Avalox® 400 mg
moxifloxacin

Package leaflet: Information for the patient
Avalox 400 mg 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 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

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

1. WHAT AVALOX IS AND WHAT IT IS USED FOR

Avalox contains the active substance moxifloxacin which belongs to a group of antibiotics called fluoroquinolones. Avalox works by killing bacteria that cause infections.
Avalox is used in patients of 18 years and older for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Avalox 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.
Avalox tablets are not sufficient for sole therapy of this kind of infections and therefore another antibiotic in addition to Avalox 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 Avalox, Warnings and precautions, Talk to your doctor before taking Avalox*).
If the following bacterial infections have shown improvement during initial treatment with Avalox solution for infusion, Avalox 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.
Avalox 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 AVALOX

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

Do not take Avalox
- ▶ 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.
- ▶ If you are under 18 years of age.
- ▶ If you have a history of tendon disease or disorder which was related to treatment with quinolone antibiotics (*see sections Warnings and precautions and 4. Possible side effects*).
- ▶ If you were born with or have had any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of abnormal heart rhythms, or you are taking other medicines that result in abnormal ECG changes (*see section Other medicines and Avalox*).
  This is because Avalox 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 Avalox, 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 Avalox
- ▶ Avalox 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 Avalox (*see also sections Do not take Avalox and Other medicines and Avalox*).
- ▶ 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**, consult your doctor before taking Avalox.
- ▶ If you have or have ever had any **mental health problems**, consult your doctor before taking Avalox.
- ▶ If you suffer from **myasthenia gravis** taking Avalox 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), inform your doctor, who will advise whether Avalox 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 Avalox 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 Avalox. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking Avalox
- ▶ 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, feeling dizzy, feeling sick or faint, or experience dizziness on standing. **If so, stop taking Avalox and seek medical advice immediately.**
- ▶ Avalox 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).
- ▶ **Serious skin reactions**
  Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalised exanthematous pustulosis (AGEP) 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.
  - ▷ AGEP 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.

  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 Avalox, may cause **convulsions**. If this happens, stop taking Avalox and contact your doctor immediately.
- ▶ **Prolonged, disabling and potentially irreversible, serious side effects**. Fluoroquinolone/quinolone antibacterial medicines, including Avalox, have been associated with very rare but serious side effects, some of them being long lasting (continuing 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, depression, memory impairment, severe fatigue, and severe sleep disorders. If you experience any of these side effects after taking Avalox, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.
- ▶ 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 Avalox and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- ▶ You may experience **mental health problems** even when taking quinolone antibiotics, including Avalox, 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 Avalox and inform your doctor immediately.
- ▶ You may develop **diarrhoea** whilst taking, or after taking, antibiotics including Avalox. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking Avalox 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 (see sections Do not take Avalox 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 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 Avalox therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Avalox, 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 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 an **increase of your blood sugar** levels above normal levels (hyperglycaemia), 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 Avalox.
- ▶ 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 Avalox*).

Other medicines and Avalox
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines besides Avalox.
For Avalox, be aware of the following:
- ▶ If you are taking Avalox and other medicines that affect your heart there is an increased risk for altering your heart rhythm. Therefore, do not take Avalox 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 Avalox.
- ▶ 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 Avalox tablets. Therefore, take your Avalox tablet 6 hours before or after taking the other medicine.
- ▶ Taking oral medicinal charcoal at the same time as Avalox tablets reduces the action of Avalox. 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.

Avalox with food and drink
The effect of Avalox is not influenced by food including dairy products.

Pregnancy, breast-feeding and fertility
Do not take Avalox 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
Avalox 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.

Avalox contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Avalox.
This medicine contains less than 1 millimole sodium (23 milligrams) per film-coated tablet, that is to say essentially "sodium-free".

3. HOW TO TAKE AVALOX

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. Avalox tablets are for oral use. Swallow the tablet as a whole (to mask the bitter taste) and with plenty of liquid. You can take Avalox 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 Avalox film-coated tablets are:
- ▶ Sudden worsening of chronic bronchitis (acute exacerbation of chronic obstructive pulmonary disease including 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 Avalox film-coated tablets are used to complete a course of therapy started with Avalox 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 Avalox 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 Avalox 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 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 Avalox, Warnings and precautions*).

If you take more Avalox 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 Avalox
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 Avalox
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 Avalox 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-threating 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 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")
- ▶ 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 Avalox 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 Avalox (very rare side effects), **tell your treating doctor immediately that you have taken Avalox 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 Avalox 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)
- ▶ 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)

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.
Cases of an enlargement and weakening of the aortic wall or a 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 Avalox: 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), 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. By reporting side effects, you can help provide more information on the safety of this medicine.

To report any side effect(s):	
United Arab Emirates (UAE): Tel: 80011111 / +971 42301000 Email: pv@mohap.gov.ae Website: www.mohap.gov.ae P.O.Box 1853 Dubai	**Jordan:** JFDA email : jpc@jfda.jo JFDA website: www.jfda.jo http://primaryreporting.who-umc.org/JO Tel: +962-6-5632000
Egypt: Egyptian Pharmaceutical Vigilance Centre Tel.: +20 -225354100 Ext.:1303 Email: pv.center@eda.mohealth.gov.eg	**Qatar:** Website: moph.gov.qa **Bahrain:** Website: moh.gov.bh
Kuwait: Hotline: 1810005 Email: health@moh.gov.kw Website: www.moh.gov.kw/kdfc/ P.O.Box: 5 Safat, 13001 Kuwait	**Oman:** Tel: +968 - 2444 1999 Fax: +968 - 24602287 Email: pharma-vigil@moh.gov.om Website: www.moh.gov.om
Other Countries: Please contact the relevant competent authority	

5. HOW TO STORE AVALOX

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 30°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 Avalox 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 Avalox contains lactose*) and Magnesium stearate.
  Film coating: Hypromellose, Macrogol 4000, Ferric oxide (E172) and Titanium dioxide (E171).

What Avalox 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.
Avalox is packaged in cartons containing colourless transparent or white opaque polypropylene/aluminium blisters or colourless transparent polyvinyl chloride/polyvinylidene chloride/aluminium blisters.
Avalox is available in commercial packs containing 5, 7, and 10 film-coated tablets.
Not all pack sizes may be marketed.

Manufacturer
Bayer HealthCare Manufacturing S.r.l.
Via delle Groane, 126
20024 Garbagnate Milanese, Italy.

Marketing Authorisation Holder
Bayer AG
51368 Leverkusen, Germany.

This leaflet was last revised in October 2020.

This is a medicament
- ▶ A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- ▶ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ▶ The doctor and the pharmacist are experts in medicine, its benefits and risks.
- ▶ Do not by yourself interrupt the period of treatment prescribed.
- ▶ Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Bayer

Avalox®

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PMR 88777026 Technical Template (GFJBE/01-N) Pantone: Black

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أفالوكس® ٤٠٠ مجم

موكسيفلوكساسين

نشرة العبوة: معلومات للمستخدم
أفالوكس ٤٠٠ مجم – أقراص مغلفة
الاستخدام للبالغين
موكسيفلوكساسين

إقرأ كل هذه النشرة بعناية قبل البدء في تناول هذا الدواء لأنها تحتوي على معلومات مهمة تخصك.
- احتفظ بهذه النشرة. قد تحتاج قراءتها مرة أخرى.
- إذا كان لديك أية أسئلة إضافية، اسأل الطبيب أو الصيدلي.
- هذا الدواء تم وصفه لك شخصياً. لا يجب أن يعطى لآخرين . يمكن أن يسبب الضرر لهم، حتى لو كان لديهم نفس الأعراض المرضية مثلك.
- إذا تم إصابتك بأية آثار جانبية، أبلغ طبيبك أو الصيدلي. هذا يشمل أية آثار جانبية غير مذكورة في هذه النشرة. انظر قسم ٤.

ماذا تحتوي هذه النشرة
١. ما هو أفالوكس و فيما يستخدم
٢. ما الذي تحتاج معرفته قبل أن تتناول أفالوكس
٣. كيفية تناول أفالوكس
٤. الآثار الجانبية المحتملة
٥. كيفية تخزين أفالوكس
٦. محتويات العبوة ومعلومات أخرى

١. ما هو أفالوكس وفيما يستخدم

يحتوي أفالوكس على موكسيفلوكساسين كمادة فعالة والتي تنتمي لمجموعة المضادات الحيوية التي تسمى الفلوروكينولون. أفالوكس يعمل عن طريق قتل البكتيريا التي تسبب الأمراض (عدوى) يستخدم أفالوكس في المرضى بداية من عمر ١٨ عاما أو أكبر لعلاج العدوى البكتيرية الناتجة عن البكتيريا المسببة لهذه العدوى. عندما تكون المضادات الحيوية المعتادة لا يمكن استخدامها أو قد فشلت.

يمكن أن تظهر في المجلد بقعة متلازمة ستيفنز جونسون / انحلال البشرة السمي (تقشير الطبقة العليا من الجلد بعد ذلك يموت الجلد بعيداً والجسم في هذه الحالة يخضع لتسمم قوي). وتفتح الجلد في المجلد تؤدي إلى شكل يشبه الصديد