

Approved Patient Information Leaflet for Medicines for Human Use:

LOSARTAN CO AUSTELL

SCHEDULING STATUS: S3

LOSARTAN CO 50/12,5 mg, 100/12,5 mg, 100/25 mg AUSTELL

Film-coated tablets

Losartan potassium and hydrochlorothiazide

Contains Sugar:

LOSARTAN CO 50/12,5 AUSTELL: each film-coated tablet contains 112,50 mg lactose monohydrate.

LOSARTAN CO 100/12,5 AUSTELL: each film-coated tablet contains 237,50 mg lactose monohydrate.

LOSARTAN CO 100/ 25 AUSTELL: each film-coated tablet contains 225,00 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking LOSARTAN CO AUSTELL

- 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.
- LOSARTAN CO AUSTELL 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 LOSARTAN CO AUSTELL is and what it is used for
2. What you need to know before you take LOSARTAN CO AUSTELL

3. How to take LOSARTAN CO AUSTELL
4. Possible side effects
5. How to store LOSARTAN CO AUSTELL
6. Contents of the pack and other information

1. What LOSARTAN CO AUSTELL is and what it is used for

LOSARTAN CO AUSTELL film-coated tablets contain the 2 active ingredients, losartan potassium and hydrochlorothiazide.

Losartan potassium belongs to a pharmacotherapeutic group called Angiotensin II antagonists and hydrochlorothiazide is a diuretics medicine.

LOSARTAN CO AUSTELL is used for the treatment of hypertension (high blood pressure).

2. What you need to know before you take LOSARTAN CO AUSTELL

Do not take LOSARTAN CO AUSTELL

- If you are hypersensitive (allergic) to losartan potassium and hydrochlorothiazide or any of the other ingredients of LOSARTAN CO AUSTELL (listed in section 6)
- If you have hereditary or idiopathic angioedema (if you have previously suffered from angioedema i.e., swelling of the face, lips or tongue)
- If you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart
- If you have severe kidney disease
- 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)
- If you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- If you have porphyria
- Thiazide water tablets in combination as with LOSARTAN CO AUSTELL should not be given to patients with Addison's disease. Ask your doctor if you are not sure what sulphonamide-derived medicines are.
- Lithium therapy: taking LOSARTAN CO AUSTELL with lithium may lead to high blood concentrations of lithium which may be harmful to you
- If you are pregnant or breastfeeding (see Pregnancy and Breastfeeding)
- If you have liver disease
- If you are suffering from gout

Warnings and precautions

You must tell your doctor if you think you are (or might become) pregnant. LOSARTAN CO AUSTELL is not recommended in pregnancy.

Tell your doctor or health care provider before taking LOSARTAN CO AUSTELL

- If you have previously suffered from swelling of the face, lips, throat or tongue
- If you take diuretics (water pills)
- If you are on a salt-restricted diet
- If you have or have had severe vomiting and/or diarrhoea
- If you have heart failure
- If your liver function is impaired (see section 2 “Do not take LOSARTAN CO AUSTELL”)

- If you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- If you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- If you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease-causing thickening of heart muscle)
- If you are diabetic
- If you have had gout
- If you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- If you have high calcium or low potassium levels or you are on a low potassium diet
- If you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets
- 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 of the following medicines used to treat high blood pressure: an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems or aliskiren
- Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood. See also information under the heading "Do not take LOSARTAN CO AUSTELL"
- If you are taking other medicines that may increase serum potassium (see section 2 "Other medicines and LOSARTAN CO AUSTELL").
- 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 LOSARTAN CO AUSTELL.

Children and adolescents

LOSARTAN CO AUSTELL should not be given to children.

Other medicines and LOSARTAN CO AUSTELL

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 potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines, or other medicines that may increase serum potassium (e.g., trimethoprim-containing medicines), as the combination with LOSARTAN CO AUSTELL is not advisable.

Diuretics such as the hydrochlorothiazide contained in LOSARTAN CO AUSTELL may interact with other medicines.

Preparations containing lithium should not be taken with LOSARTAN CO AUSTELL without close

supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take other diuretics (“water tablets”), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral medicines or insulins).

Tell your doctor if you are taking the following medicines:

- other medicines to reduce your blood pressure
- steroids
- medicines to treat cancer
- pain killers
- medicines for treatment of fungal infection
- arthritis medicines
- resins used for high cholesterol, such as colestyramine
- medicines which relax your muscles
- sleeping tablets
- opioid medicines such as morphine
- ‘pressor amines’ such as adrenaline or other drugs from the same group
- oral agents for diabetes or insulins

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take LOSARTAN CO AUSTELL” and “Warnings and precautions”).

Please also inform your doctor you are taking LOSARTAN CO AUSTELL if you will be undergoing a radiographic procedure and will be given iodine contrast media.

LOSARTAN CO AUSTELL with food and drink

You are advised not to drink alcohol whilst taking LOSARTAN CO AUSTELL. Alcohol and LOSARTAN CO AUSTELL may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of LOSARTAN CO AUSTELL.

LOSARTAN CO AUSTELL may be taken with or without food.

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 LOSARTAN CO AUSTELL.

Driving and using machines

It is not always possible to predict to what extent LOSARTAN CO AUSTELL 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 LOSARTAN CO AUSTELL affects them.

LOSARTAN CO AUSTELL contains lactose monohydrate

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

3. How to take LOSARTAN CO AUSTELL

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

Always take LOSARTAN CO AUSTELL exactly as your doctor or pharmacist has instructed you.

Check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose of LOSARTAN CO AUSTELL 50/12,5 is one tablet daily. Your doctor may

increase the dose to one LOSARTAN CO AUSTELL 100/25 tablet daily, if needed.

Your doctor will tell you how long your treatment with LOSARTAN CO AUSTELL will last. Do not stop treatment early because your blood pressure may be uncontrolled. If you have the impression that the effect of LOSARTAN CO AUSTELL is too strong or too weak, tell your doctor or pharmacist.

The maximum dose is one tablet of LOSARTAN CO AUSTELL 100/25 (100 mg losartan potassium and 25 mg hydrochlorothiazide) once daily.

If you take more LOSARTAN CO AUSTELL than you should

No specific information is available on the treatment of overdose with LOSARTAN CO AUSTELL. Treatment is symptomatic and supportive.

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 LOSARTAN CO AUSTELL

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

4. Possible side effects

LOSARTAN CO AUSTELL can have side effects.

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

If any of the following happens, stop taking LOSARTAN CO AUSTELL 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
- 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),
- erythroderma which is an intense and widespread reddening of the skin, often associated with exfoliation (skin peeling off in scales or layers), when it may also be known as exfoliative dermatitis (ED),
- an inflammation of blood vessel walls (vasculitis) with symptoms such as a skin rash, chills, fever, fatigue and weight loss (necrotising angiitis vasculitis), a disorder causing inflammation and bleeding in the small blood vessels (Henoch-Schönlein purpura),
- rash or itching
- fainting

These are very serious side effects. If you have them, you may have had a serious reaction to LOSARTAN CO AUSTELL. 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:

- heart problems with symptoms such as chest pain or tightness in the chest, slower, faster or irregular heartbeat,
- bleeding into the skin (ecchymosis)
- blood disorders where you could be feeling tired, weak, breathless, bruising or bleeding easily and more prone to infections e.g. anaemia. Changes in blood test results. Blood tests will need to be done by your doctor

- inflammation of the liver (hepatitis), gallbladder (cholecystitis) or pancreas (pancreatitis), with symptoms such as yellowing of the skin or the whites of the eyes (jaundice), severe pain and swelling in the stomach, pale or fatty stools, nausea and vomiting, swelling in the legs and ankles, itchy skin, tiredness, loss of appetite,
- kidney problems with symptoms such as muscle aches, weakness, shortness of breath, tiredness, fever, blood in the urine, dark or reddish urine, swelling, painful urination, increased urge to urinate, decreased amount of urine, confusion and problems with passing urine,
- sore or weak muscles and the destruction of red blood cells with symptoms such as dark urine,
- increased heart rate and swelling of stomach (haemolysis),
- inflammation of the lungs which causes breathlessness, cough and raised temperature (pneumonitis) and fluid accumulation in the lungs (pulmonary oedema),
- skin and lip cancer (non-melanoma skin cancer),
- 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)

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:

- abdominal (stomach) pain, nausea, diarrhoea, dyspepsia (heartburn)
- asthenia, fatigue,
- chest pain
- muscle cramp, back pain, leg pain, myalgia (muscle pain)
- headache, dizziness
- insomnia (sleeplessness)

- renal impairment, renal failure
- cough, upper respiratory infection (e.g., stuffy/blocked nose, sinus congestion or sinus problems),
- hyperkalaemia mild reduction of haematocrit and haemoglobin, hypoglycaemia (electrolyte or blood sugar imbalances which can cause tiredness and confusion, muscle twitching and coma)
- cephalalgia (chronic headache with pain in the region of the neck)

Less frequent side effects:

- decreased sexual drive, impotence or the inability to have or maintain an erection during sexual intercourse
- dry skin, hair loss, flushing or redness of the skin, sensitivity to light, sweating, fever
- severe headaches caused by local blood vessel problems (migraine), nervousness
- unintentional muscle movements or trembling (tremor), fainting
- ringing in the ears (tinnitus), sense of spinning (vertigo)
- increased levels of uric acid in the blood that causes attacks of gout in some patients (hyperuricemia), sugar in the urine, too much sugar in the blood with symptoms such as increased thirst, headaches, increased urination and blurred vision (hyperglycaemia), low blood sugar with symptoms such as excess sweating
- increase in enzymes or changes in levels from blood tests which show changes in the way the liver and kidneys are working
- restlessness; feeling of unease, such as worry or fear (anxiety), reoccurring unexpected panic attacks (panic disorder), confusion, feelings of sadness worthlessness, thoughts of suicide or death (depression), abnormal dreams, sleep disorder, sleepiness, trouble with memory
- Inflammation of the air passages of the lung (bronchitis), nose bleeds and infections of the nose and throat (upper respiratory infections) with cold or flu-like symptoms such as sore

or hoarse throat, cough, runny or blocked nose, post-nasal drip, swelling and inflammation of the nose (rhinitis), throat (pharyngitis), and your voice box (laryngitis)

- a fall in blood pressure on standing up which causes dizziness or fainting (postural hypotension), low blood pressure
- vomiting, constipation, tooth pain, dry mouth, excess amount of air/gas in the stomach (flatulence), stomach pain, nausea and vomiting (gastritis), inflammation of a salivary gland, loss of appetite
- muscle weakness, joint and bone pain due to inflammation, numbness or tingling in an arm or leg (paraesthesia), a disorder of the nerves which can cause weakness, tingling or numbness (peripheral neuropathy)
- changes in vision, blurred or yellow vision, burning/stinging in the eye, inflammation or infection of the membrane of the eyeball (conjunctivitis)
- distortion of the sense of taste (dysgeusia)
- a general feeling of being unwell (malaise)
- lower back pain (sternum area)

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 or nurse. 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 LOSARTAN CO AUSTELL.

5. How to store LOSARTAN CO AUSTELL

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in original packaging.

There are no special storage instructions for LOSARTAN CO AUSTELL.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What LOSARTAN CO AUSTELL contains

The active substance is losartan potassium and hydrochlorothiazide.

LOSARTAN CO 50/12,5 AUSTELL

Each film-coated tablet contains 50 mg losartan potassium and 12,5 mg hydrochlorothiazide.

LOSARTAN CO 100/12,5 AUSTELL

Each film-coated tablet contains 100 mg losartan potassium and 12,5 mg hydrochlorothiazide.

LOSARTAN CO 100/25 AUSTELL

Each-film coated tablet contains 100 mg losartan potassium and 25 mg hydrochlorothiazide.

Contains sugar:

LOSARTAN CO 50/12,5 AUSTELL: each film-coated tablet contains 112,50 mg lactose monohydrate.

LOSARTAN CO 100/12,5 AUSTELL: each film-coated tablet contains 237,50 mg lactose monohydrate.

LOSARTAN CO 100/25 AUSTELL: Each film-coated tablet contains 225,00 mg lactose monohydrate.

The other ingredients are:

For tablet core:

Microcrystalline cellulose PH-101, Croscarmellose Sodium, Colloidal Anhydrous Silica, Powdered Cellulose, Magnesium stearate

For tablet coating:

Opadry White OY-L-28900, Purified water

For Opadry White OY-L-28900:

HPMC 2910/Hypromellose, Titanium dioxide, Macrogol/PEG, Lactose monohydrate

What looks like and contents of the pack

LOSARTAN CO 50/12,5 AUSTELL

Yellow, oval, biconvex, film-coated tablets with 'C' debossed on one side and '80' on other side.

LOSARTAN CO 100/12,5 AUSTELL

White circular, biconvex film-coated Tablets with 'C' debossed on one side and '79' on other side

LOSARTAN CO 100/25 AUSTELL

Yellow, circular biconvex film-coated tablets with 'C' debossed on one Side and '78' on other side.

LOSARTAN CO AUSTELL is available in white blister packs packed into cardboard cartons in pack sizes of 30's.

LOSARTAN CO AUSTELL is available in HDPE containers with child resistant screw cap in pack sizes of 500's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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