1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

RIDAQ-25 tablets

Hydrochlorothiazide 25 mg

Contains sugar: Lactose monohydrate 48,59 mg

RIDAQ-50 tablets

Hydrochlorothiazide 50 mg

Contains sugar: Lactose monohydrate 100,43 mg

Read all of this leaflet carefully before you start taking RIDAQ

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- RIDAQ 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 RIDAQ is and what it is used for

2. What you need to know before you take RIDAQ
3. How to take RIDAQ
4. Possible side effects
5. How to store RIDAQ
6. Contents of the pack and other information

1. What RIDAQ is and what it is used for

RIDAQ belongs to a group of medicines called diuretics. Diuretics help the body to get rid of extra fluid and are used in patients with high blood pressure. Because they get rid of fluid, diuretics are sometimes called ‘water tablets’.

- RIDAQ can be used to treat swelling due to retained fluid (oedema) due to salt and water retention, or due to serious heart, liver or kidney problems.
- RIDAQ also appears to have the opposite effect of retaining fluids in the body (antidiuretic effect) in patients with diabetes insipidus (a condition which causes abnormally large amounts of urine to be passed and increased thirst) and may be of value in managing this disease.
- RIDAQ can be used to treat high blood pressure that has an unknown cause (essential hypertension), preferably in combination with reduced doses of other specific medicines used to treat high blood pressure.

2. What you need to know before you take RIDAQ

Do not take RIDAQ:

- if you are hypersensitive (allergic) to hydrochlorothiazide, other medicines containing sulphonamides or any of the other ingredients of RIDAQ (listed in section

6).

- if you have severe kidney problems.
- if you have severe liver problems.
- if you have Addison's disease (when your adrenal glands, located just above your kidneys, produce too little cortisol and, often, too little aldosterone).
- if you have too much calcium in your blood (hypercalcaemia).
- if you have previously had or currently have cancer of the skin and/or lip.
- if you are in the second or third trimester of pregnancy.
- if you are breastfeeding your baby.

Warnings and precautions

Take special care with RIDAQ:

- if you have high blood sugar. RIDAQ may cause increased blood sugar and aggravate or unmask diabetes mellitus (a disease that results in too much sugar in the blood with symptoms such as severe thirst, frequent urination, tiredness, weight loss and blurred vision). Your blood sugar concentrations should be monitored if you are taking any medicine to treat diabetes.
- if you are experiencing a dry mouth, thirst, weakness, tiredness, drowsiness, restlessness, confusion, fits, muscle pains, cramps or weakness, low blood pressure, passing a reduced amount of urine, a fast, irregular heartbeat, breathing problems or nausea and vomiting as these may be signs of disturbances of the amount of different salts in your body (electrolyte imbalances). You should be carefully observed for signs of fluid and electrolyte imbalance, especially if you are vomiting or receiving parenteral fluid (intravenous) therapy. If you are an elderly patient you may be more prone to electrolyte imbalances.
- if you suffer from a condition where you retain water (especially in hot weather),

RIDAQ may cause a decrease in blood sodium.

- if you suffer from gout characterised by severe pain, redness and tenderness in joints, RIDAQ may cause an attack of this condition.
- if you have low magnesium levels in your blood as RIDAQ may increase the excretion of magnesium through the urine.
- if you have high calcium levels in your blood as RIDAQ may decrease excretion of calcium through the urine, which may increase calcium in the body.
- if you are going to have a test to measure the functioning of a gland situated in your neck behind your thyroid gland, called the parathyroid gland, RIDAQ should be discontinued before the test.
- if you suffer from high cholesterol and high triglyceride (a type of fat in your blood) levels, RIDAQ may increase these levels.
- if you suffer from a chronic inflammatory disease of connective tissue, affecting the skin and various internal organs known as systemic lupus erythematosus. RIDAQ may exacerbate or activate this condition.
- if you are taking medicines for high blood pressure.
- if you have a history of allergy or asthma. RIDAQ may cause allergic reactions.
- if you are taking a lithium to treat a mental disorder.
- if you experience decreased vision and eye pain while taking RIDAQ you should stop taking RIDAQ and contact your doctor immediately as these symptoms may be caused by increased pressure in the eye (glaucoma). Your risk for developing this eye disorder is increased if you have a history of sulphonamide medicine or penicillin antibiotic allergy.
- if you had a surgery to stop excessive sweating called a sympathectomy.
- if you are going to have an anti-doping test, RIDAQ could show a false positive result.

- if you have had skin cancer or if you develop an unexpected skin lesion during treatment with RIDAQ. Treatment with RIDAQ, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect you skin from sun exposure and UV rays while taking RIDAQ.
- 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 RIDAQ. 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.

Other medicines and RIDAQ

Always tell your healthcare 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 medicines:

- Amphotericin B (injection): medicine used to treat fungal infections.
- Carbenoxolone: medicine used to treat stomach ulcers.
- Stimulant laxatives: medicines used to treat constipation.
- Digitalis glycosides (e.g. digoxin): medicines used to increase heart contractions.
- Antidiabetic medicines (insulin and oral antidiabetics): medicine used to treat high sugar in the blood caused by diabetes mellitus.
- Calcium salts: medicines used to treat calcium deficiency.
- Colestyramine resin and colestipol: medicines used to treat high cholesterol.
- Tubocurarine: Medicine used as a muscle relaxant.
- Antihypertensive medicines: Medicines used to treat high blood pressure.
- Barbiturates: Medicines used to calm you or induce sleep (sedatives).
- Opioids: Medicines used to treat pain.

- Corticosteroids: Medicines used as anti-inflammatory medicine and to prevent an immune response.
- ACTH or corticotropin: Medicine used to test if you have problems with your adrenal gland e.g. when you have Addison's disease or to treat multiple sclerosis in adults and spasms in children.
- Beta$_2$-agonists (e.g. salbutamol): Medicines used to treat asthma.
- Noradrenaline and adrenalin: Medicine used to treat low blood pressure in specific situations and serious allergic reactions.
- Lithium: Medicine used to treat mental disorders.
- Non-steroidal anti-inflammatory drugs (NSAIDs): Medicines used to treat pain, fever, blood clots (e.g. aspirin) and inflammation.
- Anti-dysrhythmics: Medicines used to treat heart rhythm disorders.
- Antipsychotics: Medicines used to treat mental disorders.
- Carbamazepine: Medicine used to treat recurrent fits (epilepsy).
- Alcohol: RIDAQ may interact with alcohol usage.
- Laboratory tests for parathyroid function: Blood or urinary tests to test the function of the parathyroid gland.
- Laboratory tests for pancreas function: Blood or urinary tests to test the function of the pancreas.

RIDAQ with food, drink and alcohol

RIDAQ should be taken with or after meals to minimise stomach upset.

RIDAQ may interact with alcohol usage.

Pregnancy, breastfeeding and fertility

You should not take RIDAQ 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 healthcare provider for advice before taking this medicine.

Driving and using machines

RIDAQ has moderate influence on the ability to drive and use machines.

It is not always possible to predict to what extent RIDAQ 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 RIDAQ affects you (see section 4).

RIDAQ contains lactose monohydrate

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

3. How to take RIDAQ

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

Always take RIDAQ exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

Check with your doctor, pharmacist or nurse if you are unsure.

Treatment should be started at the lowest dose needed to achieve the desired effect.

Treatment should be suited to the individual patient.

The usual dose is:

An initial dose of up to 200 mg may be necessary in some patients, but larger doses have no additional effect.

Adults - as an adjunct in the treatment of hypertension:

25 mg to 100 mg daily in conjunction with a reduced dose of the hypotensive medicine.

Paediatric population

2,5 mg per kg body mass daily in two divided doses.

The dosage should not be higher than necessary to achieve the desired effect.

Taking RIDAQ for a long time may cause lower levels of potassium in your blood. You may need to take potassium supplements.

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

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

If you take more RIDAQ 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 RIDAQ

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

RIDAQ can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- allergic condition which causes joint pain, skin rashes and fever known as cutaneous lupus erythematosus-like reactions,
- eruption of lesions on the skin known as erythema multiforme,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- 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 known as toxic epidermal necrolysis (TEN).

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

- abnormal, irregular heart rhythm, muscle weakness and twitching that could be caused by low blood levels of potassium,
- seizures (fits),
- yellow pigmentation of skin and eyes caused by liver or blood problems (jaundice),

- inflammation of the pancreas which causes severe pain in the stomach and back (pancreatitis),
- serious decrease of blood cells which can cause weakness, bruising or make infections more likely,
- excessive fluid accumulation in lungs,
- kidney problems, including kidney failure and swelling and inflammation in between the kidney tubules with symptoms such as fever, blood in urine, exhaustion and confusion,
- sudden blurry vision when looking at distant objects and difficulty seeing objects (acute myopia) or raised pressure in the eye with symptoms such as severe eye pain, blurred vision, tears, nausea, vomiting and headache (secondary acute angle-closure glaucoma),
- skin and lip cancer (skin cancer may be a sore that does not heal or comes back after healing, pale, white or yellow flat areas that look like scars, raised and scaly red patches, small, smooth and shiny lumps that are pearly white, pink or red, pink growths with raised edges and indents in the centre or growths that has small blood vessels on the surface). (Non-melanoma skin cancer).

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:

- electrolyte imbalances, decrease in chloride in the blood, low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (may occur in patients with severe heart problems who have swelling due to retained fluid, especially with large doses of RIDAQ in conjunction with restricted salt in the diet),
- stomach and intestine complaints and irritation, dry mouth, nausea, vomiting,

constipation, diarrhoea, cramping, loss of appetite,

- a sore or ulcer that develops on the lining of the food pipe (oesophagus), stomach or small intestine with symptoms such as pain in the upper part of the stomach,
- thirst, weakness,
- mental and physical sluggishness, drowsiness,
- restlessness,
- muscle pain, spasms and cramps,
- reduced urine production,
- metabolic (physical and chemical processes necessary to maintain life) disturbances especially at high doses,
- high blood sugar and the presence of glucose in the urine (glycosuria) in diabetic and other susceptible patients,
- increased levels of uric acid in the blood that causes attacks of gout in some patients,
- the urinary excretion of calcium is reduced,
- deficiency of magnesium in the blood,
- harmful changes in the fat in your blood called cholesterol and triglycerides,
- headache, dizziness,
- increased sensitivity of skin to sun,
- numbness, tingling, pins and needles, cold, warmth, tingling pressure of the skin (paraesthesia),
- a fall in blood pressure on standing up which causes dizziness or fainting (postural hypotension),
- yellow vision,
- infection of salivary glands,
- sense of spinning (vertigo),

- loss of male sexual ability (impotence),
- fever,
- light-headedness,
- feelings of sadness or worthlessness (depression), sleep disturbances,
- hair loss or baldness (alopecia),
- an inflammation of blood vessel walls, often with symptoms such as skin rash and lesions on the skin,
- small purple coloured spots caused by bleeding into the skin (purpura),
- 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: https://www.sahpra.org.za/Publications/Index/8.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ /+27(0)11 239-6200

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

5. How to store RIDAQ

Store all medicines out of reach of children.

Store at or below 25 °C.

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 RIDAQ contains

RIDAQ-25

The active substance is 25 mg of hydrochlorothiazide.

The other ingredients are dye P/B orange, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate, purified talc, sodium starch glycollate and starch maize.

Contains sugar: Lactose monohydrate 48,59 mg

RIDAQ-50

The active substance is 50 mg of hydrochlorothiazide.

The other ingredients are dye lennon lake yellow (C.I. 15985), lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate, purified talc, sodium starch glycollate and starch maize.

Contains sugar: Lactose monohydrate 100,43 mg

What RIDAQ looks like and contents of the pack

RIDAQ-25:

RIDAQ-25 is a round flat pale peach tablet with bevelled edges and bisected on one side, with a diameter of 6,5 mm.

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

14 or 28 tablets are packed in a printed, metallised, low-density polyethylene lay-flat bag and sealed with a lay-flat zip.

500 tablets are packed in a white polypropylene container, together with a white rayon and white foam insert, and sealed with a white low-density polyethylene cap.

RIDAQ-50:
RIDAQ-50 is a round flat pale peach tablet with bevelled edges and bisected on one side, with a diameter of 8,0 mm.

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

500 tablets are packed in a white polypropylene container, together with a white foam insert, and sealed with a white low-density polyethylene cap.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27(0)11 239-6200

This leaflet was last revised in

04 March 2023

Registration Numbers

RIDAQ-25: M/18.1/35

RIDAQ-50: M/18.1/36

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

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

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia:	NS2
25 mg:	90/18.1/001183

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