PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

HEXARONE® 100 (tablets)

HEXARONE® 200 (tablets)

Amiodarone hydrochloride

Contains sugar (lactose monohydrate 48,00 mg per 100 mg tablet and 96,00 mg per 200 mg tablet).

Read all of this leaflet carefully before you start taking HEXARONE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- HEXARONE have 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 HEXARONE is and what it is used for
2. What you need to know before you take HEXARONE
3. How to take HEXARONE
4. Possible side effects
5. How to store HEXARONE
6. Contents of the pack and other information

1. What HEXARONE is and what it is used for

HEXARONE tablets belong 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.

HEXARONE tablets can be used to:

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

2. What you need to know before you take HEXARONE

Do not take HEXARONE:

- If you are hypersensitive (allergic) to amiodarone or any of the other ingredients of HEXARONE listed in section 6.
- If you have a slower than usual heartbeat (called 'sinus bradycardia) or if 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.
- If you have low levels of potassium in your bloodstream (seen with a blood test).
- If you are allergic to iodine.
- If you are taking monoamine oxidase (MOA) inhibitors (medication for depression).
- If you are currently taking medication for an abnormal heartbeat.
- If you have serious breathing difficulty.
- If you are pregnant or breastfeeding (see 'Pregnancy, breastfeeding and fertility' below).

Warnings and precautions

Take special care with HEXARONE:

- If you have a heart condition.
- If you have any problems with your lungs or have asthma.
- If you have liver problems.
- If you suddenly develop a severe skin rash and blisters, talk to your doctor, as you may need urgent treatment.
- If you suddenly develop a weakness or numbness in your hands and feet or muscle weakness.
- If you have any problems with your eyesight. This includes an illness called 'optic neuritis'.
- If you are taking any other medication for a heart condition (Your doctor will advise you).
- If you experience weight gain, become unable to handle cold temperatures (cold intolerance), feel tired all the time and do not feel like doing anything or have a very slow heartbeat (excessive bradycardia), talk to your doctor, as your thyroid gland (a gland which produces hormones) may not be producing enough hormones, as it usually should, and you may need to have a thyroid test.
- If you experience weight loss, a very fast (tachycardia) or increased or uneven heart rate, uncontrollable shaking, feeling nervous, increased sweating, difficulty to handle high temperatures (heat intolerance), feeling weak and without any energy (asthenia), feeling restlessness or if you experience sudden chest pain (angina pectoris), talk to your doctor, as your thyroid gland (a gland which produces hormones) may be producing higher hormone levels than it usually should, and you may need to have a thyroid test.

- If 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.
- If you are exposed to sunlight for long periods. Cover your skin and use a high protection sun factor. If your treatment with HEXARONE has been stopped, you should continue to protect yourself from sunlight, as you may be sensitive to sunlight for a few months after having stopped taking HEXARONE.
- If you suffer from porphyria.
- You are about to have an operation.
- You are elderly (over 65 years of age). The doctor will need to monitor you more carefully.

Other medicines and HEXARONE

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

Tell your doctor if you are already taking any of the following medicines, as HEXARONE should not be taken together with them:

- 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 used for psychosis or schizophrenia (such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride 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).
- Medicines that lengthen your heartbeat (the QT interval) such as medicines for infection (such as clarithromycin). You should not use a fluoroquinolone antibiotic (such as moxifloxacin) when taking HEXARONE.

Using HEXARONE together with the following medicines is not recommended:

- 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).

Caution is advised when using medicines that can lower your potassium and/or magnesium levels in your bloodstream:

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

Caution is advised when you are having an operation and are given general anaesthetics or high dose oxygen when taking HEXARONE tablets.

HEXARONE tablets may have an effect of the following medicines:

- Digitalis – used for some heart conditions.
- Dabigatran – used to thin the blood.
- Digoxin – used to treat various heart conditions.

- Warfarin – used to stop your blood from clotting.
- Phenytoin – used for epilepsy, fits or seizures.
- Ciclosporin and tacrolimus – used to help prevent rejection of transplants.
- Fentanyl – used for pain relief.
- Statins – used for high cholesterol.
- Lidocaine – used as an anaesthetic.
- Medicines for impotence such as sildenafil.
- Midazolam – used to relieve anxiety or to help you relax before surgery.
- Triazolam – a sleeping tablet.
- Ergotamine – used for migraines.
- 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.
- Medicines for hepatitis C treatment (such as sofosbuvir, daclatasvir, simeprevir or ledispasvir).

HEXARONE with food, drink and alcohol

Do not drink grapefruit juice while taking this medicine. This is because drinking grapefruit juice while taking HEXARONE 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.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking this medicine.

HEXARONE must not be used if you are pregnant or if you are planning to get pregnant. Women who want to conceive should plan the beginning of a pregnancy six months after ending therapy.

HEXARONE should not be taken if you are breastfeeding, if treatment is necessary, you should not breastfeed your baby.

Driving and using machines

HEXARONE can affect your ability to drive and use machinery especially at the beginning of therapy, when your dose is increased or if you are taking alcohol.

HEXARONE contains lactose and iodine

HEXARONE tablets contain an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking HEXARONE tablets.

The active ingredient in HEXARONE tablets contain iodine. Iodine can cause problems to your thyroid. If you are allergic to iodine, you should not take HEXARONE.

3. How to take HEXARONE

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

Always take HEXARONE tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take HEXARONE 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.

Adults

- The usual starting dose is 200 mg (one 200 mg or two 100 mg HEXARONE tablets) three times each day for one week.
- The dose will then be lowered to 200 mg twice each day for a further week.
- The dose will then be lowered to 200 mg 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 you react to this medicine.

Elderly

It is important that the lowest effective dose be used. The doctor may give you a lower dose of HEXARONE tablets. Also, the doctor should check your blood pressure and thyroid function regularly.

If you take more HEXARONE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact 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 HEXARONE

If you forget a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue to take the next tablet at the usual time. Do not

take a double dose to make up for the forgotten individual doses. Then keep taking the medicine as your doctor has told you.

If you stop taking HEXARONE

Keep taking HEXARONE tablets until your doctor tells you to stop. Do not stop taking HEXARONE 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. HEXARONE 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 HEXARONE. This is because HEXARONE 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 HEXARONE tablets.

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

4. Possible side effects

HEXARONE tablets can have side effects.

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

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

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swollen eyelids, face, lips, throat or tongue.
- 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.
- 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.
- 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 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.
- 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 muscle (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).

- Feeling numb or weak, tingling or burning feelings in any part of your body.
- 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.
- Some cases of bleeding in the lungs have been reported in patients taking HEXARONE tablets. You should tell your doctor straight away if you cough up any blood.
- Chest pain and shortness of breath and irregular heartbeat. These could be signs of a condition called “Torsade de pointes”.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Blurred eyesight or seeing a coloured halo in dazzling light.
- 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.
- Eczema.
- Muscle weakness.
- 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.
- Burning more easily in the sun.
- Slightly slower heartbeat.
- Nightmares.
- Problems sleeping.

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').
- Frequent infection due to decreased number of white blood cells (neutropenia, agranulocytosis).
- 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 libido.
- Hallucinations.
- Headache.
- Balance problems, feeling dizzy.
- Dry mouth.

- Red, scaly patches of skin, loss of hair or loosening of nails (called ‘exfoliative dermatitis’).
- Hair loss, balding.
- Skin rash.
- Skin redness during radiotherapy.
- Difficulty in getting or maintaining an erection.
- Swelling of the testicles.
- Fatigue.
- Increase in blood creatine, this can be seen in blood tests.

The frequency of the following side effects are unknown:

- Feeling less hungry.
- Feeling confused or seeing or hearing things that are not there.
- Movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (Parkinsonism).
- A distorted sense of smell (parosmia).
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis.
- 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.
- Granulomas, small red lumps on the skin or inside the body which are seen by X-ray.

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, pharmacist or nurse. 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 HEXARONE.

Suspected side effects can also be reported directly to the HCR via https://pvi1.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store HEXARONE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Do not remove blisters / tablets from outer container until required for use.

Do not use the tablets after the expiry date printed on the container.

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 HEXARONE contains

The active substance is amiodarone hydrochloride.

Each HEXARONE 100 tablet contains 100 mg amiodarone hydrochloride.

Each HEXARONE 200 tablet contains 200 mg amiodarone hydrochloride.

The other excipients are anhydrous colloidal silica, lactose monohydrate, magnesium stearate, maize starch and polyvidone 25.

What HEXARONE looks like and contents of the pack

HEXARONE 100: White, round tablets, one side scored, other side convex.

Diameter: 8,0 to 8,2 mm

HEXARONE 200: White, round tablets, biconvex with a one-sided score notch.

Diameter :10,0 to 10,2 mm

HEXARONE is packed in white, opaque PP/Aluminium blisters. Packs of 30's.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

This leaflet was last revised in

30 November 2022

Registration numbers

HEXARONE® 100: 32/6.2/0650

HEXARONE® 200: 32/6.2/0651

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07