives and enemas, ~~or~~ corticosteroids (medicines to treat inflammation or suppress your immune (defence) system), or amphotericin B) or medicines that may cause a slow heart rate because these medicines can also increase the risk of developing serious heart rhythm disturbances while taking AVELON.
- Any medicine containing magnesium or aluminium such as antacids for indigestion, or any medicine containing iron or zinc, other minerals and multi-vitamins, medicine containing didanosine or medicine containing sucralfate to treat gastrointestinal disorders can reduce the uptake and action of AVELON tablets. Therefore, you should take these other medicines at least 4 hours before or 2 hours after taking your AVELON tablets.
- If you are currently taking oral anti-coagulants (e.g. warfarin, a medicine that prevents blood clotting), it may be necessary for your doctor to monitor your blood clotting times.

- Taking oral medicinal charcoal at the same time as AVELON tablets reduces the action of AVELON. Therefore, it is recommended that these medicines are not used together.
- You must tell your doctor if you are on treatment with ACE inhibitors/angiotensin-receptor blockers used to control your blood pressure.

AVELON with food and drink

AVELON tablets may be taken with or without meals (including dairy products), and you should also drink lots of fluid.

Pregnancy and breastfeeding

You should not take AVELON during pregnancy and when you are breastfeeding your baby.
If you are taking AVELON, you should not breastfeed your baby (see section *Do not take AVELON*).
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using AVELON.

Driving and using machines

AVELON may affect your ability to drive and operate machinery. AVELON may make you feel dizzy or light-headed, you may experience a sudden, transient loss of vision or you may faint for a short period.

AVELON contains lactose and sodium

If you have been told by your doctor that have an intolerance to some sugars, speak to your doctor before taking AVELON.
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 AVELON

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

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

AVELON tablets are for oral use. The usual dose is 400 mg (one tablet) once-daily.

The duration of treatment will be determined by your doctor and the severity of your condition
You should swallow the tablets whole with a glass of water. They can be taken independent of food intake.
Do not double the dose.
Do not change the dose prescribed by your doctor.
If you have the impression that the effect of AVELON is too strong or too weak, tell your doctor or pharmacist.

If you take more AVELON than you should

If you are concerned that you may have taken too much AVELON, contact your doctor immediately.
If you take more than the prescribed dose, get medical help immediately as it can cause heart rhythm problems. If possible, take your tablets or the box with you to show the doctor.

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

If you forget to take AVELON

Do not take more AVELON next time; simply continue the treatment as prescribed.

If you stop taking AVELON

If the treatment with AVELON is stopped too soon, your infection may not be completely cured. You should always consult your doctor before deciding to interrupt the course of treatment or stop taking AVELON altogether.

4. Possible side effects

AVELON can have side effects.

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

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

- angioedema (rapid swelling of the skin and mucous membranes of the face, lips, tongue, or throat with difficulty to breathe);
- anaphylactic reaction/shock which is a severe sudden allergic reaction and is rapid in onset. Symptoms of anaphylactic reaction include dizziness (feeling dizzy, sick or faint or experiencing dizziness when standing up), tightness in the chest, loss of consciousness, difficulty in breathing, 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;
- sudden severe pain in your chest, abdomen (tummy) or back;
- severe dizziness, fainting, fast or pounding heartbeats;
- sudden pain, snapping or popping sound, bruising, swelling, tenderness, stiffness, or loss of movement in any of your muscles, ligaments or joints;
- diarrhoea that is watery or bloody;
- confusion, hallucinations, depression, unusual thoughts or behaviour;
- seizure (convulsions);
- pale or yellowed skin, dark coloured urine, fever, weakness;
- urinating less than usual or not at all;
- easy bruising or bleeding;
- numbness, tingling, or unusual pain anywhere in your body;
- the first sign of any skin rash, no matter how mild; or
- 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.

Frequent side effects include

- Infections caused by fungi (oral and vaginal infections/thrush caused by Candida)
- 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), prolonged prothrombin time or increased INR (decreased blood clotting)

- Allergic reactions, pruritus (itching), rash, urticaria (skin hives), blood eosinophilia (increased specialised white blood cells – eosinophils).
- Increased blood lipids/fats
- Anxiety reactions, restlessness/agitation
- Headache, dizziness, par- and dysesthesia (tingling sensation (pins and needles) and/or numbness), taste disorders or loss of taste, confusion and disorientation, sleep disorders, tremor (shaking), vertigo (sensation of dizziness, spinning or falling over), somnolence (sleepiness)
- Visual disturbances including double and blurred vision
- QT prolongation in patients with hypokalaemia (delayed electrical recovery time within the heart as shown by ECG in patients with low blood potassium level), QT prolongation (delayed electrical recovery time within the heart shown by ECG), palpitations (irregular heart beat), tachycardia (fast heart beat), vasodilatation (widening of blood vessels)
- Dyspnoea (difficulty in breathing including asthma)
- Nausea, vomiting, gastrointestinal and abdominal pain, diarrhoea, decreased appetite and food intake, constipation, dyspepsia (upset stomach, indigestion and/or heartburn), flatulence (wind), gastroenteritis (inflammation of the stomach), increased amylase (a special digestive enzyme in the blood)
- Increase in transaminases (a special liver enzyme in the blood), impaired liver function, including LDH increase (a special liver enzyme in the blood), increase of bilirubin in the blood, increase of gamma-glutamyl-transferase and/or alkaline phosphatase in the blood (special liver enzymes in the blood)
- Arthralgia (joint pain), myalgia (muscle pain)
- Dehydration (caused by diarrhoea or reduced fluid intake)
- Feeling unwell (predominantly weakness or tiredness), unspecific aches and pains such as back, chest, pelvic and extremities pains, sweating

Less frequent side effects include

- Abnormal thromboplastin level (special enzyme in the blood involved in blood coagulation), changes in prothrombin level and INR (increased or abnormal blood clotting)
- Anaphylactic reaction (severe, sudden allergic reaction for example difficulty in breathing, drop of blood pressure, fast pulse), angioedema (swelling of the face, lips, tongue, throat and airway), anaphylactic shock (with may be life-threatening)
- Blood-glucose disorders (high blood sugar – hyperglycaemia or low blood sugar - hypoglycaemia), hyperuricemia (increased blood uric acid)
- Depression, hallucinations, feelings of not being yourself, psychotic reactions (potentially leading to self-harm, such as thought to kill oneself, or suicide attempts)
- Reduced skin sensation, smell disorders, abnormal dreams, disturbed coordination due to dizziness or vertigo (may lead to fall with injuries), seizures (fits), disturbed attention, impaired speech, amnesia (partial or total loss of memory), peripheral neuropathy and polyneuropathy (troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities), increased sensitivity of the skin
- Temporary loss of vision
- Ringing in the ears (tinnitus), hearing impairment including deafness (usually reversible)
- Abnormal fast heart rhythm, syncope (fainting), high blood pressure, low blood pressure, unspecified abnormal heart rhythms, Torsade de Pointes (life-threatening irregular heart beat), cardiac arrest (stopping of heart beat)
- Dysphagia (difficulty in swallowing), stomatitis (inflammation of the mouth), antibiotic-associated colitis (severe diarrhoea containing blood and/or mucus, which may be life-threatening)
- 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
- Tendinitis (pain and swelling of the tendons), increased muscle tone and cramping, muscular weakness, tendon rupture, arthritis (inflammation of joints), gait disturbance (caused by muscular, tendon or joint symptoms), worsening of the symptoms of myasthenia gravis
- Impairment or failure of the kidneys (due to dehydration)
- Oedema (swelling of the hands, feet, ankles, lips, mouth, throat)

The following side effects have been observed more frequently in patients treated with intravenously followed by oral treatment:
Increased gamma-glutamyl-transferase (liver enzyme in the blood), abnormal fast heart rhythm, low blood pressure, oedema (swelling of the hands, feet, ankles, lips, mouth or throat), antibiotic-associated colitis (severe diarrhoea containing blood and /or mucus), seizures (fits), hallucinations, impairment and failure of kidneys.

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. 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 AVELON.

5. How to store AVELON

Store all medicines out of reach of children.
Store at or below 25 °C in a dry place.
Do not store in bathrooms.
Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
Do not remove from the original packaging until administered.
Do not use after the expiry date stated on the label.

6. Contents of the pack and other information

What AVELON contains

The active substance moxifloxacin. Each film-coated tablet contains 400 mg of moxifloxacin (as hydrochloride).
The other ingredients are: croscarmellose sodium, ferric oxide red, hypromellose 15 cP, lactose monohydrate, macrogol 4000, magnesium stearate, microcrystalline cellulose, titanium dioxide (see section *AVELON contains lactose*).

What AVELON looks like and contents of the pack

Dull red coated oblong, convex tablet. One side is marked "BAYER" and the other "M400".

AVELON is packaged in cartons containing colourless transparent or white opaque polypropylene/aluminium blisters or colourless transparent polyvinyl chloride/polyvinylidene chloride/aluminium blisters or polyamide/aluminium/polyvinyl chloride/aluminium blisters.

The film-coated tablets are available in packs of 5, 7, and 10 film-coated tablets.

Holder of Certificate of Registration

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road, Isando, 1609

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