MEDICATION GUIDE

AVELOX® (*AV-eh-locks)*
(moxifloxacin hydrochloride)
Tablets

AVELOX® (*AV-eh-locks)*
(moxifloxacin hydrochloride)
Injection Solution for Intravenous use

Read the Medication Guide that comes with AVELOX® before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about AVELOX?

AVELOX belongs to a class of antibiotics called fluoroquinolones. AVELOX can cause serious side effects that can happen at the same time and could result in death. If you get any of the following serious side effects, you should stop taking AVELOX and get medical help right away. Talk with your healthcare provider about whether you should continue to take AVELOX.

1. Tendon rupture or swelling of the tendon (tendinitis).

- **Tendon problems can happen in people of all ages who take AVELOX.** Tendons are tough cords of tissue that connect muscles to bones. Symptoms of tendon problems may include:
  - Pain, swelling, tears and inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites.

- **The risk of getting tendon problems while you take AVELOX is higher if you:**
  - Are over 60 years of age
  - Are taking steroids (corticosteroids)
  - Have had a kidney, heart or lung transplant
  - **Tendon problems can happen in people who do not have the above risk factors when they take AVELOX.**
- **Other reasons that can increase your risk of tendon problems can include:**
  - Physical activity or exercise
  - Kidney failure
  - Tendon problems in the past, such as in people with rheumatoid arthritis (RA).
- **Stop taking AVELOX immediately and call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation.** Stop taking AVELOX until tendinitis or tendon rupture has been ruled out by your healthcare provider. Avoid exercise and using the affected area. The most common area of pain and swelling is in the Achilles tendon at the back of your ankle. This can also happen with other tendons.
- **Talk to your healthcare provider about the risk of tendon rupture with continued use of AVELOX.** You may need a different antibiotic that is not a fluoroquinolone to treat your infection.
- **Tendon rupture can happen while you are taking or after you have finished taking AVELOX.** Tendon ruptures can happen within hours or days after taking AVELOX and have happened up to several months after patients have finished taking their fluoroquinolone.
- **Stop taking AVELOX immediately and get medical help right away if you get any of the following signs or symptoms of a tendon rupture:**
  - Hear or feel a snap or pop in a tendon area
  - Bruising right after an injury in a tendon area
  - Unable to move the affected area or bear weight.

2. Changes in sensation and possible nerve damage (Peripheral Neuropathy). Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including AVELOX. Stop taking AVELOX immediately and talk to your healthcare provider right away if you get any of the following symptoms of peripheral neuropathy in your arms, hands, legs, or feet:

- pain
- burning
- tingling
- numbness
- weakness

AVELOX may need to be stopped to prevent permanent nerve damage.

3. **Central Nervous System (CNS) effects.** Seizures have been reported in people who take fluoroquinolone antibacterial medicines, including AVELOX. Tell your healthcare provider if you have a history of seizures before you start taking AVELOX. CNS side effects may happen as soon as after taking the first dose of AVELOX. Stop taking AVELOX immediately and talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:
   - seizures
   - hear voices, see things, or sense things that are not there (hallucinations)
   - feel restless
   - tremors
   - feel anxious or nervous
   - confusion
   - depression
   - trouble sleeping
   - nightmares
   - feel lightheaded or dizzy
   - feel more suspicious (paranoia)
   - suicidal thoughts or acts
   - headaches that will not go away, with or without blurred vision
4. **Worsening of myasthenia gravis (a disease which causes muscle weakness).** Fluoroquinolones like AVELOX may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Tell your healthcare provider if you have a history of myasthenia gravis before you start taking AVELOX. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

See the section "**What are the possible side effects of AVELOX?**" for more information about side effects.

What is AVELOX?

AVELOX is a fluoroquinolone antibiotic medicine used to treat certain types of infections caused by certain germs called bacteria in adults 18 years or older. These bacterial infections include:

- Community Acquired Pneumonia
- Uncomplicated Skin and Skin Structure Infections
- Complicated Skin and Skin Structure Infections
- Complicated Intra-Abdominal Infections
- Plague
- Acute Bacterial Sinusitis
- Acute Bacterial Exacerbation of Chronic Bronchitis

AVELOX should not be used in patients with acute bacterial sinusitis or acute bacterial exacerbation of chronic bronchitis if there are other treatment options available.

Studies of AVELOX for use in the treatment of plague were done in animals only, because plague could not be studied in people.

It is not known if AVELOX is safe and works in people under 18 years of age. Children have a higher chance of getting bone, joint, and tendon (musculoskeletal) problems while taking fluoroquinolone antibiotic medicines.

Sometimes infections are caused by viruses rather than by bacteria. Examples include viral infections in the sinuses and lungs, such as the common cold or flu. Antibiotics, including AVELOX, do not kill viruses.

Call your healthcare provider if you think your condition is not getting better while you are taking AVELOX.

Who should not take AVELOX?

Do not take AVELOX if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to any of the ingredients in AVELOX. Ask your healthcare provider if you are not sure. See the list of ingredients in AVELOX at the end of this Medication Guide.

What should I tell my healthcare provider before taking AVELOX?

See **"What is the most important information I should know about AVELOX?"**

Tell your healthcare provider about all your medical conditions, including if you:

- Have tendon problems; AVELOX should not be used in patients who have a history of tendon problems
- Have a disease that causes muscle weakness (myasthenia gravis); AVELOX should not be used in patients who have a history of myasthenia gravis
- Have central nervous system problems (such as epilepsy)
- Have nerve problems; AVELOX should not be used in patients who have a history of a nerve problem called peripheral neuropathy
- Have or anyone in your family has an irregular heartbeat, especially a condition called "QT prolongation"
- Have low blood potassium (hypokalemia)
- Have a slow heartbeat (bradycardia)
- Have a history of seizures
- Have kidney problems
- Have rheumatoid arthritis (RA) or other history of joint problems
- Are pregnant or planning to become pregnant. It is not known if AVELOX will harm your unborn child
- Are breast-feeding or planning to breast-feed. It is not known if AVELOX passes into breast milk. You and your healthcare provider should decide whether you will take AVELOX or breast-feed.
- Have diabetes or problems with low blood sugar (hypoglycemia).

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal and dietary supplements. AVELOX and other medicines can affect each other causing side effects. Especially tell your healthcare provider if you take:

- An NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take AVELOX or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See "**What are the possible side effects of AVELOX?**"
- A blood thinner (warfarin, Coumadin, Jantoven).
- A medicine to control your heart rate or rhythm (antiarrhythmic) See "**What are the possible side effects of AVELOX?**"
- An anti-psychotic medicine.
- A tricyclic antidepressant.
- An oral anti-diabetes medicine or insulin.
- Erythromycin.
- A water pill (diuretic).
- A steroid medicine. Corticosteroids taken by mouth or by injection may increase the chance of tendon injury. See "**What is the most important information I should know about AVELOX?**"
- Certain medicines may keep AVELOX from working correctly. Take AVELOX either 4 hours before or 8 hours after taking these products:
  - An antacid, multivitamin, or other product that has magnesium, aluminum, iron, or zinc
  - Sucralfate (Carafate®)
  - Didanosine oral suspension or solution

Ask your healthcare provider if you are not sure if any of your medicines are listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take AVELOX?

- Take AVELOX once a day exactly as prescribed by your healthcare provider.
- Take AVELOX at about the same time each day.
- AVELOX Tablets should be swallowed.
- AVELOX can be taken with or without food.

- Drink plenty of fluids while taking AVELOX.
- AVELOX Injection is given to you by intravenous infusion into your vein slowly, over 60 minutes, as prescribed by your healthcare provider.
- Do not skip any doses, or stop taking AVELOX even if you begin to feel better, until you finish your prescribed treatment, unless:
  - You have tendon effects (see "**What is the most important information I should know about AVELOX?**").
  - You have nerve problems. See **"What is the most important information I should know about AVELOX?"**
  - You have central nervous system problems. See **"What is the most important information I should know about AVELOX?"**
  - You have a serious allergic reaction (see "What are the possible side effects of AVELOX?"), or your healthcare provider tells you to stop.
- This will help make sure that all of the bacteria are killed and lower the chance that the bacteria will become resistant to AVELOX. If this happens, AVELOX and other antibiotic medicines may not work in the future.
- If you miss a dose of AVELOX, take it as soon as you remember. Do not take more than 1 dose of AVELOX in one day.
- If you take too much, call your healthcare provider or get medical help immediately.

What should I avoid while taking AVELOX?

- AVELOX can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how AVELOX affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. AVELOX can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while taking AVELOX, call your healthcare provider right away. You should use a sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

What are the possible side effects of AVELOX?

AVELOX can cause side effects that may be serious or even cause death. See "**What is the most important information I should know about AVELOX?**"

Other serious side effects of AVELOX include:

Serious allergic reactions

- Allergic reactions can happen in people taking fluoroquinolones, including AVELOX, even after only one dose. Stop taking AVELOX and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction:
  - Hives
  - Trouble breathing or swallowing
  - Swelling of the lips, tongue, face
  - Throat tightness, hoarseness
  - Rapid heartbeat
  - Faint
  - Yellowing of the skin or eyes. Stop taking AVELOX and tell your healthcare provider right away if you get yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to AVELOX (a liver problem).

Skin rash

- Skin rash may happen in people taking AVELOX even after only one dose. Stop taking AVELOX at the first sign of a skin rash and call your healthcare provider. Skin rash may be a sign of a more serious reaction to AVELOX.

Serious heart rhythm changes (QT prolongation and torsade de pointes)

- Tell your healthcare provider right away if you have a change in your heart beat (a fast or irregular heartbeat), or if you faint. AVELOX may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this event are higher in people:
  - Who are elderly
  - With a family history of prolonged QT interval
  - With low blood potassium (hypokalemia)
  - Who take certain medicines to control heart rhythm (antiarrhythmics)

Intestine infection (Pseudomembranous colitis)

- Pseudomembranous colitis can happen with most antibiotics, including AVELOX. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may have stomach cramps and a fever. Pseudomembranous colitis can happen 2 or more months after you have finished your antibiotic.

Changes in blood sugar

- People who take AVELOX and other fluoroquinolone medicines with oral anti-diabetes medicines or with insulin can get low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia). Follow your healthcare provider's instructions for how often to check your blood sugar. If you have diabetes and you get low blood sugar while taking AVELOX, stop taking AVELOX and call your healthcare provider right away. Your antibiotic medicine may need to be changed.

Sensitivity to sunlight (photosensitivity)

- See "**What should I avoid while taking AVELOX?**" The most common side effects of AVELOX include nausea and diarrhea.

These are not all the possible side effects of AVELOX. Tell your healthcare provider about any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AVELOX?

AVELOX Tablets

- Store AVELOX 59–86°F (15–30°C)
- Keep AVELOX away from moisture (humidity)

Keep AVELOX and all medicines out of the reach of children.

General Information about AVELOX

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AVELOX for a condition for which it is not prescribed. Do not give AVELOX to other people, even if they have the same symptoms that you have. It may harm them.
- This Medication Guide summarizes the most important information about AVELOX. If you would like more information about AVELOX, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about AVELOX that is written for healthcare professionals. For more information call 1-800-526-4099.

What are the ingredients in AVELOX?

AVELOX Tablets:

- Active ingredient: moxifloxacin hydrochloride
- Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol, and ferric oxide

AVELOX Injection:

- Active ingredient: moxifloxacin hydrochloride

- Inactive ingredients: sodium chloride, USP, water for injection, USP, and may include hydrochloric acid and/or sodium hydroxide for pH adjustment

Manufactured for:

Bayer HealthCare

Bayer HealthCare Pharmaceuticals Inc.
Whippany NJ, 07981

AVELOX Tablets manufactured in Germany
AVELOX Injection manufactured in Germany
or
AVELOX Injection manufactured in Norway by
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NO-1753 Halden, Norway

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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