

Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

Package leaflet: Information for the patient

Avelox 400mg film-coated tablets

For use in adults

Moxifloxacin

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 more 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:

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

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 aged 18 years and above 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 on their own for treating this kind of infection. 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 are breast-feeding.
- If you are under 18 years of age.
- If you have previously had problems with your tendons related to treatment with quinolone antibiotics (see section **Warnings and Precautions** and section **4. Possible side effects**).
- If you were born with or have
 - any condition with abnormal heart rhythm (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 rhythmsor
 - if you are taking other medicines that result in abnormal ECG changes (see section **Other medicines and Avelox**). This is because Avelox can cause changes on the ECG, that is a prolongation of the QT-interval, i.e., delayed conduction of electrical signals.
- If you have a severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including Avelox, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

Talk to your doctor before taking Avelox

- Avelox can **change your heart’s ECG**, especially if you are female, or if you are elderly. If you are currently taking any medicine that decreases your blood potassium levels, consult your doctor before taking Avelox (see also sections **Do not take Avelox** and **Other medicines and Avelox**).
- If you have ever developed a **severe skin rash or skin peeling, blistering and/or mouth sores** after taking moxifloxacin.
- If you suffer from **epilepsy** or a condition which makes you likely to have **convulsions** talk to your doctor before taking Avelox.
- If you have or have ever had any **mental health problems**, consult your doctor before taking Avelox.
- If you suffer from **myasthenia gravis** (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking Avelox may worsen the symptoms of your disease. If you think you are affected consult your doctor immediately.
- If you have been diagnosed with an **enlargement or “bulge” of a large blood vessel** (aortic aneurysm or large vessel peripheral aneurysm).
- If you have experienced a previous episode of **aortic dissection** (a tear in the aorta wall).
- If you have been diagnosed with **leaking heart valves** (heart valve regurgitation).

- If you have a family history of **aortic aneurysm or aortic dissection or congenital heart valve disease**, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).
- If you are **diabetic** because you may experience a risk of **change in blood sugar levels** with moxifloxacin.
- If you or any member of your family have **glucose-6-phosphate dehydrogenase deficiency** (a rare hereditary disease), tell your doctor, who will advise whether Avelox 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 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. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking Avelox

- There is a rare chance that you may experience a **severe, sudden allergic reaction** (an anaphylactic reaction/shock) even with the first dose. Symptoms include tightness in the chest, feeling dizzy, feeling sick or faint, or dizziness when standing up. **If so, stop taking Avelox and seek medical advice immediately.- Prolonged, disabling and potentially irreversible serious side effects. Fluoroquinolone/quinolone antibacterial medicines, including Avelox, have been associated with rare but serious side effects, some of them being long lasting (continuing for months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion, or depression, memory impairment, severe fatigue, and severe sleep disorders. There are no medicines that have been established as being effective treatments for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.**
If you experience any of these side effects after taking Avelox, then do not take any further doses and contact your doctor immediately. You and your doctor will decide on whether to continue treatment, considering alternative options.
- You may experience psychiatric reactions when taking Avelox, including when taking it for the first time. If you suffer from depression or psychosis, your symptoms may become worse under treatment with Avelox. In rare cases, depression or psychosis can progress to thoughts of suicide or suicide attempts. If this happens, stop taking Avelox and contact your doctor immediately. You may not notice some changes in your mood and behaviour so it is very important to tell your friends and family that you are taking Avelox, and that there may be rare psychiatric side effects. Others may notice changes and help you quickly identify any symptoms that you need to talk to your doctor about.
- 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.
- 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). If you suddenly feel unwell and/or are being sick and also have 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) **please contact your doctor before taking any more tablets.**
- **Serious skin reactions**
Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis (AGEP) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported with the use of moxifloxacin.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- AGEF appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities.
- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a serious rash or another of these skin symptoms, stop taking moxifloxacin and contact your doctor or seek medical attention immediately.

- Quinolone antibiotics, including Avelox, may cause **convulsions**. If this happens, stop taking Avelox and contact 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 doctor immediately in order to prevent the development of potentially irreversible condition.
- You may develop **diarrhoea** whilst 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**. 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 (see sections **Do not take Avelox** and **4. Possible side effects**). 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 also taking 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 doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- If you feel **sudden, severe pain in your abdomen, chest or back**, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.
- If you are elderly and have **kidney problems** make sure that you drink plenty whilst taking Avelox. If you get dehydrated this 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 an **increase of your blood sugar levels** above normal levels (hyperglycemia), or **lowering of your blood sugar levels** below normal levels (hypoglycaemia), potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4. *Possible side effects*). If you suffer from diabetes, your blood sugar should be carefully monitored.
- 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 (see section 4. *Possible side effects*).
- The efficacy of Avelox 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 about any other medicines that you are taking, took recently or might take.

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)
 - 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), **iron, zinc or didanosine** or any medicine containing **sucralfate** (to treat stomach disorders) can reduce the action of Avelox tablets. Take your Avelox tablet 6 hours before or after taking the other medicine.
- Taking any medicine containing **charcoal** at the same time as Avelox tablets reduces the action of Avelox. It is recommended that these medicines are not used together.
- If you are currently taking **drugs to thin your blood** (oral anti-coagulants such as warfarin), it may be necessary for your doctor to monitor your blood clotting time.

Avelox with food and drink

Avelox can be taken with or without 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 may faint for a short period. If you are affected do not drive or operate machinery.

Avelox contains lactose and sodium

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

This medicine contains less than 1 millimol sodium (23 milligramm) per film-coated tablet, that is to say essentially “sodium-free”.

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 400mg film-coated tablet once daily.

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

The same dose can be taken by elderly patients, patients with a low bodyweight or in patients with kidney problems.

The time you will take Avelox for depends on your infection. Unless your doctor tells you otherwise, your treatment will be as follows:

- for sudden worsening of chronic bronchitis (acute exacerbation of chronic obstructive pulmonary disease including bronchitis) 5 - 10 days
- for infection of the lungs (pneumonia) except for pneumonia which starts during a stay in hospital 10 days
- for 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 7 -14 days
Most patients with pneumonia were switched to oral treatment with Avelox film-coated tablets within 4 days.
- Infections of the skin and soft tissue 7 -21 days
Most patients with infections of the skin and soft tissue were switched to oral treatment with Avelox film-coated tablets within 6 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 Avelox too soon your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing your infection may become resistant to Avelox.

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, get **medical help immediately**. Try to 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 remember on the same 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 ask your doctor or pharmacist.

If you stop taking Avelox

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

If you have any further questions about 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 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))

- serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency of this side effect is 'not known')
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (drug reaction with eosinophilia and systemic symptoms which is also known as DRESS or drug hypersensitivity syndrome) (frequency of this side effect is 'not known').
- syndrome associated with impaired water excretion and low levels of sodium (SIADH) (very rare side effect)
- loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma) (very rare side effect)
- 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)
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis) (frequency of this side effect is 'not known')

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),
- discomfort or pain to the eyes, especially due to light exposure (very rare to rare side effect)

contact an eye specialist immediately.

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
- 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)

- Cases of long lasting (up to months or years) or permanent adverse drug reactions have been associated with quinolone and fluoroquinolone antibiotics. These may include tendon inflammation, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, pricking, burning, numbness or pain (neuropathy), fatigue, sleep disorders, memory impairment, mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion, or depression, as well as impairment of hearing, vision, and taste and smell. There are no medicines that have been established as being effective treatments for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.
- 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)

- a drop in the number of red and white blood cells and platelets (pancytopenia)
- 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)

Not known (frequency cannot be estimated from the available data)

- Increased sensitivity of the skin to sunlight or UV light (see also section 2, Warnings and precautions).
- Sharply demarcated, erythematous patches with/without blistering that develop within hours of administration of moxifloxacin and heals with post inflammatory residual hyperpigmentation; it usually recurs at the same site of the skin or mucous membrane upon subsequent exposure to moxifloxacin

Cases of an enlargement and weakening of the aortic wall or tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones (see also section 2, *Warnings and precautions*).

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:

- Raised pressure in the skull (symptoms include headache, visual problems including blurred vision, “blind” spots, double vision, loss of vision)
- Increased blood sodium levels
- Increased blood calcium levels
- A special type of reduced red blood cell count (haemolytic anaemia)

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 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.

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) and 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 and a dimension of 17 x 7 millimeter is marked with “M400” on one side and “BAYER” on the other side.

Avelox is packaged in cartons containing colourless transparent or white opaque polypropylene/aluminium blisters or colourless transparent polyvinyl chloride/polyvinylidene chloride/aluminium blisters. Avelox is available in commercial packs containing 5, 7, and 10 film-coated tablets, in hospital packs containing 25, 50 or 70 film-coated tablets and in hospital multipacks comprising 5 cartons, each containing 16 film-coated tablets, or 10 cartons, each containing 10 film-coated tablets.

Avelox is also available in a sample pack of 1 film-coated tablet in a carton containing aluminium/aluminium blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: Bayer plc
400 South Oak Way
Reading
RG2 6AD

Manufacturer:

The manufacturer can be identified by the batch number printed on the side flap of the carton and on each blister:

- If the first and second characters are BX, the manufacturer is
Bayer AG
Kaiser-Wilhelm-Allee
51368 Leverkusen
Germany
- If the first and second characters are IT, the manufacturer is
Bayer HealthCare Manufacturing S.r.l.
Via delle Groane, 126
20024 Garbagnate Milanese
Italy

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