

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

RENICARD 50 mg film-coated tablets

Losartan

Contains sugar: 25,5 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking RENICARD 50

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RENICARD 50 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 RENICARD 50 is and what it is used for
2. What you need to know before you take RENICARD 50
3. How to take RENICARD 50
4. Possible side effects
5. How to store RENICARD 50
6. Contents of the pack and other information

- 1. What RENICARD 50 is and what it is used for**

RENICARD 50 is an angiotensin II receptor antagonist which lowers blood pressure.

RENICARD 50 has been prescribed to you by your doctor or health care provider because you have a condition known as hypertension or high blood pressure.

Your doctor may also have prescribed RENICARD 50 because you have type 2 diabetes with protein in the urine. In type 2 diabetic patients with protein in the urine, RENICARD 50 has been shown to slow the worsening of kidney disease.

2. What you need to know before you take RENICARD 50

Do not take RENICARD 50:

- If you are allergic (hypersensitive) to losartan potassium or any of the other ingredients of RENICARD 50 (listed in section 6).
- If you have a history of swelling due to an unknown cause or to medicines of the same type as RENICARD 50.
- If you have a heart disease or disorder.
- If you have severe kidney disease.
- If you have moderate to severe kidney disease and are prescribed a course of an antibiotic of the fluoroquinolone class, for an infection. Contact your doctor to re-evaluate your treatment if you are treated with RENICARD 50 together with a fluoroquinolone antibiotic.
- If your liver function is impaired.
- If you have narrowing of the blood vessels to both kidneys, or to a single kidney.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart), or you have a heart defect causing obstruction of the blood flow through your heart.
- If you are using diuretics ("water tablets") such as spironolactone, triamterene or amiloride which can lead to an increased amount of potassium in your blood.
- If you suffer from a disorder called porphyria.

- If you need to take thiazide diuretics with your RENICARD 50 and you suffer from a condition known as Addison's disease.
- If you are receiving lithium therapy.
- If you are pregnant or breastfeeding.
- If you are taking a medicine called aliskiren to reduce blood pressure.
- If you are a child.

Warnings and precautions

Tell your doctor:

- About any medical problems you have or have had in the past and any allergies you may have.
- If you are dehydrated, you have recently suffered from excessive vomiting or diarrhoea, or you are on a salt-restricted diet.
- If you have liver or kidney disease.
- If you have diabetes (high blood sugar), your doctor may need to adjust the dose of your medicine.
- If you are taking high-dose diuretics.
- If you are an elderly patient or if you have problems with your kidneys, the potassium levels in your blood should be carefully monitored.
- If you previously had problems with your liver your doctor or health care provider could consider to half your dose. If you currently suffer from liver problems, you should not take RENICARD 50. Also see section 2 "Do not take RENICARD 50".
- If you suffer from heart failure with or without kidney disease or concomitant severe life-threatening cardiac dysrhythmias. Special caution is necessary when you are treated with a beta-blocker concomitantly.
- If you have problems with your heart valves or heart muscle.

- If you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain).
- If you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- If you are taking any other medicines used to treat high blood pressure, your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
- If you are taking other medicines that may increase serum potassium.
- If you are taking a course of a fluoroquinolone antibiotics with RENICARD 50, especially if you have moderate to severe kidney disease, or you are elderly (also see section 2 “Do not take RENICARD 50”).

Children and adolescents

RENICARD 50 should not be given to children (see section 2 “Do not take RENICARD 50”).

Other medicines and RENICARD 50

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

Do not take RENICARD 50 together with:

- Fluoroquinolone antibiotics (used to treat infections).
- Diuretics (used to treat hypertension) such as spironolactone, triamterene, amiloride.
- Lithium (used to treat mood disorders).
- Aliskiren-containing products (used to treat hypertension).

Tell your doctor if you are taking:

- Potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines (e.g. amiloride, triamterene, spironolactone) or other medicines that may increase serum potassium (e.g. heparin, trimethoprim-containing medicines).
- Other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following medicines: tricyclic antidepressants, antipsychotics, baclofen, amifostine.
- Nonsteroidal anti-inflammatory drugs, including COX-2-inhibitors and acetylsalicylic acid (aspirin) (medicines that reduce inflammation, and can be used to help relieve pain), as they may reduce the blood pressure lowering effect of losartan. If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

RENICARD 50 with food and drink

In general, RENICARD 50 does not interact with food or drink. See section 3.

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 RENICARD 50.

Your doctor will normally advise you to stop taking RENICARD 50 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of RENICARD 50. Women of childbearing age should use effective contraception while taking RENICARD 50.

The use of RENICARD 50 is contraindicated when you are pregnant or breastfeeding.

Driving and using machines

RENICARD 50 may cause dizziness or drowsiness in some people. You should be careful in performing tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how RENICARD 50 affects you.

RENICARD 50 contains lactose

RENICARD 50 contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RENICARD 50.

3. How to take RENICARD 50

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

Take RENICARD 50 every day, exactly as your doctor has instructed.

It is important to continue taking RENICARD 50 for as long as your doctor prescribes it in order to control your blood pressure. Your doctor will decide on the appropriate dose of RENICARD 50, depending on your condition and whether you are taking other medicines.

The usual dose of RENICARD 50 is 1 tablet per day to control blood pressure over the 24-hour period.

For convenience and to help you remember, try to take RENICARD 50 at the same time each day.

RENICARD 50 may be taken with or without food.

If you have the impression that the effect of RENICARD 50 is too strong or too weak, tell your doctor, pharmacist or other health care provider.

If you take more RENICARD 50 than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre as soon as possible. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take RENICARD 50

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten dose. Continue to take the next tablet at the usual time.

4. Possible side effects

RENICARD 50 can have side effects.

Not all side effects reported for RENICARD 50 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RENICARD 50, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking RENICARD 50 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RENICARD 50. 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:

- Feeling of increased heart rate (palpitations), very rapid and irregular heartbeat.

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- Severe chest pain (angina pectoris).
 - Shortness of breath (dyspnoea).
 - Brain stroke with symptoms such as trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg on one side of your body.
 - Changes in kidney function including kidney failure, urinating less often than usual.
 - Inflammation of your pancreas.
 - Yellowing of the eyes or skin, inflammation of the liver (hepatitis), liver function abnormalities.
 - Unexplained muscle pain and breakdown with dark (tea-coloured) urine (rhabdomyolysis).
 - Unexplained bruising or bleeding, nose bleeds or pinpoint bleeds on your skin (thrombocytopenia).
 - Inflammation of the blood vessels (vasculitis) with symptoms such as fever, fatigue, weight loss and muscle and joint pain.

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:

- Upper respiratory infection (cough, sore throat, fever).
- Trouble sleeping (insomnia).
- Headache, dizziness, vertigo (sensation of feeling off balance).
- Cough, sore throat, blocked nose or sinus disorders.
- Nausea (feeling sick), pain of your stomach area, diarrhoea, indigestion.
- Back pain, muscle cramps.
- Fatigue, weakness, swelling of your hands, feet, arms or legs due to excessive fluid build-up.
- Blood test results showing too little sugar in your blood. (hypoglycaemia), too much potassium in your blood (hyperkalaemia), increases in blood urea and serum creatine in your body.

Less frequent side effects:

- Drowsiness, sleep disorders.
- Light-headedness due to a sudden drop in blood pressure when standing up quickly.
- Inability to pass a stool.
- Tingling sensation in the limbs, hands and feet.

Side effects of unknown frequency:

- Anaemia (feeling tired or weak, pale skin).
- Depression.
- Migraine (severe headache).
- Disturbed taste (dysgeusia).
- Vomiting (being sick).
- Increased sensitivity to the sun (photosensitivity).
- Muscle and joint pain.
- Not being able to perform sexually, impotence (difficulty to achieve and maintain an erection).
- Generally feeling unwell (malaise).
- Ringing, buzzing in the ears (tinnitus).
- Changes in your liver function test results.
- Low levels of sodium in your blood (hyponatraemia) when tests are done.

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 “**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 RENICARD 50.

5. How to store RENICARD 50

Store at or below 25 °C in a dry place.

Protect from light.

Keep the blister strips in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What RENICARD 50 contains

The active ingredient is losartan potassium.

Each RENICARD 50 tablet contains 50 mg of losartan potassium.

The inactive ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, purified talc and Opadry Pink as the colourant (containing hypromellose, titanium dioxide, macrogol, talc, iron oxide red).

What RENICARD 50 looks like and contents of the pack

Light pink, biconvex, oblong, film-coated tablet with score mark on one side.

RENICARD 50 tablets are packed in aluminium/PVC blister strips of 10 tablets. Three strips will be packed in an outer carton.

Holder of certificate of registration

Unichem SA (Pty) Ltd

San Domenico

Ground Floor, Unit G4

10 Church Street

Durbanville

7551 Cape Town

Tel: +27 21 531 0436

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