SCHEDULING STATUS

S3

ADCO RETIC, 5 mg/50 mg, tablets
Amiloride and Hydrochlorothiazide
Contains sugar (lactose monohydrate): 7,62 mg per tablet

Read all of this leaflet carefully before you start taking ADCO RETIC

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

1. What ADCO RETIC is and what it is used for

ADCO RETIC belongs to the group of medicines known as diuretics (water tablets). They work by increasing the amount of urine that passes from your body. This lowers your blood pressure or removes excess water from your body.

ADCO RETIC is used in the treatment of:

- heart failure
- fluid retention caused by a liver disease called ‘cirrhosis’
- high blood pressure.

2. What you need to know before you take ADCO RETIC

Do not take ADCO RETIC

- if you are hypersensitive (allergic) to amiloride, hydrochlorothiazide or to any of the other ingredients of ADCO RETIC (listed in section 6).
- if you are also taking water tablets (diuretics) such as spironolactone or triamterene.
- if you have severe liver failure.
- if you have a disorder known as Addison’s disease (a disorder in which the adrenal glands don’t produce enough hormones).

- if you are also taking a medicine known as lithium (a medicine used to treat depression or mood disorders).
- if you have been told by your doctor you have high levels of urea, creatinine, calcium or potassium in your blood.
- if you are taking a medicine containing potassium or potassium supplement or you eat potassium-rich foods.
- if you suffer from kidney disease (which include advanced kidney disease), a kidney disorder known as anuria (your kidneys fail to produce urine) or acute kidney failure.
- if you have previously had or currently have cancer of the skin and/or lip.
- if you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with ADCO RETIC:

- 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 (nonmelanoma skin cancer). Protect your skin from sun exposure and UV rays while taking ADCO RETIC.
- if you have any heart conditions speak to your doctor before taking ADCO RETIC.
- if you have liver conditions as ADCO RETIC may cause complications with symptoms such as tremor, confusion or coma. ADCO RETIC may also cause the yellowing of the skin and eyes (jaundice).
- if you are diabetic you may need to have some tests to test your kidney function before receiving treatment with ADCO RETIC. ADCO RETIC 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. You should stop taking ADCO RETIC 3 days before going for a glucose-tolerance test.
- if you are likely to develop acidosis (build-up of acid in your body) for instance if you have a condition that affects your heart and lungs (cardiopulmonary disease) and have decompensated diabetes.
- long-term use of ADCO RETIC may cause changes to the parathyroid gland with increases in blood calcium levels and decrease in blood phosphorous levels.
- if you been told by your doctor that you have disorders of the adrenal gland.
- if you are seriously ill, vomiting excessively or receiving IV fluids.
- if you notice that your urine output is less than normal for you.
- if you suffer from asthma.
- if you have an autoimmune disease called systemic lupus erythematosus.
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide (as in ADCO RETIC) intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking ADCO RETIC, seek medical attention immediately.
- 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 a week of taking ADCO RETIC. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.
- if you suffer from high cholesterol; your cholesterol and triglyceride levels may increase.

Children and adolescents
ADCO RETIC should not be given to children under 18 years of age as safety has not been established.

Other medicines and ADCO RETIC
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:
- lithium - used for depression
- non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, celecoxib - used to reduce high temperature (fever), pain or for arthritis
- angiotensin converting enzyme inhibitors (ACE inhibitors) such as enalapril used to treat high blood pressure or heart problems
- angiotensin II receptor antagonists such as losartan - used to treat high blood pressure or diabetics with kidney damage
- other medicines for high blood pressure
- medicines for diabetes such as insulin or chlorpropamide
- barbiturates - used to help you sleep or to reduce anxiety
- painkillers such as codeine, dihydrocodeine, dextropropoxyphene, diamorphine, morphine, pentazocine and pethidine
- cholestyramine and colestipol - used to treat high cholesterol (hyperlipidaemia)
- steroids - used to treat lots of different conditions such as rheumatism, arthritis, allergic conditions, skin problems, asthma or a type of blood disorder
- norepinephrine (also known as noradrenaline) - used to treat life-threatening low blood pressure
- tacrolimus - used after a liver or kidney transplant to prevent rejection
- ciclosporin - used for rheumatoid arthritis or to prevent rejection after a transplant
- non-depolarising muscle relaxants such as tubocurarine
- trilostane - used to treat breast cancer or overactive adrenal glands (such as in Conn’s syndrome, Cushing’s syndrome)
- digoxin - used for heart failure and abnormal heart beat.

ADCO RETIC with food, drink and alcohol
Your doctor may have asked you to change your diet slightly and not to eat certain foods which contain a lot of potassium. These foods include milk, bananas, raisins and prunes. Your doctor will tell you what food you should not eat. If you are unsure about what food you should avoid, ask your doctor before taking ADCO RETIC tablets.

Your doctor may have told you that you should keep alcohol intake to a minimum while you are taking ADCO RETIC. Alcohol may increase the effects of ADCO RETIC so that you feel dizzy or light-headed when you stand up quickly.

Pregnancy, breastfeeding and fertility
You should not take ADCO RETIC 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 ADCO RETIC.

Driving and using machines
ADCO RETIC may make you feel weak, tired or dizzy. You should not drive or operate machinery if you feel this way.

It is not always possible to predict to what extent ADCO RETIC may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ADCO RETIC affects you.

ADCO RETIC contains lactose monohydrate and sunset yellow FCF lake
ADCO RETIC contains lactose monohydrate and this should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ADCO RETIC.

ADCO RETIC contains sunset yellow FCF lake which may cause allergic reactions.

3. How to take ADCO RETIC
Do not share medicines prescribed for you with any other person.

Always take ADCO RETIC exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of ADCO RETIC is one tablet daily.
Your doctor may change your dose depending on your condition.

Your doctor will tell you how long your treatment with ADCO RETIC will last. If you have the impression that the effect of ADCO RETIC is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO RETIC than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ADCO RETIC
Do not take a double dose to make up for forgotten individual doses.

If you stop taking ADCO RETIC
Do not stop taking ADCO RETIC 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
ADCO RETIC can have side effects.

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

If any of the following happens, stop taking ADCO RETIC 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,
- blistering or peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO RETIC. 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),
- chest pain, changes in the way your heart beats,
- 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),
- difficulty in breathing, shortness of breath, rapid breathing, fluid in the lungs,
- acute respiratory distress syndrome (ARDS) with symptoms such as severe shortness of breath, fever, low blood pressure, muscle weakness, and mental confusion,
- kidney problems including painful or difficulty in urination, excessive urination at night, unintentional urination, excessive urination, bladder spasms, blood in the urine, foamy urine,
- a brain disease with symptoms such as deceasing ability to reason and concentrate, memory loss, personality change, fits and twitching (encephalopathy),
- changes in vision, pressure in the eye(s), blurred vision, yellow vision, fluid build-up in the eye(s),
- an inflammation of blood vessel walls with symptoms such as a skin rash, chills, fever, fatigue and weight loss,

- 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,
- abnormal liver function with symptoms such as yellowing of the skin and eyes (jaundice), abdominal pain and swelling, swellings in the legs and ankles, dark urine and pale stools.

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 unknown frequency:

- infection of the salivary glands with symptoms such as enlargement, tenderness, and redness of one or more salivary glands,
- imbalances of certain minerals in your body (such as sodium, calcium, potassium), dehydration, increased levels of sugar in the blood and urine, increased uric acid levels in the blood, gout,
- difficulty in falling asleep, nervousness, depression, sleepiness, confusion, headache, restlessness,
- state of near unconsciousness (stupor), dizziness, weakness, feeling like you are spinning, pins and needles in your hands and feet, feeling shaky,
- blocked nose, cough
- anorexia (an eating disorder), nausea, vomiting, diarrhoea, constipation, appetite changes, stomach fullness, flatulence, hiccups, bad taste, stomach pain, thirst, dry mouth, indigestion, cramping, stomach irritation,
- reddening of the face or other areas of the skin (flushing), excessive sweating, loss of hair, sensitivity to light,
- leg pain, joint pain, back pain, muscle cramps, neck/shoulder pain, pain in the arms and legs,
- loss of male sexual ability (impotence), lower sex drive
- a general feeling of being unwell, fainting, fever, weakness, tiredness,
- 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,
- ringing in the ears,
- feeling light headed when you stand quickly,
- increase in blood cholesterol and triglyceride (type of cholesterol) levels.

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 “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 ADCO RETIC.

5. How to store ADCO RETIC

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a cool, dry place.
- Store in the original packaging.
- Protect from light and moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/bottle.
- 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 ADCO RETIC contains

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

The other ingredients are: colloidal anhydrous silica, lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, pregelatinized starch, stearic acid, sunset yellow FCF lake (CI 15985).

What ADCO RETIC looks like and contents of the pack

Peach coloured, diamond-shaped tablet with 'ACDO' embossed on one side and a break line on either side.

ADCO RETIC tablets are supplied in:

- white polypropylene securitainer bottles of 28, 30 and 100 fitted with white LDPE closures.
- a white polypropylene securitainer bottle of 1000 tablets fitted with a white MDPE closures.
- white cylindrical screw type HDPE containers of 100 and 1000 tablets with HDPE screw caps.
- soda glass type III amber glass vials of 30 tablets fitted with a white low density polyethylene snap-cap.
- amber glass vials of 100 and 1000 tablets fitted with a white polypropylene screw cap.

Not all pack types and pack sizes will be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road,
Erand Gardens,

Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

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