

Patient Information Leaflet for BIO-AMIODARONE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BIO-AMIODARONE 200 mg tablets

Amiodarone hydrochloride

Contains sugar (lactose monohydrate): 50 mg per tablet.

Read all of this leaflet carefully before you start taking BIO-AMIODARONE

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

1. What BIO-AMIODARONE is and what it is used for

BIO-AMIODARONE belongs to a group of medicines called anti-dysrhythmics.

It works by controlling the uneven beating of your heart (called 'dysrhythmias'). BIO-AMIODARONE is 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'.
- Treat fast heartbeats which may happen suddenly and may be uneven. BIO-AMIODARONE is used only when other medicines cannot be used.

2. What you need to know before you take BIO-AMIODARONE

Do not take BIO-AMIODARONE if you:

- Are hypersensitive (allergic) to amiodarone, iodine or any of the other ingredients of BIO-AMIODARONE (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.
- Have ever had thyroid problems. Your doctor should test your thyroid before giving you this medicine.
- Are taking certain other medicines which could affect your heartbeat (see 'How to use Bio-Amiodarone' below).
- Are pregnant or breastfeeding (see 'Pregnancy and breastfeeding' below).
- Suffer from porphyria.

- Suffer from high blood pressure.
- Are taking any other anti-dysrhythmic medicines, e.g., sotalol.
- Are taking medicines such as astemizole, bepridil, IV erythromycin, halofantrin, pentamidine, sparfloxacin, sultopride, terfenadine, and vincamin.
- Are a paediatric patient.

Warnings and precautions:

Tell your doctor if you:

- Have heart failure.
- Have liver problems.
- Have any problems with your lungs or have asthma.
- Have any 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.
- 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.
- Are on a heart transplant waiting list, as taking BIO-AMIODARONE tablets before a heart transplant 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.
- 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).

Due to substantial toxicity, BIO-AMIODARONE is intended for use only in patients with indicated life-threatening dysrhythmias. BIO-AMIODARONE has several potentially fatal toxicities of which the most important are lung toxicity, followed by liver damage.

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.

Taking BIO-AMIODARONE with food and drink:

Do not drink grapefruit juice while taking BIO-AMIODARONE. This is because drinking grapefruit juice while taking BIO-AMIODARONE can increase your chance of getting side effects.

Children and adolescents:

Do not give BIO-AMIODARONE to paediatric patients, as safety and efficacy have not been established.

Other medicines and BIO-AMIODARONE:

Always tell your health care provider if you are using any other medicines. (This includes all complementary or traditional medicines.)

Do not take BIO-AMIODARONE together with:

- Other medicines for an uneven heartbeat (such as sotalol, quinidine-like medicines,

procainamide, disopyramide).

- Medicines for infections (such as intravenous erythromycin, pentamidine, sparflloxacin).
- Medicines for malaria (such as halofantrine).
- Medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine, astemizole).
- Bepridil, used to treat angina.
- Sultopride, used to treat schizophrenia.

Tell your doctor if you are currently taking a medicine containing sofosbuvir for the treatment of hepatitis C, as it may result in a life-threatening slowing of your heart beat. You may also experience shortness of breath, chest pain, light-headedness, and palpitations. Your doctor may consider alternative treatments. If treatment with BIO-AMIODARONE and sofosbuvir is needed, you may require additional heart monitoring.

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

- Stimulant laxatives (such as bisacodyl), used to treat constipation.
- Verapamil and diltiazem, used to treat high blood pressure.
- Steroids (systemically used gluco- and mineralocorticosteroids), tetracosactide and IV administered amphotericin B, used to treat inflammation or infections.
- Oral anticoagulant medication (such as warfarin).
- Phenytoin, used to treat seizures (fits).
- Digoxin, used for some heart conditions.
- Ciclosporin, tacrolimus, sirolimus, used to prevent rejection of transplants.
- Medicines for high cholesterol (statins), such as simvastatin or atorvastatin.
- Lidocaine (lignocaine), used as an anaesthetic.

- Sildenafil, used to treat impotence.
- Fentanyl, used to treat pain.
- Midazolam, used to relieve anxiety or to help you relax before surgery.
- Flecainide, another medicine used for uneven heartbeats.
- Dabigatran, used to thin blood.

If you are to be operated, the anaesthetist should be informed that you are taking BIO-AMIODARONE as potentially serious complications can occur.

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 BIO-AMIODARONE.

You should not be given BIO-AMIODARONE if you are pregnant or breastfeeding.

Driving and using machines:

You may have blurred eyesight after taking BIO-AMIODARONE. If this happens, do not drive or use any tools or machinery.

BIO-AMIODARONE contains lactose monohydrate:

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

3. How to take BIO-AMIODARONE

Take BIO-AMIODARONE by mouth. Swallow the tablets whole; do not crush or chew your tablets.

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

Always take BIO-AMIODARONE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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 BIO-AMIODARONE.

Your doctor will tell you how long your treatment with BIO-AMIODARONE will last.

If you have the impression that the effect of BIO-AMIODARONE is too strong or too weak, tell your doctor or pharmacist.

Elderly:

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

Your doctor will take regular tests to check:

- How your liver is working. BIO-AMIODARONE can affect the way how your liver works. If this happens, your doctor will decide whether you should keep taking BIO-AMIODARONE
- Your thyroid function. This is because BIO-AMIODARONE contains iodine which can cause problems to your thyroid.
- Your blood, chest X-rays, ECG (electrical test of your heartbeat) and eyes. Your doctor may do this before, and while you are taking BIO-AMIODARONE.

If you take more BIO-AMIODARONE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

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 BIO-AMIODARONE:

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.

Effects when treatment with BIO-AMIODARONE is stopped:

Keep taking BIO-AMIODARONE until your doctor tells you to stop. Do not stop taking BIO-AMIODARONE just because you feel better. If you stop taking BIO-AMIODARONE the uneven heartbeats may come back. This could be dangerous.

4. Possible side effects

BIO-AMIODARONE can have side effects.

Not all side effects reported for BIO-AMIODARONE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO-AMIODARONE, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking BIO-AMIODARONE 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.

- Rash or itching.
- Fainting.
- 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).

These are all very serious side effects. If you have them, you may have had a serious reaction to BIO-AMIODARONE. 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:

- 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.
- Difficulty breathing or tightness in the chest, coughing which will not go away, wheezing, weight loss and fever.
- 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).
- Your heartbeat becomes very slow or stops beating.

- 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).
- 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).
- Reduction in the number of white blood cells which makes infections more likely.
- 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.
- 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.
- 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).
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis.
- 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.
- Movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (Parkinsonism).
- Feeling numb or weak, tingling or burning feelings in any part of your body.

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

Tell your doctor if you notice any of the following:

The following side effects were reported frequently:

- Changes in the way things taste.
- Micro-deposits develop in the eye in majority of patients, causing blurred eyesight of seeing a coloured halo in dazzling light. These are reversible on stopping therapy.
- Sensitivity of the skin to light and burning more easily in the sun.
- Blue-grey colouring of skin on face, neck and arms.
- Nightmares, problem sleeping.
- Constipation.
- Scaly and itchy rash (eczema).

Less frequent reported side effects are:

- Dry mouth.
- Headache.
- Balance problems, feeling dizzy (vertigo).
- Inflammation of the epididymis (a curved structure at the back of the testicle in which sperm matures and is stored).
- Difficulty in getting or maintaining an erection or in ejaculating.
- Hair loss (temporary).

Side effects reported with an unknown frequency:

- Hives (itchy, lumpy rash).
- Small red lumps on the skin or inside the body which are seen by X-ray.

- Feeling less hungry.
- Feeling confused or seeing or hearing things that are not there.
- A distorted sense of smell (parosmia).

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 “**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 BIO-AMIODARONE.

5. How to store BIO-AMIODARONE

- Store at or below 25 °C. Protect from light.
- Do not remove the blisters from the cartons until required for use.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What BIO-AMIODARONE contains:**

The active ingredient is amiodarone hydrochloride. Each tablet contains 200 mg amiodarone hydrochloride.

The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate,

maize starch, povidone and pregelatinised starch.

What BIO-AMIODARONE looks like and contents of the pack:

Scored, flat, white tablets.

Boxes containing 30 tablets in PVC/ALU blister.

Holder of certificate of registration and manufacturer:

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