PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AZYRON 100 tablets

AZYRON 200 tablets

Amiodarone hydrochloride

Contains sugar: Lactose

AZYRON 100 contains 35 mg lactose monohydrate per tablet.

AZYRON 200 contains 70 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking AZYRON.

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

1. What AZYRON is and what it is used for

AZYRON belongs to a group of medicines called antidysrhythmics. It works by controlling the

uneven beating of your heart (called “dysrhythmias”).

AZYRON 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.

AZYRON is used only when other medicines cannot be used.

2. What you need to know before you take AZYRON

Do not take AZYRON if you:

- Are hypersensitive (allergic) to amiodarone, iodine or any of the other ingredients of AZYRON (listed in section 6).
- Have a slower than usual heartbeat (called “sinus bradycardia”) or an illness called “sinoatrial” 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 “Other medicines and AZYRON”).
- Are pregnant or breastfeeding (see “Pregnancy and breastfeeding”).
- Are a paediatric patient.

Warnings and precautions

Tell your doctor if you:

- Have an inability to break down chemicals called porphyrins.
- 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 an elderly person (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 AZYRON 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).

Keep out of direct sunlight while taking AZYRON 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 sunscreen.
- Always wear a hat and clothes which cover your arms and legs.

Taking AZYRON with food and drink

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

Children and adolescents

Do not give AZYRON to paediatric patients, as safety and efficacy have not been established.

Other medicines and AZYRON

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

Do not take AZYRON together with:

- Other medicines for an uneven heartbeat (such as sotalol, quinidine-like medicines, procainamide, disopyramide).
- Medicines for infections (such as intravenous erythromycin, pentamidine, sparfloxacin).
- Medicines for malaria (such as halofantrine).
- Medicines used for hay fever, rashes or other allergies called antihistamines (such as terfenadine, astemizole).

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 heartbeat. You may also experience shortness of breath, chest pain, light-headedness and palpitations. Your doctor may consider alternative treatments. If treatment with AZYRON 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 medicine (such as warfarin).
- Phenytoin, used to treat seizures (fits).
- Digoxin, used for some heart conditions.

- Ciclosporin, tacrolimus or 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 undergo surgery, the anaesthetist should be informed that you are taking AZYRON 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 health care provider for advice before taking AZYRON.

You should not be given AZYRON if you are pregnant or breastfeeding.

Driving and using machines

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

AZYRON contains lactose monohydrate

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

3. How to take AZYRON

Take AZYRON 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 AZYRON 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 AZYRON.

Your doctor will tell you how long your treatment with AZYRON will last.

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

Elderly patients:

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

Your doctor will perform regular tests to check:

- How your liver is working. AZYRON can affect the way your liver works. If this happens, your doctor will decide whether you should keep taking AZYRON.
- Your thyroid function. This is because AZYRON contains iodine which can cause problems with the working of 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 AZYRON.

If you take more AZYRON 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 AZYRON

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 AZYRON is stopped

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

4. Possible side effects

AZYRON can have side effects.

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

If any of the following happens, stop taking AZYRON 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 AZYRON. 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 you heart stops beating.
- Chest pain, shortness of breath and irregular heartbeat. These could be signs of a condition called torsades 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 causing blurred eyesight or 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).

- Shortness of breath, dry cough, chest tightness, fever, fatigue and muscle aches.

Less frequently reported side effects were:

- 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of AZYRON.

5. How to store AZYRON

- Store at or below 25 °C in a dry place. Protect from light.

- Do not remove the blister strips from the carton 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 AZYRON contains

The active ingredient is amiodarone hydrochloride.

Each tablet contains 100 mg or 200 mg amiodarone hydrochloride.

The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, povidone and sodium starch glycolate.

What AZYRON looks like and contents of the pack

AZYRON 100: White to off-white, slightly speckled, round shaped, biconvex, uncoated tablets with break line on one side and plain on other side. Diameter is approximately 8,0 mm.

AZYRON 200: White to off-white, slightly speckled, round shaped, biconvex, uncoated tablets with break line on one side and plain on other side. Diameter is approximately 10,5 mm.

The tablets should be free of all physical defects.

The break line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

Alu/OPA/PVC blister strip containing 10 tablets each.

Or

Alu/PVC/PVDC blister strip containing 10 tablets each.

Pack size: 30 tablets.

Holder of certificate of registration

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Not applicable.

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20 August 2025