

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Amiodarone hydrochloride 100mg and 200mg Tablets

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What amiodarone tablets are and what they are used for
2. Before you take amiodarone tablets
3. How to take amiodarone tablets
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1. What amiodarone tablets are and what they are used for



Amiodarone hydrochloride 100mg or 200mg Tablets (called amiodarone tablets in this leaflet) contain a medicine called amiodarone hydrochloride. This belongs to a group of medicines called anti-arrhythmics.

It works by controlling the uneven beating of your heart (called 'arrhythmias'). Taking the tablets helps your heartbeat to return to normal.

Amiodarone tablets 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'. Amiodarone tablets are used only when other medicines cannot be used.
- Treat fast heartbeats which may happen suddenly and may be uneven. Amiodarone tablets are used only when other medicines cannot be used.

2. Before you take amiodarone tablets



Do not take this medicine and tell your doctor if:

- ✗ You are allergic (hypersensitive) to:
 - iodine
 - amiodarone
 - any of the other ingredients of amiodarone tablets (listed in Section 6 below)
- ✗ Signs of an allergic reaction include: a rash, swallowing or breathing difficulties, swelling of your lips, face, throat or tongue
- ✗ You have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sino-atrial' heart block
- ✗ You have any other problems with your heartbeat and do **not** have a pacemaker fitted
- ✗ You have ever had thyroid problems. Your doctor should test your thyroid before giving you this medicine
- ✗ You are taking certain other medicines which could affect your heartbeat (see 'Taking other medicines' below)
- ✗ You are pregnant or breast-feeding (see 'Pregnancy and breast-feeding' below)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking amiodarone tablets.

If you are on a heart transplant waiting list, your doctor may change your treatment. This is because taking amiodarone before heart transplantation has shown an increased risk of a life-threatening complication (primary graft dysfunction) in which the transplanted heart stops working properly within the first 24 hours after surgery.



Take special care with amiodarone tablets.

Check with your doctor or pharmacist before taking your medicine if:

- You have heart failure
- 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.
- You have liver problems
- You have any problems with your lungs or have asthma
- You have any problems with your eyesight. This includes an illness called 'optic neuritis'
- You are about to have an operation
- You are elderly (over 65 years of age). The doctor will need to monitor you more carefully
- You have a pacemaker or implantable cardioverter defibrillator (ICD). Your doctor will check that your device is working properly shortly after you start taking the tablets or if your dose is changed
- You have blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition 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)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking amiodarone tablets.

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.



Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes medicines you buy without prescription, including herbal medicines. This is because amiodarone tablets can affect the way some other medicines work. Also, some medicines can affect the way amiodarone tablets work.

In particular, do not take this medicine and tell your doctor, if you are taking:

- Other medicines for an uneven heartbeat (such as sotalol, quinidine, procainamide, disopyramide or bretylium)
- Medicines for infections (such as intra-venous erythromycin, co-trimoxazole, moxifloxacin or pentamidine)
- Medicines for schizophrenia (such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride or sertindole)
- Medicines for other mental illnesses (such as lithium, doxepin, maprotiline or amitriptyline)
- Medicines for malaria (such as quinine, mefloquine, chloroquine or halofantrine)
- Medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine, astemizole or mizolastine)
- Medicines for hepatitis C treatment (such as sofosbuvir, daclatasvir, simeprevir or ledipasvir)

Tell your doctor if you are taking any of the following medicines:

- Sofosbuvir, used for the treatment of hepatitis C
- Medicines that lengthen your heart beat (the QT interval) such as medicines for infection (such as clarithromycin, ciprofloxacin, ofloxacin or levofloxacin)
- Medicines for heart problems called beta-blockers (such as propranolol)
- Medicines called calcium channel blockers – for chest pain (angina) or high blood pressure (such as diltiazem or verapamil)
- Medicines for constipation (laxatives) such as bisacodyl or senna
- Medicines for high cholesterol (statins) such as simvastatin or atorvastatin

The following medicines can increase the chance of you getting side effects, when taken with amiodarone tablets:

- Amphotericin (when given directly into a vein) – used for fungal infections
- Medicines for inflammation (corticosteroids) such as hydrocortisone, betamethasone or prednisolone
- Water tablets (diuretics)
- General anaesthetics or high dose oxygen – used during surgery
- Tetracosactide – used to test some hormone problems

Amiodarone tablets may increase the effect of the following medicines:

- Ciclosporin, tacrolimus and sirolimus – used to help prevent rejection of transplants
- Medicines for impotence such as sildenafil, tadalafil or vardenafil
- Fentanyl – used for pain relief
- Ergotamine – used for migraines
- Midazolam – used to relieve anxiety or to help you relax before surgery
- Colchicine – used for the treatment of gout
- Flecainide – another medicine used for uneven heartbeats. Your doctor should monitor your treatment and may half your dose of Flecainide
- Lidocaine – used as an anaesthetic
- Warfarin – used to stop your blood from clotting
- Digitalis – used for some heart conditions
- Dabigatran – used to thin the blood

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking amiodarone tablets.

Taking amiodarone tablets with food and drink

Do not drink grapefruit juice while taking this medicine. This is because drinking grapefruit juice while taking amiodarone tablets can increase your chance of getting side effects.

Limit the amount of alcohol you drink whilst taking this medicine. This is because drinking alcohol while taking this medicine will increase the chance of you having problems with your liver. Talk to your doctor or pharmacist about the amount of alcohol you can drink.

Protect your skin from sunlight

Keep out of direct sunlight while taking this medicine and for a few months after you have finished taking 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 high factor sun cream
- Always wear a hat and clothes which cover your arms and legs

Pregnancy and breast-feeding

- Tell your doctor before taking this medicine if you are pregnant, might become pregnant or think you may be pregnant. Amiodarone tablets are not normally given during pregnancy
- Do not take if you are breast-feeding or plan to breast-feed. This is because small amounts of this medicine may pass into the mothers' milk

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.



Driving and using machines

You may have blurred eyesight after taking this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of amiodarone tablets

This medicine contains:

- **Lactose:** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Iodine:** Amiodarone tablets contain 37.5mg of iodine in a 100mg tablet and 75mg of iodine in a 200mg tablet. Iodine is present in Amiodarone hydrochloride, the medicine your tablets contain. Iodine can cause problems to your thyroid (see 'Tests' below)

3. How to take amiodarone tablets

Always take amiodarone tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole. Do not crush or chew your tablets
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

Adults

- The usual starting dose is 200mg (one 200mg or two 100mg amiodarone tablets) **three times** each day for one week
- The dose will then be lowered to 200mg **twice** each day for one week
- The dose will then be lowered to 200mg **once** each day, until you are told otherwise
- In some cases, your doctor may then decide to either increase or lower the amount you take each day. This will depend on how to react to this medicine

Turn Over

Children and adolescents

- Amiodarone tablets should not be given to children and adolescents.

Elderly

- The doctor may give you a lower dose of amiodarone tablets. Also, the doctor should check your blood pressure and thyroid function regularly

If you take more amiodarone tablets than you should

If you take more amiodarone tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling dizzy, faint or tired, confusion, slow heartbeat, damage to the liver or being sick.

If you forget to take amiodarone tablets

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking amiodarone tablets

Keep taking amiodarone tablets until your doctor tells you to stop. Do not stop taking amiodarone tablets just because you feel better. If you stop taking this medicine the uneven heartbeats may come back. This could be dangerous.

Tests

Your doctor will take regular tests to check how your liver is working. Amiodarone tablets can affect how your liver works. If this happens, your doctor will decide whether you should keep taking these tablets. Your doctor may do regular thyroid tests while you are taking this medicine. This is because amiodarone tablets contain iodine which can cause problems to 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 taking amiodarone tablets.

 If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking amiodarone tablets and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swollen eyelids, face, lips, throat or tongue
- You have blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition 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)
- You have inflammation of the skin characterised by fluid filled blisters (bullous dermatitis)
- You have flu like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (DRESS)

Common (affects less than 1 in 10 people)

- 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
- Shortness of breath or difficulty breathing (which may get progressively worse), tightness in the chest, coughing which will not go away, wheezing, weight loss and fever. This could be due to inflammation of your lungs which can be very dangerous and can happen at any time after starting treatment

Uncommon (affects less than 1 in 100 people)

- Your heartbeat becomes even more uneven or erratic. This can lead to a heart attack, so you should go to hospital straight away

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

- 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'
- Your heartbeat becomes very slow or stops beating. If this happens go to hospital straight away

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

- Lupus-Like syndrome (a disease where the immune system attacks various parts of the body and leading to pain, stiffness and swelling in joints and red skin, sometimes in the shape of butterfly wings on the face).

Stop taking amiodarone tablets and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

Uncommon (affects less than 1 in 100 people)

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

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

- Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- 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.
- Moving unsteadily or staggering, slurred or slow speech
- Feeling faint, dizzy, unusually tired and short of breath. These could be signs of a very slow heartbeat (especially in people over 65 years old) or other problems with your heart's natural beat

Not Known (frequency cannot be estimated from the available data)

- Chest pain and shortness of breath and irregular heartbeat. These could be signs of a condition called "Torsade de pointes"
- Life-threatening complication after heart transplantation (primary graft dysfunction) in which the transplanted heart stops working properly (see section 2, Warnings and precautions).

Some cases of bleeding in the lungs have been reported in patients taking amiodarone tablets. You should tell your doctor straight away if you cough up any blood.

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

Very common (affects more than 1 in 10 people)

- Blurred eyesight or seeing a coloured halo in dazzling light

Common (affects less than 1 in 10 people)

- Feeling extremely restless or agitated, weight loss, increased sweating and being unable to stand the heat. These could be signs of an illness called 'hyper-thyroidism'
- Feeling extremely tired, weak or 'run-down', weight gain, being unable to stand the cold, constipation and aching muscles. These could be signs of an illness called 'hypo-thyroidism'
- Trembling when you move your arms or legs
- Blue or grey marks on parts of your skin exposed to sunlight, especially the face

Uncommon (affects less than 1 in 100 people)

- Muscle cramps, stiffness or spasm

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

- Swelling of the testicles
- Red, scaly patches of skin, loss of hair or loosening of nails (called 'exfoliative dermatitis')
- Feeling tired, faint, dizzy or having pale skin. These could be signs of anaemia
- You may bleed or bruise more easily than usual. This could be because of a blood disorder (called 'thrombocytopenia')
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH)

Not Known (frequency cannot be estimated from the available data)

- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Very common (affects more than 1 in 10 people)

- Feeling sick (nausea) or being sick (vomiting)
- Change in the way things taste
- Changes in the amount of liver enzymes at the beginning of treatment. This can be seen in blood tests
- Burning more easily in the sun (see 'Protect your skin from sunlight' in Section 2)

Common (affects less than 1 in 10 people)

- Slightly slower heartbeat
- Nightmares
- Problems sleeping
- Constipation
- Scaly and itchy rash (eczema)
- Decrease in sex drive

Uncommon (affects less than 1 in 100 people)

- Dry mouth

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

- Headache
- Balance problems, feeling dizzy (vertigo)
- Difficulty in getting or maintaining an erection or in ejaculating
- Hair loss, balding
- Skin rash
- Skin redness during radio-therapy

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

- Hives (itchy, lumpy rash)
- Granulomas, small red lumps on the skin or inside the body which are seen by X-ray
- Feeling less hungry
- Movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (Parkinsonism)
- Feeling confused or seeing or hearing things that are not there
- A distorted sense of smell (parosmia)
- Seeing, hearing or feeling things that are not there (hallucinations)
- 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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 tablets

Keep this medicine in a safe place where children cannot see or reach it.

Do not use amiodarone tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Keep the blister strip in the outer carton in order to protect from light. Do not store above 25°C.

Do not use amiodarone tablets if you notice your tablets are crumbling, broken or discoloured. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What amiodarone tablets contain

- Each amiodarone hydrochloride 100mg Tablet contains 100mg of the active substance, amiodarone hydrochloride
- Each amiodarone hydrochloride 200mg Tablet contains 200mg of the active substance, amiodarone hydrochloride
- The other ingredients are lactose monohydrate, maize starch, povidone, colloidal anhydrous silica and magnesium stearate

What amiodarone tablets look like and contents of the pack

100mg Tablets: The tablets are round and white in colour. One side has a break-line and the other side is imprinted with '100'.

200mg Tablets: The tablets are round and white in colour. One side has a break-line and the other side is imprinted with '200'.

The tablets are available in blister-packs of 28 and 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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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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