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 receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place, even after your treatment is finished.
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 infections of the lungs, airways and sinuses. Avelox IV can also be used to treat severe and complicated skin and skin structure infections, and complicated infections within the abdomen.

Your doctor may choose to prescribe tablets to finish the course rather than keep you on Avelox IV for the whole treatment period.

Remember to read the Consumer Medicine Information for Avelox tablets if you receive them because it may contain additional information specific to the tablets.

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

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 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

You should not be given 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.

You should not be given Avelox IV if you are breastfeeding.
Avelox IV is excreted in breast milk and there is a possibility that the breastfed baby may be affected. Your doctor will tell you whether you should be given Avelox IV and temporarily stop breastfeeding while you are given this medicine.

You should not be given Avelox IV if you are under 18 years of age.

Do not take Avelox if you:
- **have a condition called 'QTc 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**

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 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

Some medical conditions may require a restricted sodium intake (e.g. congestive heart failure, kidney failure, kidney disease). Tell your doctor if you have a condition like this because Avelox IV solution contains sodium salt. The additional sodium you receive may worsen the symptoms of these conditions.

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.

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 if you are taking any medicines 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 (e.g. erythromycin, tricyclic antidepressants, antipsychotics)
- corticosteroids

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

Your doctor or pharmacist will be able to tell you what to do when receiving Avelox IV with other medicines.

HOW AVELOX IV IS GIVEN

Avelox IV is given as a slow injection into a vein, over a period of 60 minutes ('drip').

Avelox IV must only be given 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)

Immediately tell your doctor or nurse or telephone the Poisons Information Centre (New Zealand: 0800 POISON or 0800 764766), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have received too much Avelox IV. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

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) while on Avelox IV, even following a single dose.

If you develop diarrhoea, tell your doctor or pharmacist immediately.
Do this even if it occurs several weeks after you have finished 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.

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 IV. 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 heartbeats) 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 behavior.
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 attention.

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 and they worry you:
- headache
- dizziness or light-headedness
- 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)
- 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:
- 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 Avelox IV treatment.
- 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 moods 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, and Avelox IV will need to be discontinued.

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 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 people.

AFTER RECEIVING AVELOX IV

Storage

Avelox IV will be stored in the pharmacy or on the ward. It is kept in a cool, dry place away from sunlight, where the temperature stays below 30°C and above 15°C. Do not refrigerate.

Disposal

Each pack of Avelox IV is to be used once only. Any unused portion must be returned to the pharmacist for disposal.

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 made in glass bottles in packs of 1 and 5.

Not all forms and pack sizes may be marketed.

Ingredients

Active ingredient:

- moxifloxacin (as hydrochloride) 400 mg per 250 mL

Inactive ingredients:

- sodium chloride
- water for injections

Supplier

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

Date of preparation

1 October 2019

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