

AVELOX® IV

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using AVELOX IV?

AVELOX IV contains the active ingredient moxifloxacin. AVELOX IV is used in adults for the treatment of serious infections of the lungs and airways. It can also be used to treat severe, complicated skin and skin structure infections.

For more information, see Section [1. Why am I using AVELOX IV?](#) in the full CMI.

2. What should I know before I am given AVELOX IV?

Do not use if you have ever had an allergic reaction to AVELOX IV or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, in particular heart rhythm problems, severe liver problems, seizures, mental illnesses or if you have a sodium restriction, if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given AVELOX IV?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AVELOX IV and affect how it works.

The main types of medicines that affect how AVELOX works include warfarin, medicines to treat abnormal heart rhythm, medicines which affect heart rhythm and corticosteroids.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given AVELOX IV?

Avelox IV is normally given as a slow injection into a vein over a period of 60 minutes ('drip') once daily for 5-21 days. Avelox IV must only be given by a doctor or a nurse at the hospital.

More information can be found in Section [4. How am I given AVELOX IV?](#) in the full CMI.

5. What should I know while using AVELOX IV?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using AVELOX IV.Avoid exposure to ultraviolet radiation and sunlight.Call your doctor immediately if you experience allergic reaction, diarrhoea, feel any discomfort, pain, swelling or inflammation of a tendon, palpitations, symptoms of depression or self-harming, develop pain, burning, tingling, numbness or weakness in any part of the body, or develop photosensitivity.
Things you should not do	<ul style="list-style-type: none">Do not interfere with the equipment that is used to infuse AVELOX IV into your body
Driving or using machines	<ul style="list-style-type: none">AVELOX IV may cause dizziness or faintness in some people.Be careful before you drive or use any machines until you know how AVELOX affects you.

For more information, see Section [5. What should I know while receiving AVELOX IV?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects may include redness or pain at the site of injection, headache, dizziness, nausea, vomiting, stomach pains, thrush in the mouth or vagina.

Serious side effects may include allergic reactions, palpitations, fainting, seizures, diarrhoea, tendon pain, swelling or rupture, pain, burning, tingling, numbness or weakness that starts or worsens on AVELOX IV, eyesight problems, changes in mood or thoughts, skin reactions, blistering or peeling, and symptoms of liver damage.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

BOXED WARNING:***Serious disabling and potentially irreversible adverse reactions***

Fluoroquinolones, including moxifloxacin, have been associated with disabling and potentially irreversible serious adverse reactions involving different body systems that have occurred together in the same patient. Patients of any age or without pre-existing risk factors have experienced these adverse reactions. These include but are not limited to serious adverse reactions involving the nervous system (Seizures, Peripheral neuropathy), musculoskeletal system (Tendonitis and tendon rupture) and psychiatric effects (Psychiatric reactions).

AVELOX[®] IV (AV·e·lox)

Active ingredient(s): *moxifloxacin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AVELOX IV. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AVELOX IV.**

Where to find information in this leaflet:

- [1. Why am I using AVELOX IV?](#)
- [2. What should I know before I am given AVELOX IV?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given AVELOX IV?](#)
- [5. What should I know while receiving AVELOX IV?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using AVELOX IV?

AVELOX IV contains the active ingredient moxifloxacin. AVELOX IV is a sterile intravenous antibiotic belonging to a group of medicines called quinolones. These antibiotics work by killing the bacteria that are causing your infection.

AVELOX IV is used in adults for the treatment of serious infections of the lungs and airways. It can also be used to treat severe, complicated skin and skin structure infections.

Avelox IV is used to start the treatment and then your doctor may prescribe tablets to complete the course.

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

2. What should I know before I am given AVELOX IV?

Warnings

Do not use AVELOX IV if:

- you are allergic to moxifloxacin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- you are allergic to other medicines belonging to the quinolone family (e.g. ciprofloxacin, norfloxacin, nalidixic acid)
- you have a condition called 'QTc prolongation' which is a type of abnormal heart rhythm
- you are taking medicines to treat arrhythmia – fast, slow or irregular heartbeat (e.g. quinidine, procainamide, amiodarone, sotalol)
- you have a blood test that shows lower than normal potassium levels

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- 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 had a mental illness
- have diabetes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

AVELOX IV is not recommended if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

AVELOX IV passes into breast milk and may affect your baby.

Children under 18 years old

AVELOX should not be used in children under 18 years of age.

Restricted Sodium Intake

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with AVELOX IV and affect how it works.

AVELOX may have an effect on the heart rhythm. If you are using other medicines that affect the heart at the same time as AVELOX there is an increased risk of altering your heart rhythm.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AVELOX IV.

4. How am I given AVELOX IV?

- **Avelox IV must only be given by a doctor or a nurse at the hospital.**
- Avelox IV is given as a slow injection into a vein over a period of 60 minutes ('drip').

How much is given?

- **The usual adult dose is 400mg once a day for 5-21 days.**

Your doctor will determine the dose and duration of time that you are given Avelox IV depending on your infection. Your doctor will put you on Avelox tablets as soon as possible, after being given Avelox IV.

If you are given too much AVELOX IV

If you think that you have received too much AVELOX IV, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while receiving AVELOX IV?

Things you should do

- **Avoid prolonged exposure to ultraviolet radiation and sunlight.** AVELOX can make your skin more susceptible to sunburn. Protect your skin when you are in the sun, especially between 10am and 3pm. If you are outdoors, wear protective clothing and use a SPF 30+ sunscreen.

Call your doctor straight away if you:

- develop an allergic reaction (e.g. skin rash) while on Avelox IV, even following a single dose.
- **develop diarrhoea.** Contact your doctor even if it occurs several weeks after you have finished receiving AVELOX IV.
- **feel any discomfort, pain, swelling or inflammation of a tendon.**
- experience palpitations (fast or irregular heart beats) or fainting spells during treatment.
- experience symptoms of depression or self-harming behaviour. AVELOX should be discontinued.
- develop pain, burning, tingling, numbness or weakness in any part of the body. AVELOX should be discontinued immediately.
- develop photosensitivity (getting sunburnt very easily)

Remind any doctor, dentist or pharmacist you visit that you are using AVELOX IV.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AVELOX IV affects you.

AVELOX IV may cause dizziness or faintness in some people. Be careful before you drive or use any machines or tools until you know how AVELOX IV affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

How is AVELOX IV stored?

- 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.

Getting rid of any unwanted medicine

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

Less serious side effects

Less serious side effects	What to do
<p>Nervous system-related:</p> <ul style="list-style-type: none"> • headache • dizziness or light-headedness <p>Gastrointestinal system-related:</p> <ul style="list-style-type: none"> • nausea, vomiting • stomach pains, diarrhoea <p>Fungal infection</p> <ul style="list-style-type: none"> • thrush in the mouth (sore creamy-yellow raised patches in mouth) or in the vagina (itching, burning or thick white discharge) <p>Skin-related</p> <ul style="list-style-type: none"> • redness or pain at the site of injection 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Immune-related:</p> <ul style="list-style-type: none"> • allergic reactions such as skin rashes, swelling of the face, lips, mouth or throat 	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

<p>Nervous system-related:</p> <ul style="list-style-type: none"> • palpitations or fainting spells • fits (seizures, convulsions) <p>Gastrointestinal system-related:</p> <ul style="list-style-type: none"> • watery or bloody diarrhoea, even if it occurs several weeks after finishing your AVELOX treatment. <p>It may be a sign 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.</p> <p>Muscle-related:</p> <ul style="list-style-type: none"> • pain, swelling or rupture of a tendon • pain, burning, tingling, numbness or weakness that starts or worsens on AVELOX <p>Eye-related:</p> <ul style="list-style-type: none"> • visual disturbances (eyesight problems) <p>Mood-related:</p> <ul style="list-style-type: none"> • changes in your mood or thoughts that worry you <p>Liver damage:</p> <p>suddenly feeling unwell or sick and develop symptoms such as:</p> <ul style="list-style-type: none"> • 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 <p>Skin-related:</p> <ul style="list-style-type: none"> • skin reaction or blistering and/or peeling of the skin and/or mucosal reactions 	<p>your nearest hospital if you notice any of these serious side effects.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What AVELOX IV contains

Active ingredient (main ingredient)	moxifloxacin (as hydrochloride) 400 mg per 250 mL
Other ingredients (inactive ingredients)	sodium chloride water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What AVELOX IV looks like

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

Avelox IV is available in flexibags in packs of 1, 5 and 12 (Aust R 78977).

It is also made in glass bottles in packs of 1 and 5 (Aust R 81598).

Not all forms and pack sizes may be marketed.

Who distributes AVELOX IV

Bayer Australia Ltd.
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

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See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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