1.3.2. PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

RIDAQ-12,5 tablet

Hydrochlorothiazide

Contains sugar: Lactose monohydrate 62,6 mg

Read all of this leaflet carefully before you start taking RIDAQ-12,5

- 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-12,5 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-12,5 is and what it is used for
2. What you need to know before you take RIDAQ-12,5
3. How to take RIDAQ-12,5
4. Possible side effects
5. How to store RIDAQ-12,5
6. Contents of the pack and other information

1. What RIDAQ-12,5 is and what it is used for

RIDAQ-12,5 is a water tablet used for mild to moderate high blood pressure alone or in combination with other anti-high blood pressure medicines.

2. What you need to know before you take RIDAQ-12,5

Do not take RIDAQ-12,5:

- if you are hypersensitive (allergic) to hydrochlorothiazide, other medicines containing sulphonamides or any of the other ingredients of RIDAQ-12,5 (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 an increased amount of calcium in your blood.
- 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.

Warnings and precautions

Take special care with RIDAQ-12,5:

- if you have high blood sugar. RIDAQ-12,5 may cause increased blood sugar and aggravate or unmask diabetes mellitus (a disease that results in too much sugar in the blood). 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 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 are taking corticosteroids (used to reduce an immune response in your body), adrenocorticotropic hormone (ACTH) or corticotropin (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) or if you have been taking RIDAQ-12,5 for a long time, as this may cause a condition with low potassium levels in your blood (hypokalaemia). If you do not have enough potassium in your body, you may experience problems with the way your heart beats. This may be made worse if you are taking a medicine called digoxin that it used to treat heart conditions.
- if you experience symptoms such as extreme fatigue, muscle weakness, breathing problems and excessive thirst you may have chloride deficiency.
- if you suffer from a condition where you retain water (especially in hot weather), RIDAQ-12,5 may cause a decrease in blood sodium.
- if you suffer from gout characterised by severe pain, redness and tenderness in joints, RIDAQ-12,5 may cause an attack of this condition.
- if you have low magnesium levels in your blood as RIDAQ-12,5 may increase the excretion of magnesium through the urine.
- if you have high calcium levels in your blood as RIDAQ-12,5 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 your parathyroid gland, RIDAQ-12,5 should be discontinued before the test.

- if you suffer from high cholesterol and high triglyceride (a type of fat) levels, RIDAQ-12,5 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 in susceptible patients, RIDAQ-12,5 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-12,5 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-12,5 you should stop taking RIDAQ-12,5 and contact your doctor immediately.
- 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-12,5 could show a false positive result.
- if you have had skin cancer or if you develop an unexpected skin lesion during treatment with RIDAQ-12,5. Treatment with RIDAQ-12,5, 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-12,5.
- 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 when taking RIDAQ-12,5. 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.

Children

The safety and effectiveness of RIDAQ-12,5 have not been established in children.

Other medicines and RIDAQ-12,5

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

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

- Amphotericin B (parenteral): 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.
- Alcohol: RIDAQ-12,5 may interact with alcohol usage.
- 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 (salbutamol): Medicines used to treat asthma.

- Noradrenaline: Medicine used to treat low blood pressure in specific situations.
- Lithium: Medicine used to treat mental disorders.
- Non-steroidal anti-inflammatory drugs (NSAIDs): Medicines used to treat pain, fever, blood clots and inflammation.
- Anti-dysrhythmics: Medicines used to treat heart rhythm disorders.
- Antipsychotics: Medicines used to treat mental disorders.
- 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-12,5 with food and drink

RIDAQ-12,5 should be taken with or after meals to minimise stomach upset. Alcohol should be avoided.

Pregnancy, breastfeeding and fertility

You should not take RIDAQ-12,5 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-12,5 has moderate influence on the ability to drive and use machines.

Since adverse reactions such as tiredness, dizziness and blurred vision have been reported in patients receiving RIDAQ-12,5, you should not drive, use machinery or

perform any tasks that require concentration, until you are certain that RIDAQ-12,5 does not adversely affect your ability to do so (see section 4).

It is not always possible to predict to what extent RIDAQ-12,5 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 RIDAQ-12,5 affects them (see section 4).

RIDAQ-12,5 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RIDAQ-12,5.

How to take RIDAQ-12,5

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

Always take RIDAQ-12,5 exactly as your doctor has instructed you.

The usual dose is for high blood pressure in adults is:

One tablet daily.

The usual dose in adults as an additional medicine in the treatment of high blood pressure is:

One to two tablets daily in conjunction with an anti-hypertensive medicine.

The dosage should not be higher than needed to reach the desired effect. Long-term treatment may cause a decrease in electrolytes known as potassium ions. You may need to take potassium supplements.

If a single dose is indicated, RIDAQ-12,5 should preferably be taken in the morning in order to minimise the effect of increased frequency of urination during sleep.

If you have the impression that the effect of RIDAQ-12,5 is too strong or too weak, tell your doctor or pharmacist.

If you take more RIDAQ-12,5 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-12,5

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

4. POSSIBLE SIDE EFFECTS

RIDAQ-12,5 can have side effects.

Not all side effects reported for RIDAQ-12,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RIDAQ-12,5, please consult your healthcare provider for advice.

If any of the following happens, stop taking RIDAQ-12,5 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,
- 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-12,5. 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),
- a sore or ulcer that develops on the lining of the food pipe (oesophagus), stomach or small intestine with symptoms such as upper abdominal pain,
- yellow pigmentation of skin and eyes caused by liver or blood problems (jaundice),
- inflammation of the pancreas which causes severe pain in the abdomen and back,
- serious decrease of blood cells which can cause weakness, bruising or make infections more likely,
- excessive fluid accumulation in lungs,
- kidney failure, swelling and inflammation in between the kidney tubules,
- too few white blood cells known as neutropenia,
- inflammation of the lungs which causes breathlessness, cough and raised temperature (pneumonitis), difficulty breathing,
- skin 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).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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 failure who have swelling due to retained fluid, especially with large doses of RIDAQ-12,5 in conjunction with restricted salt in the diet),
- stomach and intestine complaints, dry mouth,
- thirst, weakness,
- mental and physical sluggishness, drowsiness,
- restlessness,
- muscle pain and cramps,
- reduced urine production.

Less frequent side effects:

- 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 plasma lipids (fats),
- loss of appetite, stomach irritation, nausea, vomiting, constipation, diarrhoea,
- 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,
- inflammation of a salivary gland,
- sense of spinning (vertigo),
- loss of male sexual ability.

Side effects with unknown frequency:

- fever,
- light-headedness,
- feelings of sadness or worthlessness (depression), sleep disturbances,
- muscle spasm,
- kidney problems,
- temporary blurred vision,
- hair loss,
- increases in blood levels of fat in your blood called cholesterol and triglycerides,
- an inflammation of blood vessel walls (inflammation of blood vessels, often with skin rash, inflamed blood vessels in the skin),
- small, purple-coloured spots caused by bleeding into the skin,

- 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

By reporting side effects, you can help provide more information on the safety of RIDAQ-12,5

5. How to store RIDAQ-12,5

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in a well-closed container.

Protect from light and moisture.

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-12,5 contains

The active substance is 12,5 mg of hydrochlorothiazide.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose PH 101, polysorbate 80, purified talc, sodium starch glycolate (Type A).

Contains sugar: Lactose monohydrate 62,6 mg.

What RIDAQ-12,5 looks like and contents of the pack

A round, white tablet, flat with bevelled edges, bisected on one side.

RIDAQ-12,5 is available in one of the following packaging:

- Metallised layflat bags

Silver metallised layflat “bank bag” sealed with a perforated tear line (tender purposes only). Filled patient ready packs are stored in an outer clear, low density polyethylene bag (60 µm) along with leaflets for distribution. Each metallised layflat bag will contain 28 tablets.

- HDPE bottle

The tablets are packed in a white 60 ml high density polyethylene (HDPE) bottle, together with a rayon insert and sealed with a sealing foil and a white 33 mm polypropylene cap. A leaflet is placed on top of the rayon insert prior to capping and a label is placed on the bottle. Each bottle will contain 30 tablets.

- Securitainers

The tablets are packed in a white, polypropylene securitainer (49 mm x 100 mm), together with a white foam insert and sealed with a white, low-density polyethylene (LDPE), closure (49 mm) with a tamper evident seal. A leaflet is placed on top of the

foam prior to capping and a label is placed on the securitainer. Each securitainer will contain 500 tablets.

- Blisters

The tablets are packed in a PVC or PVC/ PVDC blister of 28 and 30 tablets. The blisters are packed in a cardboard carton.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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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

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