PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AMIODARONE IV ACTIVO 150 mg/3 ml solution for injection

Amiodarone hydrochloride

Preservative: Benzyl alcohol 2,02 % w/v

Sugar free

Read all of this leaflet carefully before you are given AMIODARONE IV ACTIVO

- 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.

What is in this leaflet

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

1. What AMIODARONE IV ACTIVO is and what it is used for

AMIODARONE IV ACTIVO 150 mg/3 ml, solution for injection contains a medicine called amiodarone hydrochloride. This belongs to a group of medicines called anti-dysrhythmics. It works by controlling the uneven beating of your heart (called arrhythmias). Having the injection helps your heartbeat to return to normal.

AMIODARONE IV ACTIVO 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 heart beat.
- Treat uneven heartbeats where other medicines either have not worked or cannot be used.

2. What you need to know before you are given AMIODARONE IV ACTIVO

AMIODARONE IV ACTIVO should not be administered to you:

- If you are hypersensitive (allergic) to amiodarone, iodine (amiodarone contains iodine) or any of the other ingredients of AMIODARONE IV ACTIVO (listed in section 6).
- If you have a slower than usual heartbeat (called 'sinus bradycardia') or an illness called 'sinoatrial' heart block.
- If you have any other problems with your heartbeat and do not have a pacemaker fitted.
- If you are taking certain other medicines which could affect your heartbeat (see Other medicines and AMIODARONE IV ACTIVO).
- If you have severe breathing problems.
- If you are going to have cardio-pulmonary surgery (operation on your heart, lungs and other thoracic (chest) organs).
- It you have or have had thyroid problems. Your doctor might do some tests before AMIODARONE IV ACTIVO is given to you.
- If you are pregnant or breastfeeding (see Pregnancy and breastfeeding).

AMIODARONE IV ACTIVO is not recommended for use in paediatric patients.

Note that these contraindications do not apply in an emergency situation when AMIODARONE IV ACTIVO is used when your heart has stopped (cardiac arrest).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have porphyria, as AMIODARONE IV ACTIVO might cause you to have an attack.
- If you have or had heart problems, as AMIODARONE IV ACTIVO might worsen the condition.
- If you have or had lung problems, as AMIODARONE IV ACTIVO might you to cough and have difficulty to breath. Your doctor might take a chest x-ray to help him with a diagnosis.
- If you have liver problems. You doctor might do some blood tests to confirm that your liver is not damaged while having AMIODARONE IV ACTIVO.
- If you have problems with your thyroid (such as weight loss, lack of energy and strength (asthenia), feeling restless, increase in your heart rate (hyperthyroidism) or hypothyroidism such as weight gain, feeling as if you do not have energy or have a slow heartbeat). You doctor might do some blood tests to monitor your thyroid, even after AMIODARONE IV ACTIVO have been stopped.
- If you are going to have an operation, as your doctor might use other medicines to put you to sleep (anaesthesia) (see Other medicines and AMIODARONE IV ACTIVO).
- 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 amiodarone and sofosbuvir is needed, you may require additional heart monitoring.
- If you are on a heart transplant waiting list. Your doctor may consider an alternative treatment.
- If you notice any blistering or bleeding of your skin, and you do not feel well, you might have a serious side effect called Stevens-Johnson syndrome or Toxic Epidermal Necrolysis. Your doctor might stop your treatment with AMIODARONE IV ACTIVO immediately.

- If you cannot see from the one eye or your vision becomes blurry. You might have a reaction to AMIODARONE IV ACTIVO. Your doctor might stop your treatment with AMIODARONE IV ACTIVO and do some eye tests to confirm the reason.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before having AMIODARONE IV ACTIVO.

Other medicines and AMIODARONE IV ACTIVO

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 taking any of the following medicines, as the combination with AMIODARONE IV ACTIVO can make your condition worse:

- Betablockers used to lower blood pressure or heart rate, such as atenolol and metoprolol as very slow heart rate can occur.
- Calcium channel blockers used for chest pain (angina) or high blood pressure, such as diltiazem or verapamil.
- Laxatives used for constipation such as bisacodyl or senna, as it may cause your potassium levels to drop.
- Other medicines to treat uneven heartbeat, such as sotalol, bepridil, disopyramide, quinidine, procainamide, flecainide as their effect can become stronger.
- Vincamine used for high blood pressure.
- Medicines for infections such as intravenous erythromycin, moxifloxacin, intravenous pentamidine, fluoroquinolones, amphotericin B.
- Medicines for schizophrenia such as chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpride, sertindole.
- Medicines for other mental illnesses such as lithium, doxepin, maprotiline or amitriptyline.
- Anti-histamines used for hay fever, such as astemizole, mizolastine.
- Medicines used to prevent malaria such as quinine, mefloquine, chloroquine, halofantrine.

- Diuretics that lowers potassium levels such as spironolactone, eplerenone and triamterene.
- Corticosteroid tablets or injections, used to treat inflammation and suppress the immune system such as prednisone, prednisolone, methylprednisolone, dexamethasone, betamethasone, hydrocortisone.

Tell your doctor if you are taking any of the following medicines, as the combination with AMIODARONE IV ACTIVO can increase their concentration:

- Clonazepam used to relief panic attacks.
- Cimetidine used to lower stomach acid.
- Warfarin and dabigatran, used to thin you blood (anticoagulants).
- Phenytoin used for epilepsy.
- Digoxin, used to treat heart failure.
- Medicines to prevent organ rejection such as ciclosporin and tacrolimus.
- Fentanyl, used for severe pain.
- Lidocaine, used as an anaesthetic.
- Ergotamine and dihydroergotamine used for migraines.
- Medicines for impotence such as sildenafil, tadalafil or vardenafil.
- Statins, used to lower cholesterol levels such as simvastatin, atorvastatin and lovastatin as it increase your risk of muscle disease.
- Grapefruit, as it increase AMIODARONE IV ACTIVO concentration.
- Medicine for the treatment of hepatitis C virus infection, sofosbuvir, might slow your heart rate. Your doctor might change the medication or monitor you heart more frequently.

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 health care provider for advice before this medicine is given to you.

You should not be given AMIODARONE IV ACTIVO when you are pregnant or breastfeeding.

AMIODARONE IV ACTIVO contains iodine and benzyl alcohol

Iodine: AMIODARONE IV ACTIVO contains approximately 56 mg of iodine in a 3 ml ampoule. Iodine can cause problems to your thyroid.

Benzyl alcohol: AMIODARONE IV ACTIVO contains benzyl alcohol (2,02 % *w/v*) as a preservative. It must not be given to children, premature or newborn babies. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children under the age of 3 years old.

3. How AMIODARONE IV ACTIVO are given

You will not be expected to give yourself AMIODARONE IV ACTIVO. Your doctor or nurse will normally give you AMIODARONE IV ACTIVO, because it needs to be given as an infusion into your vein in the hospital where the doctor can monitor your progress.

The dosage is calculated by your doctor according to your weight (5 mg for every kilogram of your weight). The AMIODARONE IV ACTIVO ampoules are diluted in 5 % dextrose and given to you intravenously (into a vein in e.g. your arm) over a period of 20 minute to 2 hours. If the dosage needs to be repeated, it might be given over a longer period of 24 hours (approximately 15 mg for every kilogram of your weight).

In an emergency, your doctor may decide to give you a dose of 150 mg to 300 mg as a slow injection over 3 minutes.

Your doctor will change you to amiodarone tablets as soon as possible.

Elderly

The doctor may give you a lower dose of AMIODARONE IV ACTIVO and monitor your heart rate more closely.

Children

The safety and efficacy of AMIODARONE IV ACTIVO in paediatric patients have not been established. Therefore, its use in paediatric patients is not recommended. See also "AMIODARONE IV ACTIVO contains benzyl alcohol" above.

If you are given more AMIODARONE IV ACTIVO than you should

Since a health care provider will administer AMIODARONE IV ACTIVO, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

AMIODARONE IV ACTIVO can have side effects.

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

Note that after stopping treatment AMIODARONE IV ACTIVO may stay in your blood for up to a month. You may still get side effects in this time.

If any of the following happens, stop having AMIODARONE IV ACTIVO, tell your doctor immediately or go to the casualty department at your nearest hospital.

- You have a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. You may have an allergic reaction.
- 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 This could be a condition called Toxic Epidermal Necrolysis.

- 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 a condition called optic neuropathy or neuritis.
- Feeling extremely restless or agitated, weight loss, increased sweating and being unable to stand the heat. These could be signs of a condition called hyperthyroidism.
- Yellowing of the skin and eyes, itching, vomiting, loss of appetite. These could be sings of an acute liver disorder.

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

Tell your doctor if you notice any of the following:

Frequent

- Hypothyroidism and hyperthyroidism.
- Slow heartbeat.
- Low blood pressure or collapse.
- Eczema.
- Injection site reactions such as pain, redness, swelling, irritation discolouration of the skin.

Less frequent

- Severe reduction in the number of white blood cells which makes infections more likely.
- Allergic reaction.
- Swelling of the lips, eyelids and genitalia.
- Less urination causing your body to retain water (Syndrome of inappropriate antidiuretic hormone secretion).
- Feeling confused state.
- Nightmares, headaches, feeling dizzy (vertigo), sleeplessness.

- Loss of eyesight, blurry vision.
- Irregular heartbeat *(Torsade de pointes)*.
- 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.
- Feeling sick (nausea), vomiting, having a metallic taste in your mouth.
- Liver disorders, yellowing of your skin, laboratory liver tests is higher than it should be.
- Sweating.
- Urticaria, toxic epidermal necrolysis/Stevens-Johnson syndrome, inflammation of the skin characterized by fluid filled blisters (bullous dermatitis).
- Back pain.
- Decreased sex drive.
- After heart transplantation the transplanted heart stops working properly (primary graft dysfunction).

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 AMIODARONE IV ACTIVO.

5. How to store AMIODARONE IV ACTIVO

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Do not use after the expiry date stated on the label.

Do not use AMIODARONE IV ACTIVO if you notice visible particles or signs of deterioration.

6. Contents of the pack and other information

What AMIODARONE IV ACTIVO contains

- The active substance is amiodarone hydrochloride. Each 3 ml ampoule contains 150 mg amiodarone hydrochloride.
- The other ingredients are benzyl alcohol, polysorbate 80, hydrochloric acid 10 % (pH adjustment), sodium hydroxide 10 % (pH adjustment), water for Injections.

What AMIODARONE IV ACTIVO looks like and contents of the pack

AMIODARONE IV ACTIVO is a clear colourless or slightly yellowish solution.

It is packed in type I, amber neutral glass ampoules. The ampoules are packed in an outer carton as packs of 5's.

Holder of Certificate of Registration

Activo Health (Pty) Ltd

Block B, Arena Office Park

272 West Avenue

Centurion

0157

This leaflet was last revised in

Registration number

To be allocated.