

PART III: CONSUMER INFORMATION

Pr AVELOX®

moxifloxacin hydrochloride tablets

Pr AVELOX® I.V.

moxifloxacin hydrochloride injection

This leaflet is Part 3 of a three-part "Product Monograph" published when AVELOX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AVELOX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

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

What it does:

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

When it should not be used:

Do not use AVELOX if you are allergic to moxifloxacin, other quinolone antibiotics or to any nonmedicinal ingredient in this product (see What the nonmedicinal ingredients are).

What the medicinal ingredient is:

AVELOX tablets contain 400 mg of moxifloxacin as moxifloxacin hydrochloride (active ingredient).

AVELOX I.V. 250 mL minibags contain 400 mg of moxifloxacin as moxifloxacin hydrochloride (active ingredient).

What the nonmedicinal ingredients are:

AVELOX tablets are composed of the following non-medicinal ingredients: cellulose microcrystalline, croscarmellose sodium, lactose monohydrate, magnesium stearate, red ferric oxide, hydroxypropyl methyl cellulose, polyethylene glycol 4000, and titanium dioxide.

The non-medicinal ingredients in AVELOX I.V. are sodium chloride, USP, and Water for Injection, USP. It may also contain hydrochloric acid and/or sodium hydroxide for pH adjustment.

What dosage forms it comes in:

AVELOX tablets are available as oblong, dull red film-coated tablets containing 400 mg moxifloxacin. They are engraved with "BAYER" on one side and "M400" on the other.

AVELOX I.V. is available in ready-to-use 250 mL latex-free flexible bags containing 400 mg of moxifloxacin in 0.8% saline. AVELOX I.V. is for intravenous infusion only.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- AVELOX has been shown to lengthen the heartbeat on an electrocardiogram test (QT interval prolongation).
- Serious hypersensitivity (allergic) reactions, sometimes fatal, have been reported in some patients receiving quinolone therapy, including AVELOX.
- Seizures may occur with quinolone therapy. Tell your doctor if you have any central nervous system problems (ie, epilepsy). Your doctor will determine whether you should use this medication.
- AVELOX should not be used by pregnant women unless the doctor determines the possible benefit outweighs the possible risk to the fetus.
- AVELOX is not recommended for use by nursing mothers as the effects on the infant are unknown. Your doctor will decide whether you should discontinue nursing your baby or discontinue AVELOX.
- AVELOX is not recommended for children under the age of 18 years.
- AVELOX can cause liver injury which may be fatal.

See also **SIDE EFFECTS AND WHAT TO DO ABOUT THEM.**

BEFORE you use AVELOX talk to your doctor or pharmacist if any of the following apply to you:

- Some people are born with a rare condition which results in lengthening of the heartbeat on an electrocardiogram test (QT interval prolongation). If you or any of your family members have this condition, you should inform your health care professional.
- You should avoid taking AVELOX with certain medicines used to treat an abnormal heartbeat. These include quinidine, procainamide, amiodarone, or sotalol. Inform your health care professional if you are taking a heart rhythm drug.
- You have or have had heart problems such as heart failure, an irregular heartbeat, or a slow heartbeat.

- Some medicines such as cisapride^a, erythromycin, antipsychotics and tricyclic antidepressants may also produce an effect on an electrocardiogram test. These may increase the risk of abnormal heartbeats when taken with AVELOX. For this reason, it is important to let your health care provider know all of the medicines that you are using (including non-prescription medicines).
- You should avoid AVELOX if your doctor has told you that 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 have a history of convulsions, notify your doctor before you start taking this drug.
- You should tell your doctor if you are allergic to any of the quinolone drugs or any of the non-medicinal ingredients in AVELOX.
- AVELOX may be associated with allergic (hypersensitivity) reactions, even after a single dose. Stop taking the drug at the first sign of a skin rash or other signs of an allergic reaction and tell your doctor.
- Please tell your doctor if you are pregnant, planning to become pregnant, or if you are breast feeding. AVELOX is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.
- You should not use AVELOX if you have a history of tendon problems associated with the use of a quinolone antibiotic.
- You have a condition known as myasthenia gravis. With this condition, your muscles get weaker with physical activity and improve after periods of rest.

^a no longer marketed in Canada

INTERACTIONS WITH THIS MEDICATION

Talk to your doctor before taking any of the following medications as drug interactions and side effects may occur and they may not be suitable for you. See WARNINGS AND PRECAUTIONS and SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

Drugs that may interact with AVELOX include:

- Antacids or vitamin/mineral supplements
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Antidiabetic medicines (eg, insulin, glyburide, glibenclamide)

- Quinidine, procainamide, amiodarone, sotalol, cisapride^b, erythromycin, antipsychotics, tricyclic antidepressants, diuretics (furosemide, hydrochlorothiazide).

^b no longer marketed in Canada

PROPER USE OF THIS MEDICATION

Usual adult dose:

- You must take AVELOX exactly as prescribed by your doctor. **YOU SHOULD NOT INCREASE THE PRESCRIBED DOSE.**
- The recommended adult dose of AVELOX is one 400 mg tablet once a day.
- The recommended adult dose of AVELOX I.V. is one 250 mL minibag once a day. AVELOX I.V. is to be administered intravenously.
- AVELOX may be taken with or without food.
- Do not crush or chew AVELOX tablets. Swallow each one whole with a drink of water.
- You should drink lots of fluids while taking AVELOX.
- Avoid excessive sunlight or artificial ultraviolet light (eg, sunlamps) during treatment with AVELOX and for one day following completion of treatment. If a sunburn-like reaction or skin eruptions occur, contact your doctor.
- AVELOX may cause dizziness and lightheadedness. You should know how you react to this drug before you operate an automobile or machinery or engage in activities requiring mental alertness or coordination.
- If you are taking antacids or vitamin/mineral supplements while on AVELOX treatment, you should take AVELOX at least 4 hours before or 8 hours after taking a mineral supplement or a vitamin supplement that also contains minerals, or an antacid containing magnesium or aluminium.
- The usual length of treatment with AVELOX is 5-10 days. During the course of treatment, all tablets must be taken to make sure that all bacteria have been killed. **CONTINUE TAKING THE TABLETS UNTIL THEY ARE FINISHED, EVEN IF YOU BEGIN TO FEEL BETTER.**

Overdose:

If you take more than the recommended dose, contact your doctor, nearest hospital emergency department, or regional poison control centre immediately.

Missed Dose:

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

Stopped Treatment:

If your doctor decides to stop the treatment, do not keep any left over medicine unless your doctor tells you to. Please discard all unused AVELOX tablets.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Although most people do not have a problem with side effects when taking AVELOX, all medicines can cause unwanted side effects. Discontinue your medicine and contact your doctor at the first sign of rash, hives or skin eruptions, a rapid heartbeat, difficulty in breathing or swallowing or any other symptom of an allergic reaction. Do not take any more medicine unless your doctor tells you to do so. Your doctor may decide to stop your treatment.

Contact your health care professional and stop taking the drug if you develop an irregular heartbeat or have fainting spells.

At the first sign of tendon pain or joint pain, contact your doctor immediately, stop taking the drug, and refrain from exercise.

Other possible side effects which may occur with AVELOX are nausea, diarrhea and dizziness. Some people may have other side effects. If you notice any unusual effects, check with your doctor or pharmacist. If you feel worse or you think your condition is not improving while taking AVELOX, contact your doctor as soon as possible.

| SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM | |
|--|--|
| Symptom/ Effect | Stop taking drug and call your doctor or pharmacist |
| Rare | |
| Irregular heartbeat or fainting spells | ✓ |
| Nervous system side effects: <ul style="list-style-type: none"> • seizures/convulsions • confusion • tremors • hallucinations • depression • numbness, tingling, pain, or weakness | ✓ |
| Tendon pain, inflammation, or rupture | ✓ |
| Symptoms of an allergic reaction (which can be fatal): <ul style="list-style-type: none"> • rash • hives • skin eruption • rapid heartbeat • difficulty breathing • difficulty swallowing • swelling of face, lips, or tongue | ✓ |
| Liver problems with symptoms such as yellowing of the skin and eyes, nausea, abdominal pain, dark urine, and pale stools | ✓ |
| Symptoms of a severe bowel condition: <ul style="list-style-type: none"> • persistent diarrhea • abdominal or stomach pain/cramping • blood/mucus in stool | ✓ |

This is not a complete list of side effects. For any unexpected effects while taking AVELOX, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your AVELOX tablets in a safe place where children cannot reach them.

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.

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REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Bayer Inc., at: 1-800-265-7382

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