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PACKAGE LEAFLET: INFORMATION FOR THE USER

# Amiodarone Hydrochloride 200mg Tablets

**Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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


## 1. WHAT AMIODARONE TABLETS ARE AND WHAT THEY ARE USED FOR

Amiodarone Tablets are from a group of medicines called anti-arrhythmics which are used in the treatment of severe or life threatening cardiac arrhythmias (where the heart beats rapidly or irregularly). 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.

Amiodarone Tablets can be used for stabilisation and long term treatment.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMIODARONE TABLETS

**Do not take Amiodarone Tablets if you:**
- Are allergic to amiodarone hydrochloride, iodine or any of the other ingredients of this medicine (listed in section 6)
- Have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sino-atrial' heart block
- Have any other problems with your heartbeat and do not have a pacemaker fitted
- Are taking certain other medicines which could affect your heartbeat (see 'Other medicines and Amiodarone Tablets')
- Have ever had thyroid problems. Your doctor should test your thyroid before giving you this medicine.
- Are pregnant or breast-feeding as you should check with your doctor beforehand (see 'Pregnancy and breast-feeding')

Amiodarone must not be given to children, premature babies or neonates.

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before taking Amiodarone Tablets if you:
- Have heart failure or a heart condition such as a slow heart rate
- Have liver problems
- Have problems with your lungs, shortness of breath or have asthma
- Have problems with your eyesight. This includes an illness called 'optic neuritis'
- Are about to have an operation
- Are elderly (over 65 years of age). The doctor will need to monitor you more carefully
- Are on digitalis therapy as this may affect the rhythm of your heart
- Are undergoing a radioiodine uptake test as this medicine contains iodine which may affect the results of the test
- 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
- 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
- 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)
- 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.

**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.

**Other medicines and Amiodarone Tablets**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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 intravenous 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 ledispasvir).

**Tell your doctor if you are taking any of the following medicines:**
- Medicines that lengthen your heartbeat (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, verapamil)
- Medicines for constipation (laxatives) such as bisacodyl or senna
- Medicines for high cholesterol (statins) such as simvastatin, atorvastatin or lovastatin.

**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, dihydroergotamine – used for migraines
- Midazolam, triazolam - used to help you sleep or for 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 halve 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
- Phenytoin - used to treat epilepsy.

**Amiodarone Tablets with food and drink**
Do not drink grapefruit juice whilst taking this medicine. This is because drinking grapefruit juice whilst taking Amiodarone Tablets can increase your chance of getting side effects.

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

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine is not normally given during pregnancy.

Do not take this medicine if you are breast-feeding or plan to breast-feed. This is because small amounts of this medicine may pass into the mother's milk.

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

**Amiodarone Tablets contain lactose monohydrate**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**Amiodarone Tablets contain iodine**
These tablets also contain 75mg of iodine in a 200mg tablet and can cause problems to your thyroid.

## 3. HOW TO TAKE AMIODARONE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. 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, **three times** a day for one week
- The dose will then be lowered to 200mg, **twice** a 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 decide to either increase or lower the amount you take each day. This will depend on how you react to this medicine.

**Elderly:**
The prescribed dose may be lower than the usual dose. Your doctor should check your blood pressure and thyroid function regularly.

**Children and adolescents:**
Amiodarone Tablets should not be given to children and adolescents.

**If you take more Amiodarone Tablets than you should**
This medicine is to be taken at regular intervals, as determined by the physician. If you take too many tablets by mistake, contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you.

You may experience the following side effects: 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 dose.

**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 medicine, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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 notice any of the following serious side effects – you may need urgent medical treatment:**
- You have an allergic reaction or severe allergic reaction (anaphylactic reaction, anaphylactic shock). 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)
- 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
- Your heartbeat becomes even more uneven or erratic. This can lead to a heart attack, so you should go to hospital straight away
- Feeling numb or weak, tingling or burning feelings in any part of your body
- 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
- 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
- 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)
- Sudden inflammation of the pancreas (pancreatitis (acute))
- Chest pain and shortness of breath and irregular heartbeat. These could be signs of a condition called “Torsade de pointes”.
- Primary graft dysfunction post cardiac transplant

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** (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)
- Feeling extremely restless or agitated, weight loss, increased sweating and being unable to stand the heat. These could be signs of an illness called 'hyperthyroidism'
- 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 'hypothyroidism'
- Trembling when you move your arms or legs
- Blue or grey marks on parts of your skin exposed to sunlight, especially the face.
- Decrease in sex drive

**Uncommon** (may affect up to 1 in 100 people)
- Muscle cramps, stiffness or spasm.

**Very rare** (may affect up to 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 antidiuretic hormone secretion' (SIADH)
- Increased creatinine levels which is a sign of impaired kidney function. This can be seen in blood tests.

**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
- Life-threatening complication after heart transplantation (primary graft dysfunction) in which the transplanted heart stops working properly (see section 2, Warnings and precautions).

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

**Very common** (may affect 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.

**Common** (may affect up to 1 in 10 people)
- Slightly slower heartbeat
- Nightmares
- Problems sleeping
- Constipation
- Scaly and itchy rash (eczema).

**Uncommon** (may affect up to 1 in 100 people)
- Dry mouth.

**Very rare** (may affect up to 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 out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Amiodarone Tablets contain**
The active substance is amiodarone hydrochloride. Each tablet contains 200mg amiodarone hydrochloride.

The other ingredients are: maize starch, lactose monohydrate, povidone (K90), magnesium stearate, silica colloidal anhydrous and pregelatinised starch.

**What Amiodarone Tablets look like and contents of the pack**
Amiodarone 200mg Tablets are white, round, bevelled edge tablets, embossed with a breakline on one side and plain on the other side with an approximate diameter of 9.5mm.

Amiodarone Tablets are supplied in blister strips of 28 or 30 tablets.

Not all pack sizes may be marketed.


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