ARYCOR RANGE

PATIENT INFORMATION LEAFLET

S4
SCHEDULING STATUS:
ARYCOR 100 tablets (amiodarone hydrochloride)

Contains sugar (lactose): 48,0 mg per tablet.

Contains organic iodine: Approximately 37,5 mg per tablet.

ARYCOR 200 tablets (amiodarone hydrochloride)

Contains sugar (lactose): 96,0 mg per tablet.

Contains organic iodine: Approximately 75 mg per tablet.

Read this leaflet carefully before you start taking ARYCOR:

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

What is in this leaflet:

1. What ARYCOR is and what it is used for

2. What you need to know before you take ARYCOR

3. How to receive ARYCOR

4. Possible side effects

5. How to store ARYCOR

6. Contents of the pack and other information

1 WHAT ARYCOR IS AND WHAT IT IS USED FOR:

ARYCOR is an antidysrhythmic and is used to control an irregular or rapid heart rate where other similar medicines do not have the expected effect.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ARYCOR:

Do not take ARYCOR:

- if you are hypersensitive (allergic) to amiodarone hydrochloride, iodine or to any of the other ingredients of ARYCOR (see section 6)
- if you have heart block - which may cause a very slow, very fast or irregular pulse, or dizziness
- if you have a slower than usual heartbeat
- if you have any other problems with your heartbeat and do not have a pacemaker fitted
- if you have or have had thyroid problems. Your doctor should test your thyroid before giving you ARYCOR
- if you are pregnant or likely to become pregnant. Tell your doctor about this (see Pregnancy and breastfeeding)
- if you are breastfeeding (see Pregnancy and breastfeeding)
- if you are taking or have taken certain other prescription medicines: including other heart medicines (e.g. sotalol, disopyramide, quinidine, procainamide, bepridil), antibiotics (e.g. intravenous erythromycin, pentamidine injection, co-trimoxazole, ciprofloxacin or moxifloxacin), antipsychotics, antidepressants (including lithium), antihistamines or antimalarials

- Tell your doctor if you are taking or have recently taken any other prescription medicine (see Other medicines and ARYCOR).
- if you are taking or have taken certain other non-prescription medicines including herbal supplements like St John's Wort or other nutritional supplements. Tell your doctor if you are taking or have recently taken any other prescription or non-prescription medicine (see Other medicines and ARYCOR).

ARYCOR is not recommended for use in paediatric patients.

Do not take ARYCOR if any of the above apply to you. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking ARYCOR.

Warnings and precautions:

Take special care with ARYCOR:

Tell your doctor or other healthcare provider immediately if you notice any of the following, since you may require urgent medical care:

- difficulty breathing or lung (respiratory) problems
- unexplained weight loss or gain, cold intolerance, restlessness or slow or fast heartbeat. These could be signs of thyroid abnormalities (see Do not take ARYCOR and POSSIBLE SIDE EFFECTS)
- problems with your eyesight such as blurred or decreased vision
- worsening skin rash often with blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever (see section 4).

Whilst taking ARYCOR you should avoid exposure of your skin to direct sunlight or sunlamps. You must take sensible precaution when you are in the sun, wear a wide brimmed hat and keep your arm and legs covered. Apply a total sunblock to exposed areas of skin.

Before and during treatment your doctor may perform tests to assess your medical condition such as blood tests, chest X-Rays, ECG (electrical tracing of your heart) and eye examinations.

Tell your doctor before taking ARYCOR:

- if you have heart failure
- if you are going to have an anaesthetic, any kind of surgery (including dental) or high dose oxygen therapy
- if you are porphyric
- if you have or have had liver or kidney problems
- if you are elderly (over 65 years of age). Your doctor will need to monitor you more carefully
- if you are a heart transplant patient
- 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 taking or have taken certain other prescription medicines including anti-infectives, statin medicines used to lower cholesterol, stimulant laxatives or hepatitis C treatment (see Other medicines and ARYCOR) .

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking ARYCOR Tablets.

Other medicines and ARYCOR:

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

Do not take ARYCOR and tell your doctor if you are taking:

- other heart medicines (e.g. sotalol, quinidine, disopyramide, procainamide, bepridil)
- medicines used to treat infections (e.g. intravenous erythromycin, pentamidine injection, co-trimoxazole, fluoroquinolones such as ciprofloxacin or moxifloxacin).
- some antipsychotics (such as chlorpromazine, haloperidol)
- lithium and some antidepressants (e.g. amitriptyline)
- some antihistamines - used to treat hay fever, rashes or other allergies (such as mizolastine)
- some antimalarials (such as quinine, mefloquine, chloroquine, halofantrine).

Examples of medicines that may cause serious undesirable interactions are:

- beta-blockers and some calcium channel inhibitors – used to treat high blood pressure and angina (e.g. verapamil, diltiazem)
- stimulant laxatives – used for constipation (e.g. senna or bisacodyl)
- medicines that may change the levels of potassium or magnesium in your blood e.g. diuretics (water tablets), corticosteroids or the antifungal amphotericin (when given directly into a vein)
- general anaesthetics or high dose oxygen – medicines used during surgery
- hepatitis C treatment (such as sofosbuvir, daclatasvir, simeprevir or ledispasvir.

ARYCOR tablets may increase the effect of the following medicines:

- digoxin
- ciclosporin and tacrolimus – used after transplant operations
- anticoagulants - used to thin the blood (e.g. warfarin, dabigatran)
- phenytoin
- flecainide – another medicine used for uneven heartbeats
- simvastatin or other statins - used to lower cholesterol levels
- sildenafil, tadalafil - used to treat impotence
- clonazepam, midazolam - used to relieve anxiety
- other amiodarone containing medicines
- lidocaine – used as a local anaesthetic
- colchicine – used to treat gout
- ergotamine – used for migraines
- fentanyl – used for pain relief.

The following medicines may increase the effect of ARYCOR:

- cimetidine
- HIV-protease inhibitors.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking ARYCOR.

Taking ARYCOR with food and drink and alcohol:

Do not drink grapefruit juice while taking ARYCOR. This is because drinking grapefruit juice while taking ARYCOR can increase your chance of getting side effects (see Warnings and precautions).

Limit the amount of alcohol you drink while taking ARYCOR. This is because drinking alcohol while taking ARYCOR will increase the chance of you having problems with your liver. Talk to your doctor or pharmacist about the amount of alcohol you can drink.

Pregnancy and breastfeeding and fertility:

Pregnancy:

You should not take ARYCOR if you are pregnant.

Breastfeeding:

Do not breastfeed if you are taking ARYCOR tablets.

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

Driving and using machines:

ARYCOR may cause blurred vision in some people. Do not drive or operate machinery if you experience this side effect. Check with your doctor.

It is not always possible to predict to what extent ARYCOR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ARYCOR affects them.

ARYCOR contains lactose and iodine:

- **Lactose (a type of sugar):** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ARYCOR
- **Iodine:** Iodine is present in amiodarone hydrochloride, the medicine your tablets contain. Iodine can cause problems to your thyroid.

3 HOW TO TAKE ARYCOR:

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

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

The usual dose of ARYCOR is one 200 mg tablet (or two 100 mg tablets) three times a day for the first week, followed by one 200 mg tablet (or two 100 mg tablets) twice a day for the next week and then one 200 mg tablet (or two 100 mg tablets) daily. In some patients this may be further reduced to one 100 mg tablet a day. Elderly patients may be prescribed lower doses.

Your doctor will tell you how long your treatment with ARYCOR will last. Do not stop treatment early because your condition may get worse.

If you have the impression that the effect of ARYCOR is too strong or too weak, tell you doctor or pharmacist.

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

If you take more ARYCOR than you should:

An overdose of this medicine may be dangerous. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forgot to take ARYCOR:

If you forgot to take a dose at the right time, take it as soon as you remember, then go on as before. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ARYCOR is stopped:

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

If you are sensitive to the sun, the sensitivity may persist for some time after treatment stops and the necessary precautions need to be taken (see Warnings and precautions).

ARYCOR is very slowly eliminated from the body and adverse events may only disappear several months after treatment is stopped.

4 POSSIBLE SIDE EFFECTS:

ARYCOR can have side effects.

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

- you have an allergic reaction. The signs may include: swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching and 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. 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:

- chest pain

- angina
- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing
- signs of recurrent infections such as fever or sore throat
- yellowing of the skin and eyes, also called jaundice.

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

Frequent side effects:

- a slow pulse.
- problem with your thyroid (see Do not take ARYCOR and Warning and precautions):
  - 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 (increased thyroid function), or,
  - 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 (decreased thyroid function)
- difficulty with your vision
- nausea (feeling sick), vomiting (being sick), taste disturbance
- shakiness
- disturbed sleep patterns, nightmares
- sensitivity to the sun, skin discolouration
- increased liver enzymes.

Less frequent side effects:

- blood disorders (you may have nose bleeds, bruising, tiredness, paleness of skin).
- pins and needles, muscle pain and weakness, cramps, difficulty in walking and loss of balance
- vertigo (dizziness)
- headaches, tiredness
- painful swelling of the testicles, impotence
- skin rashes, hair loss
- inflammation of the blood vessels.
- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite and feeling irritable. This could be something called 'syndrome of inappropriate anti-diuretic hormone' (SIADH) secretion
- libido decreased.

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 report side effects directly to Sanofi's Pharmacovigilance Unit at Email: za.safety@sanofi.com or Tel: 011 256 3700 or

Nadia Le Hanie *Regulatory Affairs Specialist*	

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 ARYCOR.

5. HOW TO STORE ARYCOR:

Store all medicines out of reach of children.

The tablets should be protected from light, and stored at or below room temperature (25 °C).

Store your tablets in the original container in order to protect them from light.

Do not take ARYCOR after the expiry date shown on the pack.

Return all unused medicine 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 ARYCOR contains:

The active substance is amiodarone hydrochloride

The other ingredients are:

Colloidal silicon dioxide

Lactose monohydrate (see section 2)

Maize starch

Povidone

Magnesium stearate

What ARYCOR looks like and contents of the pack: [~~IDENTIFICATION OF ARYCOR~~]:

ARYCOR 100: White to off-white, scored, round, biconvex tablets, marked with the action potential symbol and 100, approximately 8,7 mm in diameter.

ARYCOR 200: White to off-white, scored, round, biconvex tablets, marked with the action potential symbol and 200, approximately 10,5 mm in diameter.

ARYCOR tablets are packed in blister pack of 30 with a leaflet into a carton.

Holder of Certificate of Registration:

sanofi-aventis south africa (pty) ltd.

2 Bond Street

Midrand, 1685

South Africa

This leaflet was last revised in:

To be allocated

REGISTRATION NUMBERS:

ARYCOR 100 (Tablets): Y/6.2/44

ARYCOR 200 (Tablets):] P/6.2/165

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