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ANNOTATED AMENDED PROPOSED PATIENT INFORMATION LEAFLET

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4.	**ACCORD AMIODARONE 30 mg/ml Pre-filled syringe**
5.	Solution for injection or infusion
6.	Amiodarone
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8.	**Read all of this leaflet carefully before you are given ACCORD AMIODARONE 30 mg/ml**
9.	• Keep this leaflet. You may need to read it again.
10.	• If you have further questions, please ask your doctor or your pharmacist.
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12.	**What is in this leaflet**
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20.	**1. What ACCORD AMIODARONE 30 mg/ml is and what it is used for**
21.	• **ACCORD AMIODARONE 30 mg/ml** contains the active substance amiodarone
22.	hydrochloride and it belongs to a group of medicines called anti-dysrhythmics.
23.	• It works by controlling the uneven beating of your heart (called dysrhythmias).

- Having the injection helps your heartbeat to return to normal and is normally only given in a hospital under medical supervision when a quick response is needed or when tablets cannot be given.

Your doctor has prescribed **ACCORD AMIODARONE 30 mg/ml** to treat the following:

- uneven heartbeats where other medicines either have not worked or cannot be used.
- an illness called Wolff-Parkinson-White Syndrome. This is where your heart beats unusually fast.
- other types of fast or uneven heartbeats known as ‘atrial flutter’ or ‘atrial fibrillation.

2. What you need to know before you are given ACCORD AMIODARONE 30 mg/ml

ACCORD AMIODARONE 30 mg/ml should not be given to you if you:

- are allergic to amiodarone hydrochloride, iodine or to any of the other ingredients of **ACCORD AMIODARONE 30 mg/ml** listed in section 6
- have heart problems such as heart block, which can cause a slow heart rate (such as sino-atrial heart block, sinus bradycardia, high grade AV block, bifascicular or trifascicular block or sinus node disease) and you do not have a pacemaker
- have heart failure or weakness of the heart muscle (cardiomyopathy)
- have or have had thyroid problems. Your doctor will test your thyroid before giving you this medicine
- have severe breathing problems
- have very low blood pressure

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- are taking other medicines that can make your heartbeat very quickly (these are listed below under the section 'Taking other medicines')
- are pregnant or are breastfeeding

Do not use this medicine if any of the above applies to you and talk to your doctor or nurse.

ACCORD AMIODARONE 30 mg/ml must not be given to premature babies, neonates or a child up to 3 years old.

If you are uncertain whether you can use this medicine or not, ask your doctor or pharmacist.

Warnings and precautions

Tell your doctor or health care provider before being given ACCORD AMIODARONE 30 mg/ml.

Take special care with **ACCORD AMIODARONE 30 mg/ml** if you:

- have mild to moderate low blood pressure
- have a weak heart or heart failure
- have any problem with your thyroid gland. Your doctor will test your thyroid before giving you this medicine
- have liver problems
- are receiving high dose oxygen therapy or have any other problems with your lungs including asthma
- are due to have an operation involving general anaesthesia

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- are elderly
- 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. Tell your doctor if 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

Your doctor may consider alternative treatments. If treatment with amiodarone and sofosbuvir is needed, you may require additional heart monitoring.

If any of these apply to you, your doctor may want to change your treatment or give you special advice.

Other medicines and ACCORD AMIODARONE 30 mg/ml

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

Sofosbuvir, a medicine used for the treatment of hepatitis C.

The following medicines must not be taken with ACCORD AMIODARONE 30 mg/ml as together they can cause a very severe fast heartbeat that can be fatal:

- medicines to treat irregular heart rhythms (anti-dysrhythmics), such as quinidine, procainamide, disopyramide and sotalol

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- antibiotics, such as erythromycin, moxifloxacin, cotrimoxazole and pentamidine
- medicines to treat mental illness (anti-psychotics), such as chlorpromazine, thioridazine, haloperidol, fluphenazine, amisulpiride, sertindole and pimozide
- medicines to treat depression, such as lithium and tricyclic antidepressants, including doxepin, maprotiline and amitriptyline
- certain medicines to treat allergic reactions (antihistamines), such as terfenadine, astemizole and mizolastine
- medicines used to treat or prevent malaria, such as quinine, mefloquine, chloroquine and halofantrine

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicine:

- oral anticoagulants e.g. warfarin (used to thin the blood), phenytoin (used to treat epilepsy) and digoxin (used to treat certain heart conditions). Your doctor may reduce your dose of these medicines and your blood will need to be monitored before and after treatment
- stimulant laxatives such as bisacodyl and senna, medicines called diuretics or water tablets, steroids and the antifungal medicine amphotericin (when given directly into the vein). These can cause low levels of potassium in the blood, which can increase the risk of getting a fast heart rate (tachycardia).
- rifampicin (an antibiotic) and St. John's Wort (a herbal medicine) can cause lower levels of **ACCORD AMIODARONE 30 mg/ml** in the body if they are taken at the same time

Medicines that can either be affected by or affect the level of amiodarone in the body if

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taken at the same time:

- ciclosporin, tacrolimus (immunosuppressants - used to help prevent rejection of transplants)
- flecainide, used to treat irregular heart rhythms. Your doctor should monitor your treatment closely and may adjust your dose of flecainide
- simvastatin, lovastatin, atorvastatin (medicines to reduce blood cholesterol), as there is a risk of developing muscle pains and kidney failure (rhabdomyolysis) if doses of more than 20 mg of simvastatin are taken
- lidocaine (a local anaesthetic)
- sildenafil (used for erectile dysfunction)
- fentanyl (used for pain relief)
- midazolam and triazolam (a sedative)
- ergotamine and dihydroergotamine (for migraine)
- colchicine (for gout)
- beta-blockers, such as metoprolol and sotalol
- calcium channel blockers diltiazem and verapamil, used to treat high blood pressure
- indinavir (an anti-viral medicine)
- cimetidine (an anti-ulcer medicine)
- clarithromycin (an antibiotic)
- ketoconazole and itraconazole (antifungal medicines)
- tetracosactrin (used in the treatment of inflammatory or degenerative disorders)
- sofosbuvir, used for the treatment of hepatitis C

Please consult your doctor, pharmacist or other healthcare professional for advice.

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ACCORD AMIODARONE 30 mg/ml with food, drink and alcohol

Do not drink grapefruit juice while using this medicine because it can increase amiodarone levels in your blood.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor or pharmacist for further advice before taking ACCORD AMIODARONE 30 mg/ml.

- **ACCORD AMIODARONE 30 mg/ml** must not be used during pregnancy or breast-feeding.
- Women of child-bearing age need to plan for a pregnancy starting at least half a year after finishing treatment with **ACCORD AMIODARONE 30 mg/ml**, in order to avoid exposure of the embryo/foetus to this medicine.
- If you are given amiodarone during pregnancy or breast-feeding, breast-feeding should be stopped.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine

Driving and using machines

ACCORD AMIODARONE 30 mg/ml may affect your ability to drive and use machines.

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Important information about some of the ingredients of ACCORD AMIODARONE 30 mg/ml

This medicine contains benzyl alcohol in each 10 ml syringe. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have liver or kidney disease or if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”). Benzyl alcohol has been linked with toxic and allergic reactions called gasping syndrome in infants and children up to 3 years old.

ACCORD AMIODARONE 30 mg/ml contains iodine in a 10 ml prefilled syringe. Iodine is present in amiodarone hydrochloride, the medicine your infusion contains. Iodine can cause problems with your thyroid.

3. How ACCORD AMIODARONE 30 mg/ml is given

You will not be expected to give yourself **ACCORD AMIODARONE 30 mg/ml**.

It will be given to you by a person who is qualified to do so.

This is because it needs to be given as an injection or infusion into your vein in the hospital where the doctor can monitor your progress.

The daily dose of Amiodarone depends on the severity of your illness. The dose and the treatment times will be determined by your doctor, who will adjust these especially for you.

If you receive more ACCORD AMIODARONE 30 mg/ml than you should

Your doctor will carefully calculate how much **ACCORD AMIODARONE 30 mg/ml** you should get, therefore it is unlikely your doctor or nurse will give you too much of it. If, however, you have received higher doses than those recommended you will be carefully

monitored by your doctor and will receive supportive therapy if necessary.

If you are given too much Amiodarone Injection the following effects may happen: feeling dizzy, faint, sick, tired, confused, constipation or sweating. You may have an abnormally slow or fast heartbeat. Too much amiodarone can damage the heart and liver.

If you forget to take ACCORD AMIODARONE 30 mg/ml

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you think you may have missed a dose, then talk to your doctor or nurse.

If you stop taking ACCORD AMIODARONE 30 mg/ml

It is important for you to keep having Amiodarone Injections until your doctor decides to stop them. If you stop having this medicine, the uneven heartbeats may come back and this could be dangerous.

4. Possible side effects

ACCORD AMIODARONE 30 mg/ml can have side effects.

Not all side effects for ACCORD AMIODARONE 30 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ACCORD AMIODARONE 30 mg/ml, please consult your doctor, pharmacist or other healthcare professional for advice.

Amiodarone Injection may stay in your blood for up to a month after stopping treatment. You may still get side effects in this time.

If any of the following happens, stop receiving ACCORD AMIODARONE 30 mg/ml and inform your doctor:

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- anaphylactic shock (a life-threatening allergic reaction). Signs may include a sudden rash, itching or lumpy rash (hives) and swelling of the face, lips, tongue or other parts of the body. You may also have shortness of breath, wheezing or trouble breathing.
- life-threatening skin reactions characterised by rash, blisters, hives, peeling skin and pain (toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), bullous dermatitis, drug reaction with eosinophilia and systematic symptoms (DRESS).
- excessive thyroid activity (hyperthyroidism, sometimes fatal) causing:

- Weight loss
- Weakness
- Restlessness
- Increased heart rate
- Irregular heart rate
- Angina
- Heart failure
- Shaking, Sweating
- High temperatures

- 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'.
- serious respiratory problems such as difficulty in breathing, wheezing or coughing, build-up of fluid in the lungs, sometimes fatal.

These are all very serious side effects. If you have them, you may have had a serious

reaction to ACCORD AMIODARONE 30 mg/ml. 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
- itchy, red rash (eczema)
- trembling when you move your arms or legs.
- at the site where you are given the injection or infusion you may experience: pain, skin redness or a change in skin colour, localised soft-tissue damage, fluid leakage, swelling caused by fluid within the skin, inflammation or inflamed blood vessels, abnormally hard tissue or infection
- slow or irregular heartbeat
- low blood pressure and rapid heart rate which can make you feel dizzy or faint. These side effects occur straight after injection. The effects are usually moderate and temporary. They can be serious if you are given too much **ACCORD AMIODARONE 30 mg/ml** too quickly.

Less frequent side effects

- feeling numb or weak, tingling or burning feelings in any part of your body
- the excipient benzyl alcohol may cause hypersensitivity reactions.
- feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, sweating, feeling irritable. This could be an illness called ‘syndrome of inappropriate anti-diuretic hormone secretion’ (SIADH)

- newly occurring heart rhythm disorder or worsening of existing heart rhythm disorders leading to heart attack
- heart block that can lead to slow heart rate
- reduced heartbeat, which may lead to shock
- increased liver enzymes which can show up in tests
- hot flushes, sweating and feeling sick if amiodarone injection is given too quickly
- headache
- feeling sick (nausea)
- sweating
- lung damage
- acute liver function disorders, with increased serum levels and/or jaundice, including hepatic failure, sometimes fatal.
- increase in pressure inside the skull, accompanied by headache, vomiting.
- anaemia
- low levels of platelets
- nightmares
- feeling of spinning
- sleeplessness

Frequency unknown

- sudden inflammation of the pancreas (pancreatitis (acute))
- confusion (delirium)
- back pain.
- hypothyroidism (underactive thyroid) – you may feel extremely tired, weak or

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'rundown' and experience weight gain, constipation and aching muscles. You may be unable to cope with low temperatures.

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. This includes any possible side effects not listed in this leaflet. 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 **ACCORD AMIODARONE 30 mg/ml**.

5. How to store ACCORD AMIODARONE 30 mg/ml

- Store at or below 25 °C.
- After opening the product should be used immediately.
- For single use only. Discard any unused product.
- Store all medicines out of reach of children.
- Store in original package until use.
- Do not use after the expiry date stated on the label
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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6. Contents of the pack and other information

What ACCORD AMIODARONE 30 mg/ml contains

- The active substance is amiodarone
- Each ml of solution contains 30 mg amiodarone
- The other ingredients are benzyl alcohol, polysorbate 80 and water for injection

What ACCORD AMIODARONE 30 mg/ml looks like and contents of the pack

- A clear, colourless to pale yellow solution packaged in a single 10 ml pre-filled syringe.
- Pack size: 1, 5 or 10 syringes per carton
- Not all pack sizes may be marketed

HOLDER OF CERTIFICATE OF REGISTRATION

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