

Amiodarone 50mg/ml solution for IV injection

Each 3ml ampoule contains 150mg of Amiodarone hydrochloride

OI Sciences Ltd.

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start having this medicine.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, nurse or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT AMIODARONE INJECTION IS AND WHAT IT IS GIVEN FOR

Amiodarone is used to control an irregular or rapid heart rate when other treatments have been ineffective or cannot be used. This type of medicine is known as an anti-arrhythmic.

Amiodarone Injection should only be given in a hospital by a doctor. It can be used where a rapid response is required. Your blood pressure and heart rate should be monitored whilst receiving Amiodarone Injection.

2. BEFORE YOU ARE GIVEN AMIODARONE INJECTION

Amiodarone Injection should NOT be given to you:

If you suffer from **problems with your heart**, such as heart block, which can cause a slow heart rate, a slow pulse or dizziness.

If you have or have had **thyroid problems**. (Your doctor will test your thyroid before prescribing this medicine).

If you have **serious breathing difficulties**.

If you have **very low blood pressure** (dizziness or feeling faint at times).

If it is given as a single injection and you have serious breathing difficulties, low blood pressure, heart failure or cardiomyopathy (weakness of the heart muscle).

If you have an **allergy** to:

- amiodarone,
- iodine or
- any of the other ingredients.

If you are **pregnant** or likely to become pregnant, except in exceptional circumstances.

If you are **breast-feeding**.

If you are taking certain **other medicines** such as:

- some other heart drugs (e.g. beta-blockers such as sotalol);
- antibiotics (e.g. erythromycin injection, co-trimoxazole or moxifloxacin);
- medicines to treat mental illness (antipsychotics, e.g. chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride and sertindole; or antidepressants, including lithium and tricyclic antidepressants e.g. doxepin, maprotiline amitriptyline);
- medicines to treat allergic reactions (antihistamines, e.g. terfenadine, mizolastine);
- medicines to treat or prevent malaria (antimalarials);
- pentamidine injections (used to treat e.g. AIDS or pneumonia);
- stimulant laxatives.

You must inform your doctor if you are taking any of these medications.

Grapefruit juice can increase the blood level of Amiodarone Injection and should be avoided during treatment with Amiodarone 50mg/ml solution for IV injection.

Amiodarone Injection should be given to you with SPECIAL CARE:

If it is being given as an infusion and you have low blood pressure, severe heart failure or severe cardiomyopathy (*weakness of the heart muscle*);

If you are going to have an **anaesthetic** or high dose **oxygen therapy**;

If you suffer from **asthma** or any other breathing disorder;

If you suffer from **liver disease**;

If you suffer from **porphyria** (a rare genetic blood disorder).

Pregnancy

Your doctor will prescribe Amiodarone Injection only if he/she considers the benefit of treatment outweighs the risks during your pregnancy.

Breast-feeding

You should not be given Amiodarone Injection if you are breast-feeding.

Premature and newborn babies

Amiodarone Injection should only be given to premature babies and newborns up to 1 month old if they have a heart rate disorder that is life-threatening and other treatment does not work, or is not possible. Amiodarone Injection should only be used in a special care unit under continuous monitoring (ECG and blood pressure).

Children up to 3 years old

The benzyl alcohol in this product may cause toxic and allergic reactions in infants and children up to 3 years old.

Driving and using machines

This medicine should not affect your ability to drive. However, if you experience any dizziness, make sure that you are fit to drive or operate machinery before attempting to do so.

Taking other medicines

Before Amiodarone Injection is given to you, please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine – even those which your doctor has not prescribed for you, but which you have bought yourself from your chemist/pharmacy.

In particular, please check with your doctor if you are taking any of the following, (in addition to the drugs listed in section 2, 'Before you are given Amiodarone Injection'):

- Digoxin (used to treat certain heart conditions);
- Anticoagulants (used to thin the blood e.g. warfarin);
- Phenytoin (used to treat epilepsy);
- Some calcium channel inhibitors (used to treat high blood pressure and angina e.g. verapamil, diltiazem);
- Ciclosporin (used after transplant operations);
- Simvastatin or other statins (used to lower cholesterol levels);
- other drugs like lidocaine, tacrolimus, sildenafil, fentanyl, midazolam and ergotamine;
- Flecainide (used to treat irregular heart rhythms);
- Fluoroquinolones e.g. ciprofloxacin (antibiotics used to treat a wide range of infections);

drugs which may change the levels of potassium or magnesium in your blood: e.g. diuretics (water tablets), steroid tablets or the antifungal amphotericin (when given directly into a vein).

3. HOW AMIODARONE INJECTION IS GIVEN

Amiodarone Injection should only be given in a hospital by a doctor. Your blood pressure and heart rate should be monitored whilst receiving Amiodarone Injection.

Amiodarone Injection is given directly into the blood stream using a drip (or central line). It should not be given too rapidly.

This medicine is given diluted in a sugar (5% dextrose) solution.

The usual dose of Amiodarone Injection is 5 mg for every kg body weight, given by intravenous infusion over 20 minutes to 2 hours. This may then be followed by further infusions up to 1200 mg in 24 hours.

The correct dose and dilution for you will have been decided by the doctor and will depend upon your condition.

Children and the elderly may be prescribed lower doses.

IV injection may be given at an initial dose at 5mg for every kg body weight. This dose should be given over a minimum of 3 minutes and should not be repeated less than 15 minutes after initial dose. This dose regimen may be considered only in exceptional circumstances and emergencies.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Amiodarone Injection can have side effects. The side effects mentioned here have been divided into how often they occur according to the following frequencies:

Very common:	affects more than 1 in 10 people
Common:	affects more than 1 in 100 people
Uncommon:	affects more than 1 in 1,000 people
Rare:	affects more than 1 in 10,000 people
Very rare:	affects less than 1 in 10,000 people

If you experience any of the following side effects you should tell your doctor immediately, who will decide whether to stop the medication.

The most common potentially serious side effects include:

- a slow pulse
- a decrease in blood pressure, leading to collapse

Other very rare but potentially serious side effects reported with Amiodarone Injection include:

- Chest pain or palpitations (awareness of heart beat), or abnormal heart rhythm or cardiac arrest
- Liver disorders, including jaundice (yellowing of the skin or eyes), and may lead to liver failure
- Generalised allergic reactions such as swelling of the face lips and/or tongue, shortness of breath which may be fatal
- Breathing difficulties (with or without fever), inability to breathe
- wheezing and breathing difficulties in patients with asthma
- Bone marrow disorders
- Raised pressure around the brain causing headaches and visual disturbance

Other common less serious side effects are:

- local injection site reactions including swelling, pain, redness, infection and pigmentation (skin colouring) changes

Very rare and less serious side effects reported include:

- Hot flushes, sweating
- Nausea (feeling sick)
- Headaches

5. HOW TO STORE AMIODARONE INJECTION

Keep all medicines out of the reach and sight of children.

Do not use Amiodarone Injection after the expiry date, which is marked on both the outer carton and on each ampoule.

Do not store above 25°C. Store in the original container, protected from light. Keep the ampoules in the outer carton.

6. FURTHER INFORMATION

What Amiodarone Injection contains

Each ampoule contains 150mg of the **active substance**, amiodarone hydrochloride. The **other ingredients** are benzyl alcohol, polysorbate 80 and water for injections.

What Amiodarone Injection looks like and contents of the pack

Each carton contains 10 ampoules. Each ampoule contains 3ml of clear, pale yellow solution for injection.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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