PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

AMILORETIC 5 mg/ 50 mg tablets
Amiloride hydrochloride 5 mg
Hydrochlorothiazide 50 mg
Contains sugar: Lactose monohydrate 96,00 mg

AMILORETIC H.S. TABLETS 2,5 mg/ 25 mg tablets
Amiloride hydrochloride 2,5 mg
Hydrochlorothiazide 25 mg
Contains sugar: Lactose monohydrate 48,00 mg

Read all of this leaflet carefully before you start taking AMILORETIC or AMILORETIC H.S. TABLETS (referred to collectively as AMILORETIC in the rest of this PIL)

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

1. What AMILORETIC is and what it is used for

AMILORETIC belongs to a group of medicines called Diuretics. AMILORETIC is used for the treatment of:

- High blood pressure (hypertension).
- Extra fluid in the body (oedema) and swelling which may be due to heart failure, liver disease or treatment with corticosteroids.

AMILORETIC can be used alone, or with other medicines used to lower blood pressure.

2. What you need to know before you take AMILORETIC

Do not take AMILORETIC:

- if you are hypersensitive (allergic) to amiloride, hydrochlorothiazide, other sulphonamide derived medicines or to any of the other ingredients of AMILORETIC (listed in section 6).
- if you have severe kidney disease with symptoms such as weakness, shortness of breath, tiredness, swelling, lack of urine and confusion.
- if you have severe liver disease with symptoms such as skin and eyes that appear yellowish, stomach pain, swelling in the legs and ankles, itchy skin, tiredness, nausea or vomiting, loss of appetite or a tendency to bruise easily.
- if you have been told by your doctor that you have high blood levels of potassium with symptoms such as an abnormal heart rhythm, tiredness or weakness (hyperkalaemia) or high blood levels of calcium with symptoms such as increased thirst, increased urination, stomach pain, nausea, bone pain or muscle weakness (hypercalcaemia).
- if you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).
- If you have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Take special care with AMILORETIC:

- if you are elderly, seriously ill, undergoing vigorous diuretic therapy, receiving long-term AMILORETIC therapy, vomiting excessively or receiving IV fluids.
- if you have been taking large doses of AMILORETIC while on a salt restricted diet.
- if you are experiencing a dry mouth, thirst, weakness, tiredness, drowsiness, restlessness, confusion, fits, muscle pains, cramps or weakness, passing a reduced amount of urine, irregular heartbeat or feeling sick and being sick as these may be signs of disturbances of the amount of different salts in your body (electrolyte imbalances such as low or high blood levels of potassium, low blood levels of sodium, chloride, magnesium or slightly high levels of blood calcium). AMILORETIC may need to be stopped immediately and you will need to be carefully monitored by your health care provider.
- if you are experiencing a reduced amount of urine, very dry skin, dizziness, rapid breathing or rapid heart rate (dehydration).

- if you have increased blood urea with symptoms such as tiredness, feeling sick, loss of appetite, a metallic taste in the mouth and mental confusion, AMILORETIC therapy should be discontinued.
- if your doctor has informed you that you have blood disorders, such as a severe decrease in a particular type of white blood cells which makes infections more likely (agranulocytosis) or if you have a reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia).
- if you have heart problems with symptoms such as tightness or pain in the chest, tiredness, light-headedness or an abnormal heartbeat.
- if you have impaired kidney function with symptoms such as weakness, shortness of breath, tiredness, swelling, and confusion.
- if you have liver problems with symptoms such as skin and eyes that appear yellowish (jaundice), stomach pain and swelling, swelling in the legs and ankles, itchy skin, tiredness, nausea or vomiting, loss of appetite and a tendency to bruise easily.
- if you have abnormally high levels of alkalinity in the body with symptoms such as confusion, hand tremor, light-headedness, muscle twitching, feeling sick or being sick (metabolic alkalosis) or if you have high levels of acid in the body with symptoms such as increased rate and depth of breathing, confusion and headaches (metabolic or respiratory acidosis).
- if you have water retention causing swelling (resistant oedema).
- if you have severe pain, redness and tenderness in joints (gout) or if you have been told by your doctor you have high levels of uric acid, cholesterol or triglycerides (a type of fat) in your blood.
- if you are taking medicines used to treat certain heart problems such as digoxin.
- if you are due to take a medical test for diabetes (glucose tolerance test), AMILORETIC should be discontinued for at least three days before.
- if you have diabetes you may need to have some tests before receiving treatment with AMILORETIC. AMILORETIC may cause increased blood sugar and aggravate or unmask diabetes mellitus. Your blood-sugar concentrations should be monitored if you are taking any medicine to treat diabetes.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking AMILORETIC.
- if you are going to have a test to measure the functioning of your parathyroid gland, AMILORETIC should be discontinued before the test.

- if you suffer from allergies or severe asthma with symptoms such as difficulty breathing, chest pain, cough and wheezing.
- if you suffer from a chronic inflammatory disease of connective tissue, affecting the skin and various internal organs (systemic lupus erythematosus), AMILORETIC may exacerbate or activate this condition.
- If you experience a decrease in vision, or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking AMILORETIC. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- If you have been told by your doctor that you have a disease called porphyria (A disease that results from a build-up of the natural chemicals that produce porphyrin in the body – porphyrin is essential for the function of the red blood cells that carries oxygen around the body.)

Children and adolescents

Do not give this medicine to children under 18 years of age as limited data is available.

Other medicines and AMILORETIC

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

Tell your doctor if you are taking any of the following:

- Alcohol: AMILORETIC may interact with alcohol usage and cause severe drops in blood pressure that can lead to fainting.
- Aldesleukin: medicine used to treat cancer of the kidney.
- General anaesthetics (e.g. propofol, isoflurane): medicines used to induce sleep before an operation.
- Analgesics (e.g. paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs) such as selective cyclooxygenase-2 inhibitors (COX-2 inhibitors)): medicines used to treat high temperature, pain, inflammation or arthritis.
- Opioids (e.g. codeine, morphine, pethidine): medicines used for moderate to severe pain.
- Antihypertensive medicines (angiotensin II receptor antagonists (ARBs e.g. losartan), angiotensin converting enzyme inhibitors (ACE inhibitors e.g. enalapril), calcium channel blockers, beta-blockers, alpha-blockers (e.g. prazosin), hydralazine, diazoxide, methyldopa, acetazolamide, loop diuretics): medicines used to treat high blood pressure.

- Anion exchange resins (bile acid sequestrant e.g. cholestyramine, colestipol): medicines used to treat high cholesterol. AMILORETIC and anion exchange resins should be given at least two hours apart.
- Anti-dysrhythmics (e.g. amiodarone, flecainide, disopyramide, quinidine, mexiletine, sotalol): medicines used to treat irregular heartbeats.
- Local anaesthetics (e.g. lidocaine): medicine used to numb tissue in a specific area.
- Antibacterials (e.g. trimethoprim): medicines used to treat bacterial infections.
- Antidepressants (e.g. tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs), reboxetine): medicines used to treat depression.
- Antidiabetics (e.g. insulin or chlorpropamide): medicines used to treat diabetes.
- Antiepileptics (e.g. carbamazepine): medicines used to treat epilepsy.
- Antifungals (e.g. amphotericin, fluconazole): medicines used to treat fungal infections.
- Antigout medicines (e.g. allopurinol): medicines used to prevent/treat gout.
- Antihistamines (e.g. astemizole, terfenadine): medicines used to treat allergies.
- Antimalarials (e.g. halofantrine): medicine used to treat malaria.
- Antipsychotics (e.g. primozide, sertindole, phenothiazines): medicines used to treat mental illness.
- Barbiturates: medicines used to help you sleep or to reduce anxiety.
- Cardiac glycosides (e.g. digoxin): medicines used to treat heart failure.
- Steroids (e.g. cortisone, corticosteroids, corticotrophin, hydrocortisone): medicines used to treat many different conditions such as multiple sclerosis, rheumatoid arthritis, lupus, severe allergic reactions, breathing disorders, and inflammatory conditions of the eyes.
- Dopaminergics (e.g. levodopa, amantadine): medicines used to treat Parkinson’s disease.
- Oral contraceptives (e.g. oestrogens): medicines used for birth control.
- Cytostatics (e.g toremifene): medicine used to treat breast cancer.
- Immunosuppressants (e.g. ciclosporin, tacrolimus): medicines used to suppress the immune system following an organ transplant.
- Antiepileptics (e.g. lithium): medicine used to treat depression or mental illness (see Do not take AMILORETIC).
- Muscle relaxants (e.g. tizanidine, tubocurarine): medicines used to treat the spasms, cramping, and tightness of muscles caused by medical problems or during surgery.
- Nitrates (e.g. isosorbide dinitrate, isosorbide mononitrate, nitroglycerin): medicines used to treat chest pain.

- Potassium conserving medicines (e.g. eplerenone, triamterene, spironolactone): medicines used to treat high blood pressure (see Do not take AMILORETIC).
- Prostaglandins (e.g. alprostadil): medicines used to treat erectile dysfunction.
- Sympathomimetics (e.g. beta-2 sympathomimetics, adrenaline): medicines used to treat heart attacks and low blood pressure.
- Ulcer healing medicines (e.g. carbenoxolone): medicine used to treat ulcers.
- Calcium salts and vitamins.
- Certain laboratory tests such as kidney tests or parathyroid tests.

AMILORETIC with food, drink and alcohol

Avoid excessive alcohol intake or foods which contain a lot of potassium.

Pregnancy, breastfeeding and fertility

You should not take AMILORETIC if you are pregnant or breastfeeding your baby.
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.

Driving and using machines

AMILORETIC has moderate influence on the ability to drive and use machines.
It is not always possible to predict to what extent AMILORETIC 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 AMILORETIC affects them (see section 4).

AMILORETIC contains Lactose monohydrate and sunset FCF Lake (C.I. No. 15895) yellow

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Sunset yellow FCF Lake (C.I. No. 15895) may cause allergic reactions.

3. How to take AMILORETIC

Do not share medicines prescribed for you with any other person.
Always take AMILORETIC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose of AMILORETIC is one tablet daily and the usual dose of AMILORETIC HS is one to two tablets daily.

Your doctor will tell you how long your treatment with AMILORETIC will last. Do not stop treatment early. If you have the impression that the effect of AMILORETIC is too strong or too weak, tell your doctor or pharmacist.

If you take more AMILORETIC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take AMILORETIC

Do not take a double dose to make up for forgotten individual doses.

If you stop taking AMILORETIC

Do not stop taking AMILORETIC without speaking to your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

AMILORETIC can have side effects.

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

If any of the following happens, stop taking AMILORETIC 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,
- fever, flu-like symptoms, a painful red rash (may include purplish spots) that spreads, and blisters follows where the top part of the skin dies and peels off (toxic epidermal necrolysis (TEN)).

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

- skin and lip cancer (non-melanoma skin cancer),
- high or low levels of potassium in the blood which can cause abnormal heart rhythm (hyperkalaemia, hypokalaemia),

- too much sugar in the blood with symptoms such as increased thirst, frequent urination, hunger, fatigue and blurred vision (diabetes mellitus, hyperglycaemia),
- irregular heartbeat (dysrhythmias), palpitations, severe pain in the chest (angina pectoris),
- brain disease with symptoms such as decreasing ability to reason and concentrate, memory loss, personality change, fits and twitching (encephalopathy),
- tightness in the chest, cough, wheezing, and shallow breathing (pneumonitis, pulmonary oedema),
- internal bleeding of the stomach or intestines (gastrointestinal bleeding), a sore or ulcer that develops on the lining of the food pipe, stomach or small intestine with symptoms such as upper stomach pain (peptic ulcer),
- inflammation of the pancreas which causes severe pain in the stomach and back (pancreatitis),
- weakness, shortness of breath, tiredness, swelling, and confusion (renal dysfunction including kidney failure),
- an inflammation of blood vessel walls (vasculitis) with symptoms such as a skin rash, chills, fever, fatigue and weight loss (necrotising angiitis vasculitis),
- blood disorders, determined from blood tests conducted by your health care provider, with symptoms such as tiredness, weakness, increases risk of bleeding, bruising, shortness of breath, fever and susceptibility to infection (anaemia, neutropenia, thrombocytopenia, leucopoenia, agranulocytosis, granulocytopenia).

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

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency:

- appetite changes, lack/loss of appetite (anorexia),
- dehydration, low blood levels of salt which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia),
- high blood levels of calcium with symptoms such as increased thirst, urination, stomach pain, nausea, bone pain or muscle weakness (hypercalcaemia),
- presence of sugar in the urine in abnormally large amounts (glycosuria),
- decreased blood acidity with symptoms such as confusion (can progress to coma), hand tremor, light-headedness, muscle twitching, feeling sick, being sick (hypochloraemic alkalosis),
- increased levels of uric acid in the blood that causes attacks of severe pain, redness and tenderness in joints (gout, hyperuricaemia),

- personality changes, inability to sleep (insomnia), nervousness, mental confusion, feelings of sadness, worthlessness, thoughts of suicide or death (depression), decreased libido, restlessness,
- headache, dizziness, sleepiness (somnolence), fainting (syncope), numbness, pins and needles, tingling pressure of the skin (paraesthesia), state of near unconsciousness (stupor), bad taste, unintentional muscle movement involving to-and-fro movements (oscillations) of one or more parts of the body (tremors),
- a feeling of dizziness or spinning (vertigo), ringing in the ears (tinnitus),
- drop in blood pressure, feeling lightheaded or dizzy after standing up (orthostatic hypotension), reddening of the face and/or neck (flushing),
- hiccups, stuffy nose (nasal congestion), cough,
- nausea (feeling sick), vomiting (being sick), frequent/loose watery stools (diarrhoea), constipation, stomach pain, stomach fullness, flatulence, heartburn; indigestion (dyspepsia), dry mouth, cramping, stomach irritation,
- skin and eyes that appear yellowish (jaundice, abnormal liver function, blood test that shows abnormal liver function),
- blood test indicating kidney problems with symptoms such as weakness, shortness of breath, tiredness, swelling, lack of urine and confusion (rise in blood-urea-nitrogen concentrations),
- loss of hair; baldness (alopecia), increased sweating (diaphoresis), increased sensitivity of skin to sun (photosensitivity),
- leg ache, muscle cramps, joint pain, back pain, neck/shoulder ache, pain in extremities,
- excessive urination at night (nocturia), painful/difficult urination (dysuria), lack of voluntary control of urination (incontinence), passage of a large amount of urine (polyuria), urinary frequency, bladder spasm, the presence of glucose in the urine in abnormally large amounts (glycosuria),
- loss of male sexual ability (impotence),
- tiredness (fatigue), vague feeling of bodily discomfort; a general feeling of being unwell (malaise), weakness, thirst, fever,
- decrease in chloride in the blood, low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (electrolyte imbalance),
- visual changes, blurred vision, yellow vision (xanthopsia), the appearance of rainbow-colored circles around bright lights, severe eye and head pain (increased intra-ocular pressure),

- build-up of a medicine called digoxin, with symptoms such as feeling sick, being sick, stomach pain, headache, dizziness, confusion, and vision disturbance (digoxin toxicity),
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)

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 Reactions Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8.

Or to Adcock Ingram Limited:

E-mail: Adcock.aereports@adcock.com

Tel: 011 635 0134

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

5. How to store AMILORETIC

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Keep in the original packaging until required for use.

Do not store in a bathroom.

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).

6. Contents of the pack and other information

What AMILORETIC contains

AMILORETIC: The active substances are amiloride hydrochloride 5 mg and hydrochlorothiazide 50 mg.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, purified talc, sodium starch glycollate, Sunset Yellow FCF Lake (C.I. No. 15895).
Contains sugar: Lactose monohydrate 96,00 mg

AMILORETIC H.S: The active substances are amiloride hydrochloride 2,5 mg and hydrochlorothiazide 25 mg.

The other ingredients are dye Lennon Lake Yellow (C.I No. 15985), lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, purified talc, sodium starch glycollate.
Contains sugar: Lactose monohydrate 48,00 mg

What AMILORETIC looks like and contents of the pack
AMILORETIC is a round, flat, pale peach, bevelled edged tablet, bisected on one side and engraved with a mortar and pestle on the other side.

30 or 100 tablets are packed in clear polyvinylchloride blister strips with an aluminium backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

1 000 tablets are packed in a white polypropylene container with a white linear low density polyethylene cap together with a white foam insert and a leaflet.
The tablets are also packed in a metallised lay flat bag sealed with a zip-lock for lay-flat.

AMILORETIC H.S. is a round, flat, pale peach, bisected tablet with bevelled edges imprinted with a mortar and pestle.

30 or 100 tablets are packed in clear polyvinylchloride blister strips with an aluminium backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

1 000 tablets are packed in a white polypropylene container with a white linear low density polyethylene cap together with a white foam insert and a leaflet.

The tablets are also packed in a metallised lay flat bag sealed with a zip-lock for lay-flat.
Not all packs and pack size are necessarily marketed.

PATIENT INFORMATION LEAFLET

Holder of Certificate of Registration

Adcock Ingram Limited

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Erand Gardens,

Midrand, 1685,

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

19 June 2023

Registration number

AMILORETIC: L/18.1/396

AMILORETIC H.S. TABLETS: U/18.1/40

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Namibia		
NS2	Amiloretic H.S. Tablets	90/18.1/00786
NS2	Amiloretic	90/18.1/00787
Botswana		
S2	Amiloretic H.S. Tablets	B9322045
S2	Amiloretic	B9322040