

Scheduling Status:**S4****MYORYTHM 100, 200, Tablet****Amiodarone Hydrochloride:****MYORYTHM 100 contains sugar (58,25 mg lactose monohydrate per tablet)****MYORYTHM 200 contains sugar (116,50 mg lactose monohydrate per tablet)****Read all of this leaflet carefully before you start taking MYORYTHM**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MYORYTHM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What MYORYTHM is and what it is used for

MYORYTHM contains amiodarone hydrochloride which belongs to a group of medicines called anti-dysrhythmics. It works by controlling the uneven beating of your heart (called 'dysrhythmias'). Taking the tablets helps your heartbeat to return to normal.

MYORYTHM 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'. MYORYTHM tablets are used only when other medicines cannot be used; or
- treat fast heartbeats which may happen suddenly and may be uneven. MYORYTHM tablets are used only when other medicines cannot be used.

2. What you need to know before you take MYORYTHM

Do not take MYORYTHM:

- If you are hypersensitive (allergic) to amiodarone hydrochloride, iodine or any of the other ingredients of MYORYTHM (listed in section 6).
- If you have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sino-atrial' heart block.
- If you have ever had thyroid problems. Your doctor should test your thyroid function before giving you this medicine.
- If you are pregnant.
- If you are breastfeeding.
- If you are taking certain other medicine which could affect your heartbeat (see Other medicine and MYORYTHM).
- If you are under the age of 18 years.

Warnings and precautions

Special care should be taken with MYORYTHM:

- If you are scheduled for surgery (inform your anaesthetist that you are taking MYORYTHM);
- if you have a condition called porphyria (group of disorders resulting from build-up of certain chemicals related to red blood cell proteins);
- if you have heart failure;
- if you have a pacemaker or implantable cardioverter defibrillator (ICD);
- if you currently take a medicine containing sofosbuvir for the treatment of hepatitis C as it may result in a life-threatening slowing of your heartbeat. Your doctor may consider alternative treatments. If treatment with MYORYTHM and sofosbuvir is needed, you may require additional heart monitoring;
- if you have a slow or irregular heartbeat or heart rhythm problems;
- if you have any complications with your thyroid;
- if you have any problems with your eyesight;
- if you have liver problems;
- if you have a condition in which your nerves are damaged;
- if you have any problems with your lungs or have asthma; or
- if you experience shortness of breath or worsening of existing shortness of breath, a persistent cough and fatigue.

Exposed to the sun for long periods during the day should be avoided, because your skin will become more sensitive to the sun and may burn, tingle or severely blister when exposed.

Treatment with MYORYTHM should be discontinued if you develop the following:

- 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 this may be condition is called Toxic Epidermal Necrolysis;
- blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This condition is called Stevens-Johnson syndrome.

Before starting MYORYTHM treatment, your doctor may perform an ECG and blood tests. Monitoring of ECG is recommended during treatment.

Other medicines and MYORYTHM

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, do not take this medicine and tell your healthcare provider, 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 or pentamidine);
- medicines for schizophrenia (such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpiride or sertindole.);
- medicines for other mental illnesses (such as lithium, doxepin, maprotiline or amitriptyline);
- medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine, astemizole or mizolastine);
- medicines for malaria (such as quinine, mefloquine, chloroquine or halofantrine);
- antibiotic called moxifloxacin; or
- medicines for hepatitis C treatment (such as sofosbuvir).

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

- *Medicines that lengthen your heartbeat (the QT interval):*
- Medicines for infection (i.e., clarithromycin and fluoroquinolones).
- *Medicines used to lower your heart rate:*
- Medicines for heart problems called beta-blockers (such as atenolol, propranolol or carvedilol).
- Medicines called calcium channel blockers - for chest pain (angina) or high blood pressure (such as diltiazem or verapamil).
- *Medicines that may cause low potassium and magnesium levels:*

- Medicines for constipation (laxatives) containing sennosides or bisacodyl (stimulant laxatives).
- Diuretics (water tablets).
- Medicines for inflammation (systemic corticosteroids) such as prednisolone, beclomethasone or hydrocortisone.
- Amphotericin (when given directly into a vein) – used for fungal infections.
- *General anaesthesia*: General anaesthetics or high dose oxygen – used during surgery.

MYORYTHM may increase the effect of the following medicines:

- Digitalis – used for some heart conditions;
- dabigatran – used to thin the blood;
- warfarin – used to stop your blood from clotting;
- phenytoin – used as an anti-epileptic;
- ciclosporin and tacrolimus – used to help prevent rejection of transplants;
- simvastatin, atorvastatin and lovastatin – used to lower the amount of lipids present in the blood;
- lidocaine – used as an anaesthetic;
- sildenafil – used to treat impotency;
- fentanyl – used for pain relief;
- midazolam, triazolam – used to relieve anxiety or to help you relax;
- ergotamine, dihydroergotamine – used for migraines;
- colchicine – used for the treatment of gout; or
- flecainide – another medicine used for uneven heartbeats. Your doctor should monitor your treatment and may half your dose of flecainide.

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

- Clarithromycin, diltiazem, erythromycin, itraconazole, ketoconazole, ritonavir, and verapamil (CYP3A4 inhibitors);
- candesartan cilexetil (cyclohexylcarbonate ester prodrug of candesartan), zafirlukast, clotrimazole, felodipine, and mometasone furoate (CYP2C8 inhibitors); or
- grapefruit juice.

MYORYTHM with food, drink and alcohol

Do not drink grapefruit juice while taking MYORYTHM because it can increase your chance of getting side effects.

Limit the amount of alcohol you drink whilst taking MYORYTHM, because drinking alcohol will increase the chance of you having side effects.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

MYORYTHM should not be taken if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent MYORYTHM may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which MYORYTHM affects you.

MYORYTHM may impair your vision and thus effect your ability to drive or operate machinery (see section 4).

MYORYTHM contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MYORYTHM.

3. How to take MYORYTHM

Do not share medicines prescribed for you with any other person.

Always use MYORYTHM exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- The starting dose is MYORYTHM 200 mg three times a day and may be continued for 1 week.
- The dosage is then lowered MYORYTHM to 200 mg twice daily for one week.
- The dose will then be lowered to MYORYTHM to 200 mg daily unless 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 you react to MYORYTHM.

MYORYTHM should not be taken by children or adolescents.

Your doctor will tell you how long your treatment with MYORYTHM will last. Do not stop treatment early because the dangerous uneven heartbeat may return. If you have the impression that the effect of MYORYTHM is too strong or too weak, tell your doctor or pharmacist.

If you take more MYORYTHM than you should

If you take more MYORYTHM 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 MYORYTHM

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 forgotten individual doses.

If you stop taking MYORYTHM

Keep taking MYORYTHM until your doctor tells you to stop. Do not stop taking MYORYTHM just because you feel better. If you stop taking this medicine, without the consent of your doctor, the uneven heartbeats may come back. This could be dangerous.

4. Possible side effects

MYORYTHM can have side effects.

Not all side effects reported for MYORYTHM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYORYTHM, please consult your health care provider for advice.

If any of the following happens, stop taking MYORYTHM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- skin rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MYORYTHM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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);
- 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;
- 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); or
- difficulty breathing or 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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;
- nightmares and sleep disorders;
- blurred eyesight or seeing a coloured halo in dazzling light;
- slower than normal heart rate;
- feeling sick (nausea) or being sick (vomiting), change in the way things taste, constipation;
- changes in the amount of liver enzymes at the beginning of treatment. This can be seen in blood tests;
- blue or grey marks on parts of your skin exposed to sunlight, especially the face; or
- scaly and itchy rash (eczema).

Less frequent side effects:

- 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);
- decreased appetite;
- feeling numb or weak, tingling or burning feelings in any part of your body;
- 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;
- balance problems, feeling dizzy (vertigo);
- moving unsteadily or staggering, slurred or slow speech;
- 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';

- you may experience eye conditions such as swelling of the optic disc (Papilloedema), deterioration of the clear outer layer of the eye (corneal degeneration), increased sensitivity to light (photosensitivity), general eye discomfort, areas of reduced or lost vision (scotoma), clouding or loss of transparency in the eye's lens (lens opacities), and progressive loss of central vision (macular degeneration). These conditions have been reported in some cases;
- your heartbeat becomes even more uneven or erratic. This can lead to a heart attack, so you should go to hospital straight away;
- 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;
- skin rash caused by narrow or blocked blood vessels (called 'vasculitis');
- dry mouth;
- 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;
- skin redness during radiotherapy;
- skin rashes;
- red, scaly patches of skin, loss of hair or loosening of nails (called 'exfoliative dermatitis');
- hair loss, balding;
- swelling of the testicles;
- difficulty in getting or maintaining an erection or in ejaculating; or
- higher than normal level of creatinine in the bloodstream.

Side effects with frequency unknown:

- Granulomas, small red lumps on the skin or inside the body which are seen by X-ray;
- small area of inflammation or irritation that occurs in the bone marrow;
- confusional state/ delirium (a sudden and significant confusion and disorientation);
- movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (Parkinsonism);
- a distorted sense of smell (parosmia);
- chest pain and shortness of breath and irregular heartbeat. These could be signs of a condition called "Torsade de pointes";
- coughing blood due to bleeding from the lungs;
- severe stomach pain which may reach through to our back. This could be a sign of pancreatitis;
- hives (itchy, lumpy rash); or

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the

“6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MYORYTHM.

5. How to store MYORYTHM

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container until required for use.

Do not use this medicine after the expiry date printed on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What MYORYTHM contains

The active substance in MYORYTHM 100 is 100 mg Amiodarone HCl.

The active substance in MYORYTHM 200 is 200 mg Amiodarone HCl.

The other ingredients are lactose monohydrate, croscarmellose sodium, allura red AC aluminium lake, polysorbate 80, povidone K-90, pregelatinised starch, colloidal anhydrous silica, purified talc, magnesium stearate.

What MYORYTHM looks like and contents of the pack

MYORYTHM 100 is a light pink to pink, round, debossed with “A” on one side of the tablet and “100” on other side.

MYORYTHM 200 is a light pink to pink, debossed with “A vertical scoreline A (A|A)” on one side of the tablet and “200” on other side.

MYORYTHM 100 and 200 is packed in a clear PVC/PVDC Aluminium blister strips in an outer cardboard carton.

The pack size is 28 or 30 tablets.

Holder of Certificate of Registration:

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