

AVELOX[®] TABLETS (AV•e•lox)

moxifloxacin hydrochloride

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

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 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.

WHAT AVELOX IS USED FOR

Avelox tablets are used in adults for the treatment of infections of the lungs, airways and sinuses.

In women Avelox tablets can be used to treat a condition called pelvic inflammatory disease which is an infection of the female upper genital tract.

In certain infections, you may require treatment with Avelox IV injection followed by a course of Avelox tablets e.g. severe and complicated skin and skin structure infections, complicated abdominal infections.

Even if you have read the Consumer Medicine Information

for Avelox IV, you should read this leaflet as well as it contains information specific to the tablets.

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

Avelox tablets will not work against infections caused by viruses such as colds or the flu. 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.

BEFORE YOU TAKE AVELOX

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 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 breastfeeding.

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 give Avelox to children under 18 years of age.

Do not take Avelox if you:

- **have a condition called ‘QT prolongation’ which is a type of abnormal heart rhythm**
- **are taking medicines used to treat arrhythmia – fast, slow or irregular heart beat (e.g. quinidine, procainamide, amiodarone, sotalol)**
- **have a blood test that shows lower than normal potassium levels**

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 18 refers to November 2018). 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 shows 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 someone in your family has a history of heart rhythm problems
- are taking any medicine that might affect heart rhythm (e.g. quinidine, procainamide, amiodarone, sotalol, erythromycin, tricyclic antidepressants, antipsychotics)
- have low potassium levels
- have had any condition affecting the brain, particularly if you have ever had a seizure (‘fit’)
- have severe liver problems
- have a condition called myasthenia gravis (a disease causing muscle weakness)
- have or have had a mental illness
- have diabetes
- have a history of tendon disease or disorder which was related to treatment with fluoroquinolone antibiotics
- have ever been told that you have an aortic aneurysm

If you have not told your doctor about any of the above, tell him/her before you are given Avelox.

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.

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 if you are taking any medicine that might affect the heart rhythm.

In particular, tell your doctor if you are taking:

- warfarin, a medicine used to stop blood clots. Your doctor should perform INR testing and may adjust your warfarin dose
- medicines used to treat abnormal heart rhythm (e.g. quinidine, procainamide, amiodarone, sotalol)
- medicines that can affect the heart rhythm (erythromycin, tricyclic antidepressants, antipsychotics)
- corticosteroids

These medicines may affect each other or increase the chance of you getting a side effect.

Some medicines may interfere with the absorption of Avelox tablets. 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.

Your doctor or pharmacist will be able to tell you what to do when taking AVELOX with other medicines.

HOW TO TAKE AVELOX

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 Avelox tablets 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 dose your doctor has prescribed for

you. The risk of heart rhythm problems may increase with an increase of the dose.

How to take it

Swallow the tablet whole with water. Do not chew the tablet.

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 antacids (containing magnesium, calcium, or aluminium), multivitamins (containing iron or zinc), sucralfate (a medicine to treat stomach ulcers) or didanosine (a medicine to treat viral infections).

Taking these medicines at the same time as Avelox can interfere with the absorption of Avelox tablets and reduce their effectiveness in fighting the infection.

You must take Avelox at least 2 hours before, or 4 hours after taking any of these medicines.

How long to take it

The length of treatment with Avelox tablets may vary depending on the type of infection. The usual duration of treatment is from five to ten days, but can be longer. 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 (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.

WHILE YOU ARE TAKING AVELOX

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Avelox

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.

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 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.

Tell your doctor immediately if you feel any discomfort, pain, swelling or inflammation of a tendon.

Medicines like Avelox have been reported to cause tendon damage (especially the Achilles tendon). This may occur even within the first 48 hours of treatment and up to several months after completing treatment with Avelox. The risk of tendon damage may be increased in elderly patients, during strenuous physical activity, if you are currently being treated with a type of medicine called corticosteroids, if you have reduced kidney function or have received solid organ transplants.

If you experience palpitations (fast or irregular heart beat) or fainting spells during the period of treatment, tell your doctor immediately.

Tell your doctor or nurse if you experience symptoms of depression or self-endangering behaviour. Avelox should be discontinued.

Tell your doctor or nurse if you develop photosensitivity (getting sunburnt very easily). Avoid exposure to ultraviolet radiation and sunlight. Protect your skin when you are in the sun, especially between 10am and 3pm. If you are outdoors, wear protective clothing and use a 30+ sunscreen.

Tell your doctor or nurse as soon as possible if you develop pain, burning, tingling, numbness or weakness in any part of the body.

If you experience sudden stomach, chest or back pain, immediately seek medical help at an emergency department.

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 change the dose.

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. The ability to drive and/or operate machinery may be impaired. If you drink alcohol, dizziness or faintness may be worse.

SIDE EFFECTS

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
- nausea, vomiting
- stomach pains, diarrhoea
- thrush in the mouth (sore creamy-yellow raised patches in mouth) or in the vagina (itching, burning or thick white discharge)

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:

- allergic reactions such as skin rashes, swelling of the face, lips, mouth or throat
- palpitations or fainting spells
- watery or bloody diarrhoea, even if it occurs several weeks after finishing your tablets
- pain, swelling or rupture of a tendon
- fits (seizures, convulsions)
- pain, burning, tingling, numbness or weakness that starts or worsens on Avelox
- changes in your mood or thoughts that worry you
- sudden stomach, chest or back pain

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

In isolated instances, some serious adverse drug reactions may be long-lasting (> 30 days) and disabling; such as tendinitis, tendon rupture, musculoskeletal disorders, and other reactions affecting the nervous system including psychiatric disorders and disturbance of senses.

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.

AFTER TAKING AVELOX

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.

PRODUCT DESCRIPTION

What it looks like

Avelox 400 mg tablets are dull red oblong, film-coated, convex tablets marked with M 400 on one side and BAYER on the other side.

It is available in blister packs of 1 tablet and 5 tablets.

Not all forms and pack sizes may be marketed.

Ingredients

Active ingredient per tablet:
moxifloxacin (as hydrochloride)
400 mg

Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- lactose

- magnesium stearate
- ferric oxide red
- hypromellose
- macrogol 4000
- titanium dioxide

Supplier

Made in Germany for:

Bayer New Zealand Limited
3 Argus Place, Hillcrest
North Shore, Auckland 0627
New Zealand
Telephone: 0800 229 376

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1 October 2019

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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