

**Amiodarone 30mg/ml
Solution for injection/infusion
in pre-filled syringe**

amiodarone hydrochloride

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, pharmacist or nurse
- If you get any of the side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

This medicine will be referred to as Amiodarone Injection in the rest of this leaflet.

What is in this leaflet:

1. What Amiodarone Injection is and what it is used for
2. What you need to know before you are given Amiodarone Injection
3. How Amiodarone Injection is given
4. Possible side effects
5. How to store Amiodarone Injection
6. Contents of the pack and other information

1. What Amiodarone Injection is and what it is used for

Amiodarone Injection contains the active substance amiodarone hydrochloride. It belongs to a group of medicines called anti-arrhythmics.

It works by controlling the uneven beating of your heart (called arrhythmias).

Having the injection helps your heartbeat to return to normal.

Amiodarone Injection is normally only given in a hospital when a quick response is needed or when tablets cannot be given. Amiodarone Injection can be used to:

- Treat uneven heartbeats where other medicines either have not worked or cannot be used
- Treat an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast
- Treat other types of fast or uneven heartbeats known as 'atrial flutter' or 'atrial fibrillation'.

2. What you need to know before you are given Amiodarone Injection

You must not be given Amiodarone Injection if:

- You are allergic to amiodarone hydrochloride, iodine or to any of the other ingredients of this medicine (listed in section 6)
- You have heart problems such as heart block, which can cause a slow heart rate (such as sino-atrial heart block, sinus bradycardia, high grade AV block, bifascicular or trifascicular block or sinus node disease) and you do not have a pacemaker
- You have heart failure or weakness of the heart muscle (cardiomyopathy)
- You have or have had thyroid problems. Your doctor will test your thyroid before giving you this medicine.
- You have severe breathing problems.
- You have very low blood pressure
- You are taking other medicines that can make your heartbeat very quickly (these are listed below under the section 'Taking other medicines')
- You are pregnant, think you may be pregnant or are

breastfeeding (unless treatment is considered absolutely essential by your doctor)

- Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.
- Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.
- Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding.

Do not use this medicine if any of the above applies to you and talk to your doctor or nurse.

Amiodarone Injection must not be given to premature babies, neonates or a child up to 3 years old.

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before you are given Amiodarone Injection if:

- You have mild to moderate low blood pressure
- You have a weak heart or heart failure
- You have any problem with your thyroid gland. Your doctor will test your thyroid before giving you this medicine.
- You have liver problems
- You are receiving high dose oxygen therapy or have any other problems with your lungs including asthma
- You are due to have an operation involving general anaesthesia
- You are elderly
- You currently take a medicine containing sofosbuvir for the treatment of hepatitis C as it may result in a life-threatening slowing of your heart beat. Your doctor may consider alternative treatments. If treatment with amiodarone and sofosbuvir is needed, you may require additional heart monitoring.

Check with your doctor, pharmacist or nurse if:

- you have any problems with your eyesight. This includes an illness called 'optic neuropathy' or 'neuritis'.
- the person having the medicine is an infant or child under 3 years old you have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.
- you have a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may also feel generally unwell, have a fever, chills and aching muscles (Toxic epidermal necrolysis).

Taking other medicines

Tell your doctor immediately if you are taking a medicine containing sofosbuvir for the treatment of hepatitis C and during treatment you experience:

- slow or irregular heartbeat or heart rhythm problems;
- shortness of breath or worsening of existing shortness of breath;
- chest pain;
- light-headedness;
- palpitations;
- near-fainting or fainting.

The following medicine must not be taken with Amiodarone Injection as together they can cause a very severe fast heartbeat that can be fatal:

- Medicines to treat irregular heart rhythms (anti-arrhythmics), such as quinidine, procainamide, disopyramide and sotalol
- Medicines to improve blood supply to the brain (e.g. vincamine)
- Antibiotics, such as erythromycin, moxifloxacin, co-trimoxazole and pentamidine
- Medicines to treat mental illness (anti-psychotics), such as

chlorpromazine, thioridazine, haloperidol, fluphenazine, amisulpride, sertindole and pimozide

- Medicines to treat depression, such as lithium and tricyclic antidepressants, including doxepin, maprotiline and amitriptyline
- Medicines used for digestive problems (e.g. cisapride).
- Medicines for infections (e.g. moxifloxacin, erythromycin).
- Injections of pentamidine (used in certain types of pneumonia).
- Certain medicines to treat allergic reactions (antihistamines), such as terfenadine, astemizole and mizolastine
- Medicines used to treat or prevent malaria, such as quinine, mefloquine, chloroquine and halofantrine

If any of the above applies to you, do not use this medicine and talk to your doctor or nurse.

Other medicines and Amiodarone Injection

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicine.

- Oral anticoagulants e.g. warfarin (used to thin the blood), phenytoin (used to treat epilepsy) and digoxin (used to treat certain heart conditions). Your doctor may reduce your dose of these medicines and your blood will need to be monitored before and after treatment
 - Stimulant laxatives such as bisacodyl and senna, medicines called diuretics or water tablets, steroids and the antifungal medicine amphotericin (when given directly into the vein). These can cause low levels of potassium in the blood, which can increase the risk of getting a fast heart rate (tachycardia).
 - Rifampicin (an antibiotic) and St. John's Wort (a herbal medicine) can cause lower levels of Amiodarone Injection in the body if they are taken at the same time
 - Medicines that can either be affected by or effect the level of amiodarone in the body if taken at the same time:
 - Ciclosporin, tacrolimus (immunosuppressants- used to help prevent rejection of transplants)
 - Flecainide, used to treat irregular heart rhythms. Your doctor should monitor your treatment closely and may adjust your dose of flecainide.
 - Simvastatin, lovastatin, atorvastatin (drugs to reduce blood cholesterol), as there is a risk of developing muscle pains and kidney failure (rhabdomyolysis) if doses of more than 20 mg of simvastatin are taken
 - Lidocaine (a local anaesthetic)
 - Sildenafil (used for erectile dysfunction)
 - Fentanyl (used for pain relief)
 - Midazolam and triazolam (a sedative)
 - Ergotamine and dihydroergotamine (for migraine)
 - Colchicine (for gout)
 - Beta-blockers, such as metoprolol and sotalol
 - Calcium channel blockers diltiazem and verapamil, used to treat high blood pressure
 - Indinavir (an anti-viral drug)
 - Cimetidine (an anti-ulcer drug)
 - Clarithromycin (an antibiotic)
 - Ketoconazole and itraconazole (antifungal drugs)
 - Tetracosactrin (used in the treatment of inflammatory or degenerative disorders)
 - Sofosbuvir, used for the treatment of hepatitis C
 - Corticosteroids - used for inflammation (e.g. prednisolone).
 - Tetracosactide - used to test some hormone problems.
 - Amphotericin, when give directly into a vein - used for fungal infections.
- Amiodarone may increase the effects of the following medicines:
- Phenytoin - used to treat fits.

Surgery

If you are to have any surgery, you must tell the doctors

treating you that you are using Amiodarone

Amiodarone Injection with food and drink

Do not drink grapefruit juice while using this medicine because it can increase amiodarone levels in your blood.

Protect your skin from sunlight

Keep out of direct sunlight while using this medicine and for a few months after you have finished using it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:

- make sure you use a high factor sun cream
- always wear a hat and clothes which cover your arms and legs

Pregnancy and breast-feeding

Your doctor will prescribe amiodarone injection only in exceptional circumstances, if the benefit of treatment outweighs the risks during your pregnancy. Amiodarone can be used during pregnancy in life-threatening circumstances only.

- You should not be given amiodarone if you are breast-feeding. If you are given amiodarone during pregnancy or breast-feeding, breast-feeding should be stopped. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Some of the side effects in section 4 together with how you feel after your treatment may make it unsafe for you to drive or operate machinery. If you feel unwell, you must speak to your doctor or nurse before driving or operating machinery.

Important information about some of the ingredients of Amiodarone Injection

Amiodarone Injection contains Benzyl Alcohol

This medicine contains 200mg of Benzyl Alcohol in each 10ml syringe. Benzyl Alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have liver or kidney disease or if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Benzyl alcohol has been linked with toxic and allergic reactions called gasping syndrome in infants and children up to 3 years old

Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding.

This medicine contains:

- Iodine: Amiodarone Injection contains approximately 112mg of iodine in a 10ml pre-filled syringe. Iodine is present in amiodarone hydrochloride, the medicine your infusion contains. Iodine can cause problems with your thyroid (see 'Tests' below)

3. How Amiodarone Injection is given

Your doctor or nurse will normally give you Amiodarone Injection. This is because it needs to be given as an injection or infusion into your vein in the hospital where the doctor can monitor your progress.

Dosage

The daily dose of Amiodarone depends on the severity of your illness. The dose and the treatment times will be determined by your doctor, who will adjust these especially for you.

Unless otherwise prescribed by your doctor, the usual dose

Continued overleaf

is 5 mg per kg of body weight. Your medicine will be injected over a period of at least 3 minutes.

When Amiodarone is given as an injection

- you should not be given a dose greater than 5 mg per kg of body weight.
- the dose should be given to you slowly over a period of at least 3 minutes (unless you are being given the medicine for resuscitation).
- the doctor must wait for at least 15 minutes before giving you another injection.
- repeated or continuous administration may cause inflammation of the vein and damage to the skin at the injection site (the surrounding skin may feel warm and tender and redness may be present) and in such situations a "central venous catheter" is recommended for use by your doctor.

When Amiodarone is given as an infusion

- you should be given a dose of 5 mg/kg bodyweight diluted in 250 ml of 5% dextrose solution.
- the dose should be given to you over a period of 20 minutes to 2 hours.
- the administration may be repeated 2-3 times per day. Most of the side effects which occur during treatment occur if you are given too much Amiodarone. You should therefore be given the lowest possible dose of Amiodarone. This will keep side effects to a minimum. See also "If you have received more Amiodarone than you should".

Adults:

The usual dose is 5 mg for every kilogram of your weight given over a period of 20 minutes to 2 hours.

You may be given another dose of 10 to 20 mg for every kilogram of weight every 24 hours depending on your illness.

In an emergency, your doctor may decide to give you a dose of 150 mg to 300 mg as a slow injection over 3 minutes.

Your doctor will monitor your response to Amiodarone and the dose will be adjusted accordingly.

Children and adolescents:

- There is only limited information on the use in children. The child's doctor will carefully calculate the amount of Amiodarone Injection depending on the child's body weight.

This medicine is not for use in neonates, infants and children up to 3 years old.

Elderly:

- As with all patients it is important that the minimum effective dose is used. Your doctor will carefully calculate how much Amiodarone you should get and monitor your heart rate and thyroid function more closely. Your doctor will change you over to amiodarone tablets as soon as possible.

If you are given too much Amiodarone Injection

Your doctor will carefully calculate how much Amiodarone Injection you should get, therefore it is unlikely your doctor or nurse will give you too much of it. If, however, you have received higher doses than those recommended you will be carefully monitored by your doctor and will receive supportive therapy if necessary.

If you are given too much Amiodarone Injection the following effects may happen: feeling dizzy, faint, sick, tired, confused, constipation or sweating. You may have an abnormally slow or fast heartbeat. Too much amiodarone can damage the heart and liver.

If you forget to have Amiodarone Injection

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the

medicine as it has been prescribed. However, if you think you may have missed a dose, then talk to your doctor or nurse.

If you stop having Amiodarone Injection

It is important for you to keep having Amiodarone Injections until your doctor decides to stop them. If you stop having this medicine, the uneven heartbeats may come back and this could be dangerous.

Tests

- Your doctor will take regular tests to check how your liver is working. Amiodarone Injection can affect how your liver works. If this happens, your doctor will decide whether you should keep having this medicine
- Your doctor will do regular thyroid tests while you are taking this medicine. This is because Amiodarone Injection contains iodine which can cause problems with your thyroid
- Your doctor may also do other regular tests such as blood tests, chest X-rays, ECG (electrical test of your heartbeat) and eye tests both before and while you are having Amiodarone Injection. If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Amiodarone Injection may stay in your blood for up to a month after stopping treatment. You may still get side effects in this time.

Stop having Amiodarone Injection and tell a doctor or nurse, or go to a hospital straight away if you notice any of the following:

- Anaphylactic shock (a life-threatening allergic reaction). Signs may include a sudden rash, itching or lumpy rash (hives) and swelling of the face, lips, tongue or other parts of the body. You may also have shortness of breath, wheezing or trouble breathing.
- Life-threatening skin reactions characterised by rash, blisters, hives, peeling skin and pain (toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), bullous dermatitis, drug reaction with eosinophilia and systematic symptoms (DRESS).
- Excessive thyroid activity (hyperthyroidism, sometimes fatal) causing:
 - Weight loss
 - Weakness
 - Restlessness
 - Increased heart rate
 - Irregular heart rate
 - You have life-threatening irregular heartbeat (Torsade de pointes)
 - Angina
 - Heart failure
 - Shaking, Sweating
 - High temperatures

- Loss of eyesight in one eye or your eyesight becomes dim and colourless. Your eyes may feel sore or tender and feel painful to move. This could be an illness called 'optic neuropathy or neuritis'.
- Serious respiratory problems such as difficulty in breathing, wheezing or coughing, build-up of fluid in the lungs, sometimes fatal.
- Your heartbeat becomes very slow or stops beating.
- Your heartbeat becomes even more uneven or erratic. This can lead to a heart attack, so you should go to hospital straight away
- You get yellowing of the skin or eyes (jaundice), feel tired or sick, loss of appetite, stomach pain or high temperature. These can be signs of liver problems or damage which can be very dangerous

Tell a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Very rare (affects less than 1 in 10,000 people)

- Headache (which is usually worse in the morning or happens after coughing or straining), feeling sick (nausea), fits, fainting, eyesight problems or confusion can occur. These could be signs of problems with your brain

Tell your doctor if you have any of the following side effects:

Very common (may affect more than 1 in 10 people):

- Blurred eyesight or seeing a coloured halo in dazzling light

Common (may affect up to 1 in 10 people):

- Itchy, red rash (eczema)
- Trembling when you move your arms or legs.
- At the site where you are given the injection or infusion you may experience: Pain, skin redness or a change in skin colour, localised soft-tissue damage, fluid leakage, swelling caused by fluid within the skin, inflammation or inflamed blood vessels, abnormally hard tissue or infection
- Slow or irregular heartbeat
- Low blood pressure and rapid heart rate which can make you feel dizzy or faint. These side effects occur straight after injection. The effects are usually moderate and temporary. They can be serious if you are given too much Amiodarone too quickly.

Uncommon (may affect up to 1 in 100 people)

- feeling numb or weak, tingling or burning feelings in any part of your body

Rare: (may affect up to 1 in 1,000 people)

- The excipient benzyl alcohol may cause hypersensitivity reactions.

Very rare (may affect less than 1 in 10,000 people):

Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, sweating, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH)

- Newly occurring heart rhythm disorder or worsening of existing heart rhythm disorders leading to heart attack
- Heart block that can lead to slow heart rate
- Reduced heartbeat, which may lead to shock
- Increased liver enzymes which can show up in tests
- Hot flushes, sweating and feeling sick if Amiodarone Injection is given too quickly
- Headache
- Feeling sick (nausea)
- Sweating
- Lung damage
- Acute liver function disorders, with increased serum levels and/or jaundice, including hepatic failure, sometimes fatal.
- Increase in pressure inside the skull, accompanied by headache, vomiting.

Not known (frequency cannot be estimated from the available data):

Sudden inflammation of the pancreas (pancreatitis (acute)); confusion (delirium); back and abdomen pain.

- You may get more infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia)
- Severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis).
- You get loss of eyesight in one eye or your eyesight becomes dim and colourless. Your eyes may feel sore or

tender and feel painful to move. This could be an illness called 'optic neuropathy' or 'neuritis'

- Overgrowth of tissue found inside the body's larger bones (bone marrow granulomas).
- Hypothyroidism (underactive thyroid) – you may feel extremely tired, weak, 'run-down', restless or agitated, and experience weight loss or gain, constipation, aching muscles, increased sweating and being unable to stand the heat. You may be unable to cope with low temperatures
- Back pain
- Decrease in sex drive

Tell your doctor as soon as possible if you have any of these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amiodarone Injection

Keep this medicine out of the sight and reach of children.

- Your doctor or pharmacist is responsible for storing Amiodarone Injection. They are also responsible for disposing of any unused Amiodarone Injection correctly
- You should not be given Amiodarone Injection after the expiry date (EXP) which is stated on the outer packaging. The expiry date refers to the last day of that month. Your doctor or nurse will check that the date has not passed before giving this medicine to you
- This medicine will be stored below 25°C in the original container. Only clear solutions free of particles should be used
- Reconstituted/diluted solution should be used immediately.
- For single use only. Discard any unused product.

6. Contents of the pack and other information

What Amiodarone Injection contains

- Each 10ml pre-filled syringe contains 300mg 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

- Amiodarone Injection is a clear, pale yellow solution and is available as a single 10ml pre-filled syringe.

Marketing Authorisation Holder:

Aurum Pharmaceuticals Limited
Bampton Road, Harold Hill Romford, Essex RM3 8UG, UK

Manufacturers:

Macarthy's Laboratories Limited
Bampton Road, Harold Hill,
Romford
Essex
RM3 8UG, United Kingdom

Product Licence Number: PL 12064/0047

This leaflet was last revised in August 2021

 **MARTINDALE PHARMA**
Bampton Road, Harold Hill, Romford, RM3 8UG, UK

0553700000