

Package Leaflet: Information for the patient Avelox[®] 400 mg film-coated tablets

(moxifloxacin)

For use in adults

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1 What Avelox is and what it is used for

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

Avelox is used in patients of 18 years and older for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Avelox should only be used to treat these infections when usual antibiotics cannot be used or have not worked:

Infection of the sinuses, sudden worsening of long term inflammation of the airways or infection of the lungs (pneumonia) acquired outside the hospital (except severe cases).

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.

Avelox tablets are not sufficient for sole therapy of this kind of infections and therefore another antibiotic in addition to Avelox tablets should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see section 2. *What you need to know before you take Avelox, Warnings and precautions, Talk to your doctor before taking Avelox*).

If the following bacterial infections have shown improvement during initial treatment with Avelox solution for infusion, Avelox tablets may also be prescribed by your doctor to complete the course of therapy: Infection of the lungs (pneumonia) acquired outside the hospital, infections of the skin and soft tissue. Avelox tablets should not be used to initiate therapy for any type of infections of the skin and soft tissue or in severe infections of the lungs.

2 What you need to know before you take Avelox

Contact your doctor if you are not sure if you belong to a patient group described below.

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 (listed in section 6).
- If you are pregnant or breast-feeding.

6 Contents of the pack and other information

What Avelox contains

- The active substance is moxifloxacin. Each film-coated tablet contains 400 milligram moxifloxacin as hydrochloride.
- The other ingredients are: Tablet core: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate (*see section Avelox contains lactose*) and magnesium stearate. Film coating: hypromellose, macrogol 4000, ferric oxide (E172), titanium dioxide (E171)

What Avelox looks like and contents of the pack

Each dull red film-coated tablet with an oblong, convex shape with facet, a dimension of 17 x 7 mm, and marked with "M400" on one side and "BAYER" on the other side.

Avelox is available in packs containing 5 film-coated tablets.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Bayer AG, D-51368 Leverkusen, Germany.

Avelox is a registered trademark of Bayer AG.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,

Tel: +44 (0)1527 505414 for help.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovak Republic, Slovenia, Sweden, United Kingdom: **Avelox**
France: **Izilox**
Germany, Italy: **Avalox**

- allergic reaction
- increase of bilirubin in the blood
- inflammation of the stomach
- dehydration
- severe heart rhythm abnormalities
- dry skin
- angina pectoris

Rare (may affect up to 1 in 1,000 people)

- muscle twitching
- muscle cramp
- hallucination
- high blood pressure
- swelling (of the hands, feet, ankles, lips, mouth, throat)
- low blood pressure
- kidney impairment (incl. increase in special kidney laboratory test results like urea and creatinine)
- inflammation of the liver
- inflammation of the mouth
- ringing/noise in the ears
- jaundice (yellowing of the whites of the eyes or skin)
- impairment of skin sensation
- abnormal dreams
- disturbed concentration
- difficulty in swallowing
- changes in smell (incl. loss of smell)
- balance disorder and poor co-ordination (due to dizziness)
- partial or total loss of memory
- hearing impairment including deafness (usually reversible)
- increased blood uric acid
- emotional instability
- impaired speech
- fainting
- muscle weakness

Very rare (may affect up to 1 in 10,000 people)

- inflammation of joints
- abnormal heart rhythms
- increase of skin sensitivity
- a feeling of self-detachment (not being yourself)
- increased blood clotting
- muscle rigidity
- significant decrease of special white blood cells (agranulocytosis)

Furthermore, there have been very rare cases of the following side effects reported following treatment with other quinolone antibiotics, which might possibly also occur during treatment with Avelox: increased blood sodium levels, increased blood calcium levels, a special type of reduced red blood cell count (haemolytic anaemia), muscle reactions with muscle cell damage, increased sensitivity of the skin to sunlight or UV light.

Reporting of side effects

If you get any 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 directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Avelox

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and on the carton. The expiry date refers to the last day of that month. Do not store above 25°C.

Store in the original package in order to protect from moisture.

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.

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- You may experience **symptoms of neuropathy nerve damage** such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs hands and arms. If this happens, inform your doctor immediately prior to continuing treatment with Avelox.
- You may experience **mental health problems** even when taking quinolone antibiotics, including Avelox, for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts (see section 4. *Possible side effects*). If you develop such reactions, stop taking Avelox and inform your doctor immediately.
- You may develop **diarrhoea** whilst taking, or after taking, antibiotics including Avelox. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking Avelox immediately and consult your doctor. In this situation, you should not take medicines that stop or slow down bowel movement.
- Avelox may cause **pain and inflammation of your tendons**, even within 48 hours of starting treatment and up to several months after discontinuing Avelox therapy. The risk of inflammation and rupture of tendons is increased if you are elderly or if you are currently being treated with corticosteroids. At the first sign of any pain or inflammation you should stop taking Avelox, rest the affected limb(s) and consult your doctor immediately. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture (see sections *Do not take Avelox* and 4. *Possible side effects*).
- If you are elderly with existing **kidney problems** take care that your fluid intake is sufficient because dehydration may increase the risk of kidney failure.
- If your **eyesight becomes impaired** or if your eyes seem to be otherwise affected, consult an eye specialist immediately (see sections *Driving and using machines* and 4. *Possible side effects*).
- Fluoroquinolone antibiotics may cause **disturbances in blood sugar**, including both a decrease in blood sugar below normal levels (hypoglycemia) and an increase in blood sugar above normal levels (hyperglycemia). In patients treated with Avelox, disturbances in blood sugar occurred predominantly in elderly patients receiving concomitant treatment with oral antidiabetic medicines that lower blood sugar (e. g. sulfonylurea) or with insulin. If you suffer from diabetes, your blood sugar should be carefully monitored (see section 4. *Possible side effects*).
- Quinolone 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 Avelox.
- The efficacy of moxifloxacin solution for infusion in the treatment of severe burns, infections of deep tissue and diabetic foot infections with osteomyelitis (infections of the bone marrow) has not been established.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 because efficacy and safety have not been established for this age group (see section *Do not take Avelox*).

Other medicines and Avelox

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines besides Avelox.

For Avelox, be aware of the following:

- If you are taking Avelox and other **medicines that affect your heart** there is an increased risk for altering your heart rhythm. Therefore, do not take Avelox together with the following medicines: Medicines that belong to the group of anti-arrhythmics (e.g. quinidine, 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), some antihistamines (e.g. terfenadine, astemizole, mizolastine), 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 Avelox.

- Any **medicine containing magnesium or aluminium** such as antacids for indigestion, or any **medicine containing iron or zinc**, **medicine containing didanosine** or **medicine containing sucralfate to treat gastrointestinal disorders** can reduce the action of Avelox tablets. Therefore, take your Avelox tablet 6 hours before or after taking the other medicine.
- 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.
- If you are currently taking **oral anti-coagulants** (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting times.

Avelox with food and drink

The effect of Avelox is not influenced by food including dairy products.

Pregnancy, breast-feeding and fertility

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 this medicine. Animal studies do not indicate that your fertility will be impaired by taking this medicine.

Driving and using machines

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.

Avelox contains lactose

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

3 How to take Avelox

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

The recommended dose for adults is one 400 mg film-coated tablet once daily.

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, patients with a low bodyweight or in patients with kidney problems.

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 chronic bronchitis (acute exacerbation of chronic bronchitis) 5 - 10 days
- Infection of the lungs (pneumonia) acquired outside the hospital, except severe cases 10 days
- Acute infection of the sinuses (acute bacterial sinusitis) 7 days
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infection of the fallopian tubes and infection of the uterus mucous membrane 14 days

When Avelox film-coated tablets are used to complete a course of therapy started with Avelox solution for infusion, the recommended durations of use are:

- Infection of the lungs (pneumonia) acquired outside the hospital Most patients with pneumonia were switched to oral treatment with Avelox film-coated tablets within 4 days. 7 - 14 days
- Infections of the skin and soft tissue Most patients with infections of the skin and soft tissue were switched to oral treatment with Avelox film-coated tablets within 6 days. 7 - 21 days

It is important that you complete the course of treatment, even if you begin to feel better after a few days. If you stop taking this medicine too soon your infection may not be completely cured, the infection may return or your condition may get worse, and you may also create a bacterial resistance to the antibiotic.

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 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 take your tablet you should take it as soon as you remember on the same day. If you do not take your tablet on one day, take your normal dose (one tablet) on the next day. 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

If you stop taking this medicine too soon your infection may not be completely cured. Consult your doctor if you wish to stop taking your tablets before the end of the course of treatment.

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

4 Possible side effects

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

The **most serious side effects** observed during the treatment with Avelox are listed below:

If you notice

- an abnormal fast heart rhythm (rare side effect)
- that you suddenly start feeling unwell or notice yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or disturbances of thought or wakefulness (these can be signs and symptoms of fulminant inflammation of the liver potentially leading to life-threatening liver failure (very rare side effect, fatal cases have been observed))
- alterations of the skin and mucous membranes like painful blisters in the mouth/nose or at the penis/vagina (Stevens-Johnson syndrome or toxic epidermal necrolysis) (very rare side effects, potentially life threatening)
- inflammation of blood vessels (signs could be red spots on your skin, usually on your lower legs or effects like joint pain) (very rare side effect)
- a severe, sudden generalised allergic reaction incl. very rarely a life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse) (rare side effect)
- swelling incl. swelling of the airway (rare side effect, potentially life-threatening)
- convulsions (rare side effect)
- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (rare side effect)
- depression (in very rare cases leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (rare side effect)
- insanity (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (very rare side effect)
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis incl. pseudomembranous colitis), which in very rare circumstances, may develop into complications that are life-threatening (rare side effects)
- pain and swelling of the tendons (tendonitis) (rare side effect) or a tendon rupture (very rare side effect) **stop taking Avelox and tell your doctor immediately** as you may need urgent medical advice.

In addition, if you notice

- transient loss of vision (very rare side effect), **contact an eye specialist immediately.**

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If you have experienced life-threatening irregular heart beat (Torsade de Pointes) or stopping of heart beat while taking Avelox (very rare side effects), **tell your treating doctor immediately that you have taken Avelox and do not restart the treatment.**

A worsening of the symptoms of myasthenia gravis has been observed in very rare cases. If this happens, **consult your doctor immediately.**

If you suffer from diabetes and you notice that your blood sugar is increased or decreased (rare or very rare side effect), **inform your doctor immediately.**

If you are elderly with existing kidney problems and you notice decrease in urine output, swelling in your legs, ankles or feet, fatigue, nausea, drowsiness, shortness of breath or confusion (these can be signs and symptoms of kidney failure, a rare side effect), **consult your doctor immediately.**

Other side effects which have been observed during treatment with Avelox are listed below by how likely they are:

Common (may affect up to 1 in 10 people)

- nausea
- diarrhoea
- dizziness
- stomach and abdominal ache
- vomiting
- headache
- increase of a special liver enzyme in the blood (transaminases)
- infections caused by resistant bacteria or fungi e.g. oral and vaginal infections caused by Candida
- change of the heart rhythm (ECG) in patients with low blood potassium level

Uncommon (may affect up to 1 in 100 people)

- rash
- stomach upset (indigestion/heartburn)
- changes in taste (in very rare cases loss of taste)
- sleep problems (predominantly sleeplessness)
- increase of a special liver enzyme in the blood (gamma-glutamyl-transferase and/or alkaline phosphatase)
- low number of special white blood cells (leukocytes, neutrophils)
- constipation
- itching
- sensation of dizziness (spinning or falling over)
- sleepiness
- wind
- change of the heart rhythm (ECG)
- impaired liver function (incl. increase of a special liver enzyme in the blood (LDH))
- decreased appetite and food intake
- low white blood cells count
- aches and pains such as back, chest, pelvic and extremities pains
- increase of special blood cells necessary for blood clotting
- sweating
- increased specialised white blood cells (eosinophils)
- anxiety
- feeling unwell (predominantly weakness or tiredness)
- shaking
- joint pain
- palpitations
- irregular and fast heart beat
- difficulty in breathing incl. asthmatic conditions
- increase of a special digestive enzyme in the blood (amylase)
- restlessness / agitation
- tingling sensation (pins and needles) and/or numbness
- skin hives
- widening of blood vessels
- confusion and disorientation
- decrease of special blood cells necessary for blood clotting
- visual disturbances incl. double and blurred vision
- decreased blood clotting
- increased blood lipids (fats)
- low red blood cell count
- muscle pain