

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICATION

PATIENT MEDICATION INFORMATION

Pr**AVELOX**[®]

Moxifloxacin tablets (as moxifloxacin hydrochloride)

Pr**AVELOX**[®] I.V.

Moxifloxacin injection (as moxifloxacin hydrochloride)

Read this carefully before you start taking **AVELOX** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AVELOX**.

Serious Warnings and Precautions

- Quinolone antibiotics, like **AVELOX**, are related to disabling and possibly long lasting effects such as:
 - inflamed tendon (tendonitis), tendon rupture.
 - nerve damage (peripheral neuropathy).
 - problems in the brain such as:
 - convulsions
 - nervous breakdown
 - confusion
 - and other symptoms
- Quinolone antibiotics, like **Avelox**:
 - have lengthened the heartbeat (QT prolongation)
 - have led to serious allergic reactions, including death
 - may be related to increased tendonitis (inflamed tendon)
 - may worsen myasthenia gravis (a muscle disease)
 - may lead to seizures and nervous breakdowns. Tell your doctor if you have brain or spinal cord problems (such as epilepsy)
 - may cause liver injury which may lead to death
- For further information and symptoms see:
 - the “**To help avoid side effects and ensure proper use,...**” section
 - the “**What are possible side effects from using AVELOX?**” section

Talk to your doctor to see if **AVELOX** is right for you.

What is AVELOX used for?

Your doctor has prescribed AVELOX because you have a certain type of bacterial infection.

Antibacterial drugs like AVELOX treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, AVELOX should be used exactly as directed. Misuse or overuse of AVELOX could lead to the growth of bacteria that will not be killed by AVELOX (resistance). This means that AVELOX may not work for you in the future. Do not share your medicine.

How does AVELOX work?

AVELOX is an antibiotic. It kills many of the types of bacteria that can infect the lungs, sinuses, abdomen, and skin.

What are the ingredients in AVELOX Tablets?

Medicinal ingredients: 400 mg of moxifloxacin as moxifloxacin hydrochloride

Non-medicinal ingredients: cellulose microcrystalline, croscarmellose sodium, lactose monohydrate, magnesium stearate, red ferric oxide, hydroxypropyl methyl cellulose, polyethylene glycol 4000, and titanium dioxide.

What are the ingredients in AVELOX I.V.?

Medicinal ingredients: 250 mL minibags contain 400 mg of moxifloxacin as moxifloxacin hydrochloride

Non-medicinal ingredients: sodium chloride, USP, and Water for Injection, USP. It may also contain hydrochloric acid and/or sodium hydroxide for pH adjustment.

AVELOX Tablets come in the following dosage forms:

Tablets: oblong, convex-shaped, dull red film-coated tablets containing 400 mg moxifloxacin (as hydrochloride). They are engraved with “BAYER” on one side and “M400” on the other.

AVELOX I.V. comes in the following dosage forms:

Intravenous infusion: ready-to-use 250 mL latex-free flexible bags containing 400 mg of moxifloxacin (as hydrochloride) in 0.8% saline.

Do not use AVELOX if:

- you are allergic to AVELOX (moxifloxacin hydrochloride) or other quinolone antibiotics.
- you are allergic to any other ingredient in the formulation (see “[What are the ingredients in AVELOX?](#)”).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AVELOX. Talk about any health conditions or problems you may have, including if you:

- have or have a family history of irregular heart rhythm (such as QT prolongation).
- have or have had heart problems such as heart failure, an irregular heartbeat, or a slow heartbeat.
- have low potassium blood levels (see “[The following may interact with AVELOX](#)”).
- have a history of seizures.
- are pregnant, planning to become pregnant, or if you are breast feeding.
- are less than 18 years of age.
- have a history of tendon problems (such as pain, swelling or rupture of a tendon) related to the use of quinolone antibiotics.
- have myasthenia gravis (a muscle disease).
- have diabetes as AVELOX may affect blood sugar levels. AVELOX may also affect blood sugar levels in those without diabetes.

Other warnings you should know about:

While taking Avelox:

- Avoid too much sunlight or artificial ultraviolet light (such as sunlamps).
 - Contact your doctor if a sunburn or rash occurs.
- Do not drive or use machinery if you feel dizzy or lightheaded.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with AVELOX:

- Antacids or vitamin/mineral supplements
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Antidiabetic medicines (such as, insulin, glyburide, glibenclamide)
- Quinidine, procainamide, amiodarone, sotalol, cisapride^b, erythromycin, antipsychotics, tricyclic antidepressants, diuretics (furosemide, hydrochlorothiazide).

^b no longer marketed in Canada

How to take AVELOX:

- You must take AVELOX exactly as prescribed by your doctor. **YOU SHOULD NOT INCREASE THE PRESCRIBED DOSE.**
- You can take AVELOX with or without food.
- You should drink lots of fluids while taking AVELOX.

- If your doctor decides to stop the treatment, dispose of all unused AVELOX tablets.

Usual dose:

- Take one 400 mg AVELOX tablet once a day.
- Swallow each AVELOX tablet whole with a drink of water. Do not crush or chew AVELOX tablets.
- If you are taking antacids or vitamin/mineral supplements which contain magnesium or aluminium, take AVELOX at least 4 hours before or 8 hours after taking the supplement or antacid.
- Your doctor has decided on the best dose for you and for how long based on your needs. The usual adult dose of AVELOX I.V. (injectable medicine) is one 250 mL minibag once a day.
- The usual length of treatment with AVELOX is 5-10 days. **IT IS IMPORTANT TO COMPLETE THE FULL LENGTH OF TREATMENT, EVEN IF YOU BEGIN TO FEEL BETTER.**

Overdose:

If you think you have taken too much AVELOX, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, take another as soon as you remember. Take the next dose 24 hours later. Do not take two doses in any 24 hour period.

What are possible side effects from using AVELOX?

All medicines, including AVELOX, can cause side effects, although not everyone gets them.

These are not all the possible side effects you may feel when taking AVELOX. If you have any side effects not listed here or if conditions worsen or do not improve then:

- contact your healthcare professional.
- see the **“To help avoid side effects and ensure proper use, ...”** section.

Stop taking AVELOX and contact your doctor if:

- a) you have symptoms of an allergic reaction such as:
 - rash, hives, blistering or other skin reaction
 - swelling of the mouth, throat, limbs
 - difficulty breathing
 - irregular or rapid heartbeat, or fainting spells

- b) you have pain, swelling or rupture of a tendon. You should:
 - rest
 - avoid physical exercise
- c) you have neuropathy (damage to the nerves) with symptoms such as:
 - pain, burning, tingling, numbness or weakness
- d) you have severe diarrhea (bloody or watery) with or without:
 - fever
 - stomach pain or tenderness

You may have Clostridium difficile colitis (bowel inflammation). See your doctor right away.

Other side effects include:

- your eyesight worsens or changes. See your doctor or eye specialist right away.
- nausea, dizziness
- worsening of myasthenia gravis (a muscle disease) with symptoms such as:
 - weakness
 - difficulty walking, swallowing, drooping eyelids

Do not use AVELOX if you have this condition.

- mental problems such as:
 - confusion, headache, shaking
 - hallucinations, depression, agitation
 - difficulty sleeping, anxiety, nervousness, suicidal thoughts

Contact your doctor if you have suicidal thoughts.

If any of these affect you severely, tell your doctor or pharmacist.

Serious Side Effects and What to do About Them			
Symptom/ Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Irregular heartbeat or fainting spells			✓

Serious Side Effects and What to do About Them			
Symptom/ Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Nervous system side effects: <ul style="list-style-type: none"> • seizures/convulsions • confusion • tremors • hallucinations • depression • symptoms of neuropathy (damage to the nerves): numbness, tingling, pain, burning or weakness 			✓
Tendon pain, inflammation, or rupture			✓
Symptoms of an allergic reaction (which may lead to death): <ul style="list-style-type: none"> • rash • hives • rapid heartbeat • difficulty breathing • difficulty swallowing • swelling of face, lips, or tongue 			✓
Liver problems with symptoms such as yellowing of the skin and/or eyes, nausea, abdominal pain, dark urine, and pale stools			✓
Symptoms of a severe bowel condition (Clostridium difficile colitis): <ul style="list-style-type: none"> • persistent diarrhea • bloody or watery diarrhea • abdominal or stomach pain/cramping • blood/mucus in stool 			✓
VERY RARE			
Symptoms of hypoglycemia (low blood sugar) such as: <ul style="list-style-type: none"> • feeling tired 		✓	

Serious Side Effects and What to do About Them			
Symptom/ Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<ul style="list-style-type: none"> • dizziness • sweating • shaking 			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect \(www.healthcanada.gc.ca/medeffect\)](http://www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9
 Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

AVELOX tablets should be stored:

- at room temperature (15°C –30°C)
- in a tightly closed container away from heat and direct light.

Do not freeze the tablets.

AVELOX I.V. should be stored:

- at room temperature (15°C –30°C)
- away from heat and direct light.

Do not refrigerate.

Keep out of reach and sight of children.

If you want more information about AVELOX:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (www.healthcanada.gc.ca); the manufacturer's website <http://www.bayer.ca> or by contacting Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

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