AVELOX®

Moxifloxacin (400 mg film-coated tablets)

What is in this leaflet

What *Avelox* is used for

Avelox is used for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active:

- Infections of the respiratory tract: Sudden worsening of long term inflammation of the airways (chronic bronchitis), infection of the lungs (pneumonia) acquired outside the hospital, or acute infection of the sinuses
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and infections of the uterus mucous membrane.
- Severe infections of the skin and associated soft tissues (e.g. major abscesses, infected burns and ulcers, infected bite wounds, diabetic foot infections)
- Severe infections of the abdominal cavity such as abscesses

How *Avelox* works

Avelox contains the active substance moxifloxacin which belongs to a group of antibiotics called fluoroquinolones. Avelox works by killing bacteria that cause infections.

Before you use *Avelox*

- *When you must not use it*

Do not take Avelox

- If you are allergic to the active substance moxifloxacin, any other quinolone antibiotics or any of the other ingredients of this medicine
- If you are pregnant or breastfeeding.

Do not take Avelox and tell your doctor if any of these apply to you.

- *Before you start to use it*

You should not take fluoroquinolone antibacterial medicines, including Avelox, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

Warnings and precautions

Talk to your doctor before taking Avelox for the first time.

- Avelox can change your heart's ECG (electrical recording of the heart), especially if you are female, or if you are elderly. If you were born with or have had any condition with abnormal heart rhythm (seen on ECG), have salt imbalance in the blood (especially low level of potassium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a coronary heart disease, have a severe liver disease (liver cirrhosis), or you are taking other medicines that may affect your heart rhythm (see section Other medicines and Avelox), consult your doctor before taking/using Avelox.
- If you are currently taking any medicine that decreases your blood potassium levels, consult your doctor before taking/using Avelox (see also section Other medicines and Avelox).
- If you suffer from epilepsy or a condition which makes you likely to have convulsions, consult your doctor before taking/using Avelox.
- If you have myasthenia gravis (a type of muscle weakness) because taking/using Avelox may worsen the symptoms of your disease. If you think you are affected consult your doctor immediately.
- If you have or have ever had any mental health problems, consult your doctor before taking/using Avelox.
- If you have a history of tendon disease or disorder which was related to treatment with fluoroquinolone antibiotics (see sections Warnings and precautions and 4. Possible side effects), consult your doctor before taking/using Avelox.
- If you have diabetes, consult your doctor before taking Avelox. Fluoroquinolone antibiotics, including Avelox, 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 treatment with Avelox.
- If you have a severe 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 Avelox 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 Avelox.

Children and adolescents

The efficacy of Avelox in children and adolescents has not been established. No recommendation on a posology can be made. - Taking other medicines

- *Taking other medicines*

Other medicines and Avelox

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

For Avelox, be aware of the following:

- If you are taking/using Avelox and other medicines that affect your heart there is an increased risk for altering your heart rhythm. Therefore, you must tell your doctor, if you are taking any of the following medicines:
  - Medicines that belong to the group of anti-arrhythmics (e.g. quinidine, procainamide, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), antipsychotics (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride), tricyclic antidepressants, some antimicrobials (e.g. saquinavir, sparfloxacin, intravenous erythromycin, pentamidine, antimalarials particularly halofantrine), and other medicines (e.g. cisapride, intravenous vincamine, bepridil and diphemanil).
  - 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 [high doses] or corticosteroids [anti-inflammatory drugs], amphotericin B) or cause a slow heart rate because these can also increase the risk of serious heart rhythm disturbances while taking/using Avelox.
  - [Film-coated tablets only] 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 action of Avelox tablets. Therefore, you should take these other medicines at least 4 hours before or 2 hours after taking your Avelox tablets.
  - If you are currently taking oral anti-coagulants (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting times.
  - Taking oral medicinal charcoal at the same time as Avelox tablets reduces the action of Avelox. Therefore it is recommended that these medicines are not used together.

Avelox with food and drink:
- The effect of Avelox is not influenced by food including dairy products.

Pregnancy and lactation

Do not take Avelox if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking/using this medicine.

How to use *Avelox*

- *How much to use*

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

- *How much to take*

The recommended dose for adults is one 400 mg film-coated tablet once daily and should not be exceeded.

Avelox tablets are for oral use. Swallow the tablet as a whole (to mask the bitter taste) and with plenty of liquid. You can take Avelox with or without food. It is recommended that you take the tablet at approximately the same time each day.

No adjustment of the dose is required in elderly patients, ethnic groups, in patients with impaired liver function or in patients with kidney problems (see section Warnings and Precautions for patients with liver cirrhosis).

- *How long to use it*

The duration of treatment depends upon the type of infection. Unless otherwise indicated by your doctor the recommended durations of use of Avelox film-coated tablets are:

- Sudden worsening of chronicbronchitis: 5 days
- Infection of the lungs (pneumonia) acquired outside the hospital: 10 days
- Acute infection of the sinuses: 7 days
- Mild to moderate infections of the skin and associated soft tissues: 7 days
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease): 14 days
- Severe infections of the skin and associated soft tissues: 7-21days (total treatment duration for intravenous therapy followed by oral therapy)
- Severe infections of the abdominal cavity: 5-14 days (total treatment duration for intravenous/ therapy followed by oral therapy)

The recommended dose and duration of treatment should not be exceeded (see section 2. What you need to know before you take Avelox, Warnings and precautions).

If you take more Avelox than you should

- *If you use too much (overdose)*

If you take more than the prescribed one tablet a day, seek medical advice immediately and, if possible, take any remaining tablets, the packaging or this leaflet with you to show the doctor or pharmacist what you have taken.

If you forget to take Avelox

- *If you forget to use it*

If you forget to take your tablet and it is:
- 8 hours or more until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
- less than 8 hours until your next scheduled dose, do not take the

missed dose. Take the next dose at your regular time.

Do not take a double dose to make up for a forgotten dose. If you are unsure about what to do, consult your doctor or pharmacist.

If you stop taking Avelox

It is important that you finish the course of treatment even if you begin to feel better. 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, or the bacteria may become resistant to the medicine.

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

If you receive more Avelox than you should

If you are concerned that you may have been received too much Avelox, contact your doctor immediately.

While you are using it
- *Things to be careful of*

Driving and operating machinery

Avelox may make you feel dizzy or light-headed, you may experience a sudden, transient loss of vision, or you might faint for a short period. If you are affected in this way do not drive or operate machinery.

- If you experience palpitations or irregular heart beat during the period of treatment, you should inform your doctor immediately. He/she may wish to perform an ECG to measure your heart rhythm.
- The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed.
- There is a rare chance that you may experience a severe, sudden allergic reaction (an anaphylactic reaction/shock) even with the first dose, with the following symptoms: tightness in the chest, chest pain, shortness of breath, feeling dizzy, feeling sick or faint, or experience dizziness on standing. If so, stop taking/using Avelox and seek medical advice immediately.
- Avelox may cause a rapid and severe inflammation of the liver which could lead to life threatening liver failure (including fatal cases, see section 4. Possible side effects). Please contact your doctor before you continue the 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 or liver induced disease of the brain (symptoms of a reduced liver function or a rapid and severe inflammation of the liver).
- If you develop a skin reaction or blistering and/or peeling of the skin and/or mucosal reactions (see section 4. Possible side effects) contact your doctor immediately before you continue the treatment.
- Fluoroquinolone antibiotics, including Avelox, may cause convulsions. If this happens, stop taking/using Avelox and contact your doctor immediately.
- You may develop diarrhoea whilst taking/using, or after taking/using, antibiotics including Avelox. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking/using Avelox immediately and consult your doctor. In this situation, you should not take medicines that stop or slow down bowel movement.
- Pain and swelling in the joints and inflammation or rupture of tendons may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of Avelox therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Avelox, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- Fluoroquinolone antibiotics may make your skin become more sensitive to sunlight or UV light. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while taking/using Avelox.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, inform your doctor immediately prior to continuing treatment with Avelox.
- You may experience mental health problems even when taking/using fluoroquinolone antibiotics, including Avelox, for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behavior such as suicide attempts (see section 4. Possible side effects). If you develop such reactions, stop taking/using Avelox and inform your doctor immediately.
- You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Avelox and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.
- Fluoroquinolone antibacterial medicines, including Avelox, have

been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

- Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:
  - Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
  - Pain in your joints or swelling in your shoulder, arms, or legs.
  - Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
  - Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping. • Changes in your vision, taste, smell, or hearing.
  - Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone - this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves - in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

[Common: may affect up to 1 in 10 people]

- Mycotic superinfections (infections caused by fungi e.g. oral and vaginal infections caused by Candida).
- Headache, dizziness
- QT prolongation in patients with hypokalaemia (delayed electrical recovery time within the heart (shown by ECG) in patients with low blood potassium level)
- Nausea, vomiting, gastrointestinal and abdominal pain, diarrhea
- Increase in transaminases (a special liver enzyme in the blood)

[Uncommon: may affect up to 1 in 100 people]

- Anemia (low red blood cell count), leukopenia (low white blood cell count), neutropenia (low numbers of special white blood cells (neutrophils)), thrombocytopenia or thrombocythemia (decrease or increase of special blood cells necessary for blood clotting), prolonged prothrombin time / INR increased (decreased blood clotting).
- Allergic reaction
- Pruritus (itching), rash, urticaria (skin hives)
- Blood eosinophilia (increased specialized white blood cells (eosinophils))
- Hyperlipidemia (increased blood lipids (fats))
- Anxiety reactions, psychomotor hyperactivity / agitation (restlessness).
- Par- and Dysesthesia (tingling sensation (pins and needles) and/or numbness), taste disorders (in very rare cases ageusia (loss of taste)), confusion and disorientation, sleep disorders (predominately sleeplessness), tremor (shaking), vertigo (sensation of dizziness, spinning or falling over), somnolence (sleepiness).
- Visual disturbances incl. double and blurred vision
- 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)
- Dyspnea (difficulty in breathing) incl. asthmatic conditions.
- Decreased appetite and food intake, constipation, dyspepsia (stomach upset, indigestion, heartburn), flatulence (wind), gastroenteritis (inflammation of the stomach), increased amylase (a special digestive enzyme in the blood).
- Impaired liver function, incl. 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 diarrhea or reduced fluid intake)
- Feeling unwell (predominantly weakness or tiredness), unspecific aches and pains such as back, chest, pelvic and extremities pains, sweating.

[Rare: may affect up to 1 in 1,000 people]

- Abnormal thromboplastin level (special enzyme in the blood involved in blood coagulation).
- Anaphylactic / anaphylactoid reaction (severe, sudden generalised allergic reaction, e.g. difficulty in breathing, drop of blood pressure, fast pulse), allergic edema / angioedema incl. laryngeal edema (swelling incl. potentially life-threatening swelling of the airway).
- Hyperglycemia (increased blood sugar), hyperuricemia (increased blood uric acid).

- Emotional lability, depression (in very rare cases leading to selfharm, such as suicidal ideations/thoughts (desire to kill oneself), or suicide attempts), hallucinations.
- Hypoesthesia (reduced skin sensation), smell disorders (incl. anosmia (loss of smell)
- Abnormal dreams.
- Disturbed coordination (incl. gait disturbances, esp. due to dizziness or vertigo; in very rare cases leading to fall with injuries, esp. in elderly).
- Seizures incl grand mal convulsions (loss of consciousness and violent muscle contractions).
- 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).
- Tinnitus (ringing/noise in the ears), hearing impairment including deafness (usually reversible).
- Ventricular tachyarrhythmias (abnormal fast heart rhythm), syncope (fainting).
- Hypertension (high blood pressure), hypotension (low blood pressure).
- Dysphagia (difficulty in swallowing), stomatitis (inflammation of the mouth), antibiotic associated colitis (severe diarrhoea containing blood and/or mucus) , which in very rare circumstances, may develop into complications that are life-threatening.
- Jaundice (yellowing of the whites of the eyes or skin), hepatitis (inflammation of the liver).
- Tendonitis (pain and swelling of the tendons), increased muscle tone and cramping, muscular weakness.
- Impairment or failure of the kidneys (due to dehydration esp. in the elderly with pre-existing disorders of the kidneys).
- Edema (swelling of the hands, feet, ankles, lips, mouth, throat)

[Very rare: may affect up to 1 in 10,000 people]

- Prothrombin level increased / INR decreased (increased blood clotting) prothrombin level / INR abnormal (abnormal blood clotting).
- Anaphylactic / anaphylactoid shock (severe, sudden generalised allergic shock), potentially life threatening.
- Hypoglycemia (decreased blood sugar).
- Depersonalization (feeling of selfdetachment, not being yourself), psychotic reactions (potentially leading to self-harm, such as suicidal ideations/thoughts (desire to kill oneself), or suicide attempts).
- Hyperesthesia (increase of skin sensitivity)
- Transient loss of vision.
- Unspecified arrhythmias (abnormal heart rhythms), Torsade de Pointes (lifethreatening irregular heart beat), cardiac arrest (stopping of heart beat).
- Fulminant hepatitis (severe inflammation of the liver) potentially leading to lifethreatening liver failure (incl. fatal cases).
- Bullous skin reactions (painful blisters in the mouth/nose or at the penis/vagina), like StevensJohnson-Syndrome or Toxic Epidermal Necrolysis, potentially life-threatening.
- Tendon rupture, arthritis (inflammation of joints), gait disturbance (caused by muscular, tendon or joint symptoms), worsening of the symptoms of myasthenia gravis.

[Not known: frequency cannot be estimated from the available data]

Acute myocardial ischemia (painful heart condition caused by lack of blood flow to the heart) with or without myocardial infarction (heart attack) occurring as part of an allergic reaction (Kounis syndrome).

In isolated instances, some serious adverse drug reactions may be long lasting (> 30 days) and disabling; such as tendinitis, tendon rupture, musculoskeletal disorders, and other reactions affecting the nervous system including psychiatric disorders and disturbance of senses.

The following symptoms have been observed more frequently in patients treated intravenously (followed by oral therapy):

- Common: Increased gamma-glutamyl-transferase (a special liver enzyme in the blood)
- Uncommon: Ventricular tachyarrhythmias (abnormal fast heart rhythm), hypotension (low blood pressure), edema (swelling of the hands, feet, ankles, lips, mouth, throat), antibiotic associated colitis (severe diarrhea containing blood and/or mucus), which in very rare circumstances, may develop into complications that are life-threatening, Seizures incl grand mal convulsions (loss of consciousness and violent muscle contractions), hallucinations, impairment and failure of the kidneys (due to dehydration esp. in the elderly with preexisting disorders of the kidneys).

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Avelox

- *Storage*

Keep this medicine out of the sight and reach of children. Store below 30 °C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- *What it looks like*

Avelox are dull red film-coated tablet with an oblong, convex shape with facet and a dimension of 17 x 7 millimeters.

The film-coated tablets are marked with “M400” on one side and “blanc” on the other side.

- *Ingredients*
  - Active ingredient(s)
    The active substance is moxifloxacin. Each film-coated tablet contains 400 mg of moxifloxacin.

  - Inactive ingredients
    Tablet core:
    - Croscarmellose sodium
    - Microcrystalline cellulose
    - Lactose monohydrate
    - Magnesium stearate

    Film coat:
    - Ferric oxide red
    - Hypromellose 15cP
    - Macrogol 4000
    - Titanium dioxide

- *MAL number(s):*
  MAL20012664AZ

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