

# AVELOX<sup>®</sup> TABLETS (AV•e•lox)

moxifloxacin hydrochloride

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## Consumer Medicine Information

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### WHAT IS IN THIS LEAFLET

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This leaflet answers some common questions about AVELOX tablets.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking AVELOX tablets against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### WHAT AVELOX IS USED FOR

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AVELOX tablets are used in adults for the treatment of infections of the lungs, airways and sinuses. It can also be used to treat severe and complicated skin and skin structure infections that initially require intravenous therapy followed by oral treatment, complicated intra-abdominal infections including infections such as abscesses that also initially require intravenous therapy followed by oral treatment, and a condition called pelvic inflammatory disease which may occur in women due to infections of the female upper genital tract. However, your doctor may prescribe this medicine for another use. If you

want more information, ask your doctor.

AVELOX tablets contain the active ingredient called moxifloxacin, which is an antibiotic belonging to a group of medicines called quinolones. These antibiotics work by killing the bacteria that are causing your infection.

AVELOX tablets are available by prescription only.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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### BEFORE YOU TAKE AVELOX

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#### *When you must not take it*

**Do not take Avelox tablets if you have an allergy to:**

- moxifloxacin, the active ingredient in AVELOX
- any of the ingredients listed at the end of this leaflet
- other medicines belonging to the quinolone chemical family (e.g. ciprofloxacin, norfloxacin, nalidixic acid).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you are pregnant or think you might be pregnant.**

It may affect your developing baby if you take it during pregnancy. It is not known if it is safe for you to take AVELOX tablets while you are pregnant. Drugs similar to AVELOX have caused joint disease in immature animals. Tell your doctor if you are or may be pregnant.

**Do not take this medicine if you are breast-feeding.**

AVELOX is excreted in breast milk and there is a possibility that your baby may be affected. Your doctor will tell you whether you should take AVELOX and temporarily stop breastfeeding while you are taking the tablets.

**Do not take AVELOX if you:**

- have abnormal heart rhythm (specifically, the medical condition known as “prolongation of the Q-T interval” or “prolonged Q-T syndrome”).
- are taking another medicine used to treat abnormal heart rhythm (e.g. medicines containing the active ingredient quinidine, procainamide, amiodarone or sotalol).
- have low potassium levels in your body.

**Do not give AVELOX to children and growing adolescents.**

**Do not take this medicine after the expiry date printed on the pack and blister.**

The expiry date is printed on the carton and on each blister after

“EXP” (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

**Do not take this medicine if the packaging is torn or show signs of tampering.**

If the packaging is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you:**

- or your family have a history of heart rhythm problems.
- have low potassium levels.
- suffer or have suffered from fits (seizures, convulsions), have had a stroke, liver problems, or other medical problems.

***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including those that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking AVELOX with other medicines.

Some medicines may interfere with the absorption of AVELOX. These medicines include:

- antacids, multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium.

- sucralfate, a medicine used to treat duodenal or stomach ulcers.
- didanosine, a medicine used to treat viral infections. You can still take these medicines while you are taking AVELOX. However, you must take AVELOX at least 2 hours before or 4 hours after taking any of these medicines to make sure there is no problem with absorption.
- AVELOX may have an effect on the electro-cardiogram (ECG - an electrical record of the activity of the heart) and may add to the effect of other medicines on the ECG. You should advise your doctor of any other medicines you are currently taking, particularly those affecting the heart rhythm.

**Tell your doctor if you are taking warfarin, an anticoagulant medicine. You may still take Avelox. Your doctor may wish to perform a clotting test (INR) and adjust your warfarin dose as appropriate.**

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## HOW TO TAKE AVELOX

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.**

***How much to take***

Your doctor or pharmacist will tell you how much and how often you should take AVELOX.

It is important that you take the full course of treatment that your doctor has prescribed for you.

The usual adult dosage for most infections is one 400 mg tablet once daily for 5 to 10 days. However, some types of infections may require longer treatment. Your doctor will determine the duration of time that you take the tablets depending on the type of infection you have.

You should not exceed the recommended dose your doctor has prescribed for you. The risk of cardiac abnormalities may increase with an increase of the dose. Therefore, you should adhere to the dosage.

***How to take it***

Swallow the tablet whole with a glass of water or other fluid. Do not chew the tablets.

***When to take it***

AVELOX tablets are usually taken once a day.

Take your tablet at the same time each day. It can be taken with or without food. It is advisable to drink fluids liberally.

Do not take AVELOX at the same time as taking iron or zinc supplements (or multivitamins containing them), antacids or sucralfate. Taking AVELOX at the same time or even within two hours of taking these can interfere with the absorption of AVELOX and reduce its effectiveness in fighting the infection.

***How long to take it***

The length of treatment may vary from five to ten days depending on the type of infection. Your doctor will determine the duration of time that you need to take the tablets.

### ***If you forget to take it***

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

**Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26; New Zealand 0800 POISON or 0800 764 766), or go to the accident and emergency department at your nearest hospital, if you think you or anyone else may have taken too much AVELOX. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

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## **WHILE YOU ARE TAKING AVELOX**

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking AVELOX tablets.**

**If you become pregnant while you are taking AVELOX, tell your doctor immediately.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking AVELOX.** If you develop an allergic reaction e.g. a skin rash while taking AVELOX, even

following a single dose, stop taking it and tell your doctor.

**If you get severe diarrhoea, tell your doctor or pharmacist immediately.** Do this even if it occurs several weeks after you have stopped taking AVELOX. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medications for diarrhoea without checking with your doctor.

**If you experience palpitations or irregular heart beat during the period of treatment, tell your doctor immediately.** He/she may wish to perform an ECG to measure your heart rhythm. AVELOX can change your heart's ECG, especially if you are female, or if you are elderly.

### ***Things you must not do***

Do not give your AVELOX tablets to anyone else, even if they have the same condition as you.

Do not use AVELOX to treat other conditions unless your doctor tells you to. Do not stop taking your tablets because you are feeling better, unless your doctor told you to do so.

If you do not complete the full course prescribed by your doctor, some of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear up completely or it may return.

### ***What to be careful of***

Be careful driving or operating machinery until you know how AVELOX affects you. AVELOX tablets may cause dizziness or faintness in some patients, especially after the first few doses. The ability to drive and/or operate machinery may be

impaired. If you drink alcohol, dizziness or faintness may be worse.

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## **SIDE EFFECTS**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AVELOX.**

All medicines can have side effects. Sometimes they are serious; most of the time they are not. You may need to stop taking the tablets or have medical treatment if you get some of the serious side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- headache
- dizziness or lightheadedness
- stomach upsets such as feeling sick (nausea), diarrhoea, heartburn or stomach pains
- vomiting.

These are the more common side effects of AVELOX. They are usually mild and short-lived.

**Tell your doctor immediately, or go to the accident and emergency department at your nearest hospital if you notice any of the following:**

- palpitations or fainting spells
- severe skin rashes
- swelling of the face, lips, mouth or throat
- inflammation of the mouth
- fainting
- severe watery or bloody diarrhoea, even if it occurs

several weeks after taking your tablets

- fits (seizures, convulsions).

These are serious side effects. If you have them, you may need urgent medical attention or hospitalisation.

The Achilles tendon (extending from the calf to the heel of the foot) or other tendons have been torn after therapy with quinolone antibiotics. Stop taking it and call your doctor if you feel any discomfort, pain or inflammation of this or any other tendon.

AVELOX may cause rapid and severe inflammation of the liver, which can lead to life-threatening liver failure including fatal cases. Tell your doctor immediately if you suddenly feel unwell or sick and develop symptoms such as:

- yellowing of the skin and in the whites of your eyes, also called jaundice
- pain in liver area
- dark urine
- itchy skin
- tendency to bleed

If you develop a skin reaction or blistering and/or peeling of the skin and/or mucosal reactions contact your doctor immediately before you continue the treatment.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## AFTER TAKING AVELOX

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### **Storage**

**Keep your tablets in the blister pack until it is time to take**

**them.** If you take the tablets out of the box or the blister pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store AVELOX or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.** Heat and damp can destroy some medicines.

**Keep your tablets where children cannot reach them.** A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

### **Disposal**

**If your doctor tells you to stop taking AVELOX tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

**Return any unused medicine to your pharmacist.**

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## PRODUCT DESCRIPTION

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### **What it looks like**

AVELOX 400 mg tablets are dull red oblong, film-coated, convex tablets marked M 400 on top and BAYER on the bottom (available in blister packs of 5 tablets).

### **Ingredients**

Active ingredient per tablet:

AVELOX tablet - moxifloxacin (as hydrochloride) 400 mg

Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- lactose
- magnesium stearate

- iron oxide red
- hypromellose
- macrogol 4000
- titanium dioxide

### **Supplier**

Made in Germany for:

Bayer Australia Limited  
ABN 22 000 138 714  
875 Pacific Highway  
Pymble, NSW 2073  
Australia

Bayer New Zealand Limited  
3 Argus Place, Hillcrest  
North Shore, Auckland 0627  
New Zealand

### **Australian Registration Number:**

AVELOX tablets - AUST R 75766

### **Date of preparation**

May 2010

See TGA website ([www.tga.gov.au](http://www.tga.gov.au)) for latest Australian Consumer Medicine Information.

See MEDSAFE website ([www.medsafe.govt.nz](http://www.medsafe.govt.nz)) for latest New Zealand Consumer Medicine Information.

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