

REFERENCES: 1. Clinical and Laboratory Standards Institute, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically-Sixth Edition. Approved Standard CLSI Document M7-A6, Vol. 23, No. 2, CLSI, Wayne, PA, January, 2003.
2. Clinical and Laboratory Standards Institute, Performance Standards for Antimicrobial Disk Susceptibility Tests-Eighth Edition. Approved Standard CLSI Document M2-A8, Vol. 23, No. 1, CLSI, Wayne, PA, January, 2003.
3. Clinical and Laboratory Standards Institute, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard CLSI Document M11-A6, Vol. 24, No. 2, CLSI, Wayne, PA, 2004.

Patient Information About:
AVELOX[®]
(moxifloxacin hydrochloride)
400 mg Tablets

This section contains important information about AVELOX (moxifloxacin hydrochloride), and should be read completely before you begin treatment. This section does not take the place of discussions with your doctor or health care professional about your medical condition or your treatment. This section does not list all benefits and risks of AVELOX. The medicine described here can be prescribed only by a licensed health care professional. If you have any questions about AVELOX talk with your health care professional. Only your health care professional can determine if AVELOX is right for you.

What is AVELOX?

AVELOX is an antibiotic used to treat lung, sinus, abdominal or skin infections caused by certain germs called bacteria. AVELOX kills many of the types of bacteria that can infect the lungs and sinuses and has been shown in a large number of clinical trials to be safe and effective for the treatment of bacterial infections.

Sometimes viruses rather than bacteria may infect the lungs and sinuses (for example the common cold). AVELOX, like all other antibiotics, does not kill viruses.

You should contact your doctor if you think your condition is not improving while taking AVELOX.

AVELOX Tablets are red and contain 400 mg of active drug.

How and when should I take AVELOX?

AVELOX should be taken once a day for 5-21 days depending on your prescription. It should be swallowed and may be taken with or without food. Try to take the tablet at the same time each day.

You may begin to feel better quickly; however, in order to make sure that all bacteria are killed, you should complete the full course of medication. Do not take more than the prescribed dose of AVELOX even if you missed a dose by mistake. You should not take a double dose.

Who should not take AVELOX?

You should not take AVELOX if you have ever had a severe allergic reaction to any of the group of antibiotics known as “quinolones” such as ciprofloxacin or levofloxacin. If you develop hives, difficulty breathing, or other symptoms of a severe allergic reaction, seek emergency treatment right away. If you develop a skin rash, you should stop taking AVELOX and call your health care professional.

You should avoid AVELOX if you have a rare condition known as congenital prolongation of the

QT interval. If you or any of your family members have this condition you should inform your health care professional. You should avoid AVELOX if you are being treated for heart rhythm disturbances with certain medicines such as quinidine, procainamide, amiodarone or sotalol. Inform your health care professional if you are taking a heart rhythm drug.

You should also avoid AVELOX if the amount of potassium in your blood is low. Low potassium can sometimes be caused by medicines called diuretics such as furosemide and hydrochlorothiazide. If you are taking a diuretic medicine you should speak with your health care professional.

If you are pregnant or planning to become pregnant while taking AVELOX, talk to your doctor before taking this medication. AVELOX is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.

AVELOX is not recommended for children.

What are the possible side effects of AVELOX?

AVELOX is generally well tolerated. The most common side effects caused by AVELOX, which are usually mild, include dizziness, nausea, and diarrhea. If diarrhea persists call your health care provider. You should be careful about driving or operating machinery until you are sure AVELOX is not causing dizziness. If you notice any side effects not mentioned in this section or you have any concerns about the side effects you are experiencing, please inform your health care professional.

Avelox may cause a rare heart problem known as prolongation of the QTc interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this event are increased in those with a family history of prolonged QT interval, low potassium (hypokalemia), and those who are taking drugs to control heart rhythm, called class IA (quinidine, procainamide), or class III (amiodarone, sotalol) antiarrhythmic agents. You should call your healthcare provider right away if you have any symptoms of prolongation of the QTc interval including prolonged heart palpitation (a change in the way your heart beats) or a loss of consciousness (fainting spells).

Convulsions have been reported in patients receiving quinolone antibiotics. Be sure to let your physician know if you have a history of convulsions. Quinolones, including AVELOX, have been rarely associated with other central nervous system events including confusion, tremors, hallucinations, and depression.

Pain, swelling, and tears of Achilles, shoulder, or hand tendons have been reported in patients receiving fluoroquinolones, including AVELOX. The risk for tendon effects is higher if you are over 65 years of age, and especially if you are taking corticosteroids. If you develop pain, swelling, or tear of a tendon you should stop taking AVELOX, avoid exercise and strenuous use of the affected area, and contact your health care provider.

Diarrhea that usually ends after treatment is a common problem cause by antibiotics. A more serious form of diarrhea can occur during or up to 2 months after the use of antibiotics. This has been reported with all antibiotics including with AVELOX. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your physician as soon as possible.

Sun sensitivity (photosensitivity), which can appear as skin eruption or severe sunburn, can occur in some patients taking quinolone antibiotics after exposure to sunlight or artificial ultraviolet light (UV) (e.g. tanning beds). AVELOX[®] has been infrequently associated with photosensitivity. Avoid excessive exposure to sunlight or artificial UV light while taking

AVELOX[®]. Use a sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your physician.

What about other medicines I am taking?

Tell your doctor about all other prescription and non-prescription medicines or supplements you are taking. You should avoid taking AVELOX with certain medicines used to treat an abnormal heartbeat. These include quinidine, procainamide, amiodarone, and sotalol.

Some medicines also produce an effect on the electrocardiogram test, including cisapride, erythromycin, some antidepressants and some antipsychotic drugs. These may increase the risk of heart beat problems when taken with AVELOX.

Many antacids and multivitamins may interfere with the absorption of AVELOX and may prevent it from working properly. You should take AVELOX either 4 hours before or 8 hours after taking these products.

Remember

Take your dose of AVELOX once a day.

Complete the course of medication even if you are feeling better.

Keep this medication out of the reach of children.

This information does not take the place of discussions with your doctor or health care professional about your medical condition or your treatment.

For more complete information about AVELOX request full prescribing information from your health care professional, pharmacist, or visit our website at www.aveloxusa.com.

Manufactured by:



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Bayer Pharmaceuticals Corporation

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