

AVELOX[®] IV (AV•e•lox)

moxifloxacin hydrochloride

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about AVELOX IV.

It does not contain all of the available information on AVELOX IV. 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 receiving AVELOX IV 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 IV IS USED FOR

AVELOX IV is a sterile intravenous antibiotic used in adults for the treatment of serious respiratory tract infections (e.g. lungs and airway), severe and complicated skin and skin structure infections that initially require intravenous therapy followed by oral treatment, and complicated intra-abdominal infections including infections such as abscesses that also initially require intravenous therapy followed by oral treatment. However, your doctor may prescribe this medicine for another use. If you want more information, ask your doctor.

AVELOX IV contains 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 IV is available by prescription only, and is used in a hospital environment 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 ARE GIVEN AVELOX IV

When you must not be given it

You must not be given AVELOX IV if you have an allergy to:

- moxifloxacin, the active ingredient in AVELOX IV
- 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 AVELOX IV if you have a medical condition of abnormal heart rhythm (specifically, the medical condition known as “prolongation of the Q-T interval” or “prolonged Q-T syndrome”).

Do not take AVELOX IV if you are taking another medicine used to treat abnormal heart rhythm (e.g. medicines containing the active ingredient quinidine, procainamide, amiodarone, sotalol).

Do not take AVELOX IV if you have low potassium levels in your body.

Do not take AVELOX IV if you are pregnant or think you may be pregnant. It is not known if it is safe for you to receive AVELOX IV while you are pregnant. Drugs similar to AVELOX IV have caused joint disease in immature animals. Tell your doctor if you are or may be pregnant.

Do not take AVELOX IV if you are breast-feeding. AVELOX IV is excreted in breast milk and there is a possibility that the breast-fed baby may be affected. Your doctor will tell you whether you should be given AVELOX IV and temporarily stop breast-feeding while you are given this medicine.

Do not take AVELOX IV if you are under 18 years of age.

Do not use AVELOX IV after the expiry date printed on the

pack. The expiry date is printed on the bag as well as on the carton label 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.

Note: The contents of the bag are not to be used if it is cloudy or has little specs in it.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given 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.
- have congestive heart failure
- have kidney failure or impairment

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

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 receiving AVELOX IV with other medicines.

AVELOX IV 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 IV. Your doctor may wish to perform a clotting test (INR) and adjust your warfarin dose as appropriate.

HOW AVELOX IV IS GIVEN

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 given, ask your doctor for help.

How it is given

AVELOX IV is given as a slow injection into a vein, usually as a drip, by a doctor or a nurse.

How much is given

This depends on your condition, and will be prescribed by your doctor.

The usual adult dose is 400mg once a day for 7-14 days.

How long it is given

Your doctor will determine the duration of time that you are given AVELOX IV depending on your infection. In some cases, your doctor will put you on AVELOX tablets as soon as

possible, after being given AVELOX IV.

If you are given too much (overdose)

The doctor will treat you as appropriate if you have any ill effects from having been given too much AVELOX IV.

In cases of overdose, it is advisable to contact the Poisons Information Centre (Australia: 13 11 26; New Zealand: 0800 POISON or 0800 764766) for recommendations on the management of overdose.

WHILE YOU ARE RECEIVING AVELOX IV

Things you must do

Tell your doctor or nurse:

- If you develop an allergic reaction (e.g skin rash, hives, difficulty breathing, flushing, faster or slower heart rate) while receiving AVELOX IV, even following a single dose.
- If you get severe diarrhoea, tell your doctor or nurse immediately. Do this even if it occurs several weeks after you have stopped receiving AVELOX IV. 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.
- Photosensitivity (getting sunburnt very easily) can occur with AVELOX IV. However, it is temporary and staying out of direct sunlight while on AVELOX IV therapy will prevent it from happening.
- If you feel unwell or you develop symptoms

mentioned in the **SIDE EFFECTS** section (see below).

Things you must not do

Do not interfere with the equipment that is used to infuse AVELOX IV into your body.

Changes to the settings of the equipment must only be carried out by your doctor or the nurse who is looking after you.

SIDE EFFECTS

Tell your doctor or nurse as soon as possible if you do not feel well while you are receiving AVELOX IV.

All medicines can have side effects. Sometimes they are serious; most of the time they are not. You may need to stop receiving the injection 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 side effects which have been reported after treatment with AVELOX IV:

- headache
- dizziness or light-headedness
- stomach upsets such as feeling sick (nausea), diarrhoea, heartburn or stomach pains
- vomiting
- redness or pain at the site of injection.

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

Tell your doctor immediately, 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 receiving your AVELOX IV treatment.
- fits (seizures, convulsions).

These are serious side effects. If you have them, you may need urgent medical attention, and AVELOX IV will need to be discontinued.

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

AVELOX IV 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 patients.

AFTER RECEIVING AVELOX IV

When treatment is to be stopped, your prescribing doctor may need to alter the dose of other medicine(s) accordingly and monitor your condition.

Storage

AVELOX IV will be stored in the pharmacy or on the ward. The bags are kept in a cool, dry place away from sunlight, where the temperature stays below 30°C. Do not refrigerate.

Disposal

Each bag of AVELOX IV is to be used once only. Any unused portion remaining in the bag must be discarded.

If you have any further questions on AVELOX IV, or are unsure of the information given above, please see your doctor or nurse, who will be able to assist you.

PRODUCT DESCRIPTION

What it looks like

AVELOX IV 400 mg is a ready to use, clear yellow solution for infusion.

AVELOX IV is available in flexibags in packs of 1 and 12. It is also available in glass bottles in packs of 1 and 5.

Not all pack sizes may be marketed.

Ingredients

Active ingredient:

- AVELOX IV - moxifloxacin (as hydrochloride) 400 mg per 250 mL

Inactive ingredients:

- sodium chloride
- water for injections

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 Numbers

AVELOX IV - AUST R 78977

AVELOX IV – AUST R 81598

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See TGA website
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Australian Consumer Medicine
Information.

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