335 mm

475 mm

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM

LOSARTAN MACLEODS 50 mg (Film Coated Tablets)
LOSARTAN MACLEODS 100 mg (Film Coated Tablets)

COMPOSITION

Each film coated tablet contains 50 mg/100 mg losartan potassium. Contains lactose.
Excipients: Lactose monohydrate, dried corn starch, povidone, methylene chloride, silicified microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, film coating consisting of hydroxypropyl cellulose, hypromellose and titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION

A7.1.3 Other hypotensives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties
Angiotensin II, a potent vasoconstrictor, is the primary active hormone of the renin-angiotensin system, and a major determinant of the pathophysiology of hypotension. Angiotensin II binds to the AT1 receptor found in many tissues (e.g. vascular smooth muscle, adrenal gland, kidneys and heart) and elicits several important biological actions, including vasoconstriction and the release of aldosterone. Angiotensin II also stimulates smooth muscle cell proliferation.
Losartan is a synthetic, orally active compound which binds selectively to the AT1 receptor. Both losartan and its pharmacologically active carboxylic acid metabolite block the actions of angiotensin II, regardless of the source or route of synthesis.
Losartan binds selectively to the AT1 receptor and does not bind to or block other hormone receptors or ion channels important in the cardiovascular regulation. Furthermore, losartan doses not inhibit ACE (kininase II), the enzyme that degrades bradykinin.

Pharmacokinetic properties
Absorption:
Following oral administration of losartan it is well absorbed and undergoes substantial first pass metabolism by cytochrome P450 enzymes. It is converted, in part, to an active carboxylic acid metabolite that is responsible for most of the angiotensin II receptor antagonism that follows losartan treatment. In addition to the active metabolite, several inactive metabolites are formed. The systemic bioavailability of losartan tablets is approximately 33 %. Mean peak concentrations of losartan and its active metabolite are reached in 1 hr and in 3 to 4 hrs, respectively.
Effect of food:
Food slows absorption of losartan and decreases its C_{max} but has only minor effects on losartan AUC or on the AUC of the metabolite.
Distribution:
Both losartan and its active metabolite are bound to plasma proteins by 99 % or more primarily albumin. The volume of distribution of losartan is 34 liters. Studies in rats indicate that losartan crosses the blood-brain barrier poorly, if at all.
Metabolism:
About 14 % of intravenously- or orally-administered dose of losartan is converted to its active metabolite.
Elimination:
Plasma clearance of losartan and its active metabolite is about 600 ml/min and 50 ml/min, respectively. Renal clearance of losartan and its active metabolite is about 74 ml/min and 26 ml/min, respectively. When losartan is administered orally, about 4 % of the dose is excreted unchanged in urine, and about 6 % of the dose is excreted in the urine as the active metabolite. The pharmacokinetics of losartan and its active metabolite are linear with oral losartan doses up to 200 mg.
Following oral administration in normal volunteers, plasma concentrations of losartan and its metabolite decline polyexponentially with a terminal half-life of about 2 hrs and 6 to 9 hrs, respectively.
Both biliary and urinary excretion contributes to the elimination of losartan and its metabolites. Following an oral dose of 14C-labelled losartan in man, about 35 % of radioactivity is recovered in the urine and 58 % in the faeces. Following an intravenous dose of 14C-labelled losartan in man, about 43 % of radioactivity is recovered in the urine and 50 % in the faeces.

Characteristics in patients
Following oral administration in patients with mild to moderate alcoholic cirrhosis of the liver, plasma concentrations of losartan and its active metabolite were, respectively 5-fold and 1,7-fold greater than those seen in young male volunteers. Plasma concentrations of losartan are not altered in patients with creatinine clearance above 10 ml/min. Compared to patients with normal renal function, the AUC for losartan is approximately 2-fold greater in haemodialysis patients. Plasma concentrations of the active metabolite are not altered in patients with renal impairment or in haemodialysis patients. Neither losartan nor the active metabolite can be removed by haemodialysis.

INDICATIONS

LOSARTAN MACLEODS is indicated for the treatment of hypertension.

Renal protection in type 2 diabetic patients with hypertension and proteinuria.

CONTRA-INDICATIONS

- Hypersensitivity to any of the ingredients of **LOSARTAN MACLEODS.**
- A history of angioedema related to previous therapy with ACE inhibitors or angiotensin receptor blockers (ARBs): These patients must never again be given these medicines.
- Hereditary or idiopathic angioedema.
- Hypertrophic obstructive cardiomyopathy (HOCM).
- Severe renal function impairment (creatinine clearance less than 30 ml/min).
- Bilateral renal artery stenosis.
- Renal artery stenosis in patients with a single kidney.
- Aortic stenosis.
- Concomitant therapy with potassium sparing diuretics such as spironolactone, triamterene, amiloride (see INTERACTIONS).
- Porphyria.
- Lithium therapy: Concomitant administration with **LOSARTAN MACLEODS** may lead to toxic blood concentrations of lithium (see INTERACTIONS).
- Pregnancy and lactation (see HUMAN REPRODUCTION).
- The concomitant use of **LOSARTAN MACLEODS** with aliskiren-containing products is contraindicated. (see WARNINGS & SPECIAL PRECAUTIONS AND INTERACTIONS)
- Concomitant use of fluoroquinolones with ACE inhibitors/Renin-Angiotensin blockers is contraindicated in patients with moderate to severe renal impairment.

Paediatric use
Safety and effectiveness in children have not been established.

WARNINGS AND SPECIAL PRECAUTIONS

Should a woman become pregnant while receiving **LOSARTAN MACLEODS**, the treatment must be stopped promptly and changed to a different class of antihypertensive medicine (see CONTRA-INDICATIONS and HUMAN REPRODUCTION).

Serum potassium levels should be monitored regularly.

Hypotension and electrolyte/fluid imbalance
In patients who are intravascularly volume-depleted (e.g. those treated with high-dose diuretics), symptomatic hypotension can occur. These conditions should be corrected prior to administration of **LOSARTAN MACLEODS**, or a lower starting dose should be used.
Electrolyte imbalances are common in patients with renal impairment, with or without diabetes, and should be addressed (see SIDE-EFFECTS).

Liver function impairment
Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of losartan in cirrhotic patients, a dose of 25 mg should be considered for patients with a history of hepatic impairment (see DOSAGE AND DIRECTIONS FOR USE).

Renal function impairment
When impaired renal function is present, changes in renal function as a consequence of inhibiting the renin angiotensin system, including renal failure, have been reported in susceptible individuals; in some patients these changes in renal function may be reversible upon discontinuation of therapy.
In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure), treatment with angiotensin converting enzyme inhibitors has been associated with oliguria and/or progressive uraemia and with acute renal failure and/or death. Similar outcomes have been reported with **LOSARTAN MACLEODS**.
Medicines that affect the renin-angiotensin system may increase blood urea and serum creatinine in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney. Similar effects have been reported with **LOSARTAN MACLEODS** (see CONTRA-INDICATIONS).

Porphyria
Limited information is available regarding the effect of antihypertensive medication in patients with porphyria. Safety of **LOSARTAN MACLEODS** in patients with porphyria has not been fully established (see CONTRA-INDICATIONS).

Use in the elderly
In clinical studies there was no age related difference in efficacy or safety profile of losartan.

Dual blockade of the renin-angiotensin-aldosterone system (RAAS)
There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers (ARBs) or aliskiren may increase the risk of hypotension, hyperkalaemia and decreases renal function (including acute renal failure). Dual blockade of RAAS through the combined use of **LOSARTAN MACLEODS** and aliskiren is therefore contraindicated (see CONTRAINDICATIONS). **LOSARTAN MACLEODS** should not be used concomitantly with aliskiren. (see CONTRAINDICATIONS).

Concomitant use of ACE inhibitors/renin-angiotensin receptor blockers and fluoroquinolones in renal impairment and elderly patients
Concomitant use of ACE inhibitors/renin-angiotensin receptor blockers including **LOSARTAN MACLEODS** and Fluoroquinolones may precipitate acute kidney injury (AKI) in patients, especially those with moderate to severe renal impairment and elderly patients. (See CONTRAINDICATIONS). Renal function should be assessed before initiating treatment, and monitored during treatment, with **LOSARTAN MACLEODS** or ACE inhibitors/renin-angiotensin receptor blockers.

Effects on ability to drive and use machines
LOSARTAN MACLEODS may cause dizziness, somnolence and fatigue. Patients should be cautioned about operating hazardous machinery, including motor vehicles until they are reasonably certain that **LOSARTAN MACLEODS** does not adversely affect them.

Lactose intolerance:
LOSARTAN MACLEODS contains lactose and is unsuitable for patients with known hereditary problems, or a history of galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption.

INTERACTIONS

No interactions of clinical significance have been identified with hydrochlorothiazide, digoxin, warfarin, cimetidine, phenobarbital, ketoconazole and erythromycin. Rifampicin and fluconazole have been reported to reduce levels of active metabolite. The clinical consequences of these interactions have not been evaluated.
Concomitant use of medicines that block angiotensin II or its effects and potassium-sparing diuretics (e.g. spironolactone, triamterene, amiloride), potassium supplements or salt substitutes containing potassium, may lead to increases in serum potassium (see CONTRA-INDICATIONS).
Lithium excretion may be reduced (see CONTRA-INDICATIONS).
Non-steroidal anti-inflammatory drugs (NSAIDs) including selective cyclooxygenase-2 inhibitors (COX-2 inhibitors) may reduce the effect of diuretics and other antihypertensive medicines. Therefore, the antihypertensive effect of angiotensin II receptor antagonists may be attenuated by NSAIDs including selective COX-2 inhibitors.
In some patients with compromised renal function who are being treated with non-steroidal anti-inflammatory drugs, including selective cyclo-oxygenase-2 inhibitors, the co-administration of angiotensin II receptor antagonists may result in a further deterioration of renal function. These effects are usually reversible.

Dual blockade of the RAAS with ARBs, ACE inhibitors, or aliskiren:
Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of ACE inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (see CONTRAINDICATIONS, WARNINGS AND SPECIAL PRECAUTIONS).

Fluoroquinolones:
Concomitant use of ACE inhibitors/renin-angiotensin receptor blockers including **LOSARTAN MACLEODS** and Fluoroquinolones may precipitate acute kidney injury (see CONTRAINDICATIONS). A potential mechanism for the observed interaction has not been identified. Most of the published reports indicate acute interstitial nephritis as the underlying cause of AKI with fluoroquinolones. Interstitial nephritis or other pathology due to a fluoroquinolone could be a trigger for ACE inhibitor-related AKI or more severe AKI leading to admission .

HUMAN REPRODUCTION Safety in pregnancy and lactation has not been established (see CONTRA-INDICATIONS).

Pregnancy
When pregnancy is planned or confirmed **LOSARTAN MACLEODS** should be discontinued. Medicines affecting the renin-angiotensin system, such as **LOSARTAN MACLEODS**, can cause embryonal toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women.
Women of childbearing age should ensure effective contraception.
If a woman is contemplating, a different class of medicine should be used.

Breastfeeding It is not known whether losartan is excreted in human milk. Safety of breastfeeding in mothers taking losartan has not been established. However, significant levels of losartan and the active metabolites were shown to be present in rat milk.

DOSAGE AND DIRECTIONS FOR USE

LOSARTAN MACLEODS may be administered with or without food.
LOSARTAN MACLEODS may be administered with other antihypertensive agents.

Hypertension
The usual starting and maintenance dose is 50 mg once daily. The maximal anti-hypertensive effect is attained 3 - 6 weeks after initiation of therapy. The dose may be increased to 100 mg once daily.
For patients with intravascular volume-depletion (e.g. those treated with high-dose diuretics), a starting dose of 25 mg once daily should be considered (see WARNINGS AND SPECIAL PRECAUTIONS).
No initial dosage adjustment is necessary for elderly patients or for patients with mild to moderate renal impairment, including patients on dialysis. A lower dose should be considered for patients with a history of hepatic impairment (see WARNINGS AND SPECIAL PRECAUTIONS).

Renal Protection in Type 2 diabetic patients with hypertension and proteinuria
The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once daily based on blood pressure response. **LOSARTAN MACLEODS** may be administered with other antihypertensive agents (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used hypoglycaemic agents (e.g. sulfonylurea, glitazones and glucosidase inhibitors).

SIDE-EFFECTS

Infections and infestations
Frequent: Upper respiratory tract infection

Psychiatric disorders
Frequent: Insomnia

Nervous system disorders
Frequent: Headache
Less frequent: Dizziness, somnolence, sleep disorders

Ear and labyrinth disorders:
Less frequent: Vertigo

Cardiac disorders
Frequent: Palpitation, tachycardia
Less frequent: Angina pectoris

Vascular disorders
Frequent: Orthostatic hypotension

Respiratory, thoracic and mediastinal disorders
Frequent: Cough, pharyngitis, nasal congestion, sinus disorder

Gastro-intestinal disorders
Frequent: Diarrhoea, nausea, abdominal pain, dyspepsia

Skin and subcutaneous tissue disorders
Less frequent: Rash

Musculoskeletal, connective tissue and bone disorders
Frequent: Back pain, muscle cramps

General disorders and administration site conditions
Frequent: Asthenia/fatigue, oedema/swelling, chest pain

Investigations
Less frequent: Hyperkalaemia, elevations of ALT

The following adverse reactions have been reported in post-marketing experience; they are derived from spontaneous reports for which precise incidences cannot be determined, therefore the frequency is unknown.

Blood and lymphatic system disorders
Anaemia

Immune system disorders
Anaphylactic reactions, angio-oedema including swelling of the larynx and glottis causing airway obstruction and/or swelling of the face, lips, pharynx, and/or tongue

Nervous system disorders
Migraine, dysgeusia

Vascular disorders
Vasculitis, including Henoch-Schönlein purpura

Respiratory, thoracic and mediastinal disorders
Cough

Hepato-biliary disorders
Hepatitis

Skin and subcutaneous tissue disorders
Urticaria, pruritus, erythroderma

Musculoskeletal, connective tissue and bone disorders
Myalgia, arthralgia

Investigations
Liver function abnormalities

Haematological disorders
Thrombocytopenia

Gastro-intestinal disorders
Vomiting

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Signs and symptoms
Limited data are available in regard to overdosage in humans. The most likely manifestations of overdosage would be hypotension and tachycardia, bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted.
Neither losartan nor the active metabolite can be removed by haemodialysis.

IDENTIFICATION

For LOSARTAN MACLEODS 50 mg
White to off white oval shaped biconvex film coated tablets having 'CL14' debossed on one side and break line on other side.

For LOSARTAN MACLEODS 100 mg
White to off white oval shaped biconvex film coated tablets having 'CL17' debossed on one side and plain on other side.

PRESENTATION

HDPE container pack of 30 tablets: The tablets are packed in a white HDPE container with a white, child resistant with pulp and heat seal liner, polypropylene closure.
Cold formed aluminium blister pack of 10 tablets. Pack of 30s.
The HDPE container and blisters are packed in a pre-printed outer carton.

STORAGE INSTRUCTIONS

Store in a dry place at or below 30 °C. Protect from light. Keep container tightly closed. Keep the blister in the carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

LOSARTAN MACLEODS 50 mg: 46/7.1.3/0205
LOSARTAN MACLEODS 100 mg: 46/7.1.3/0206

NAME AND BUSINESS ADDRESS OF the holder of the certificate of registration

Macleods Pharmaceuticals SA (Pty)
Office Block 1, Bassonia Estate Office Park (East)
1 Cussonia Drive, Bassonia Rock,
Ext 12 Alberton, South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT

Date of registration: 6 August 2015

The date of the most recently revised package insert as approved by SAHPRA:
20 December 2019

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LOSARTAN MACLEODS 50 mg (Film Coated Tablets)
LOSARTAN MACLEODS 100 mg (Film Coated Tablets)

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING LOSARTAN MACLEODS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **LOSARTAN MACLEODS** 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 LOSARTAN MACLEODS CONTAINS

Each film-coated tablet contains:
Losartan potassium 50/100 mg
Contains lactose.
The other ingredients are lactose monohydrate, dried corn starch, povidone, methylene chloride, silicified microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate , film coating consisting of hydroxypropyl cellulose, hypromellose and titanium dioxide.

WHAT LOSARTAN MACLEODS IS USED FOR

LOSARTAN MACLEODS is an angiotensin II receptor antagonist which lowers blood pressure.
Your doctor has prescribed **LOSARTAN MACLEODS** because you have a condition known as hypertension or high blood pressure.

BEFORE YOU TAKE LOSARTAN MACLEODS

Do not take LOSARTAN MACLEODS:

- If you are allergic to any of its ingredients.
- If you have had angioedema previously (swelling of the face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking an ACE inhibitor or angiotensin receptor blocker such as losartan.
- If you have inherited or idiopathic (unknown cause) type angioedema.
- If you have aortic stenosis; a narrowing of the aortic valve opening between the ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart).
- 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 narrowing of the blood vessels to both kidneys or to a single functioning kidney.
- If you are taking diuretics (water pills) that cause your body to retain your potassium such as spironolactone, triamterene and amiloride.
- If you have severe kidney disease and have difficulty in producing urine.
- If you have porphyria.
- If you are taking medicines containing lithium.
- If you are or think you may be pregnant.
- If you are planning to become pregnant.
- If you are breastfeeding.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren, an ACE inhibitor (e.g. enalapril, lisinopril, ramipril).
- If you have kidney damage and/or taking antibiotic medicines that belong to the class Fluoroquinolones (see section Taking other medicines).

Take special care with LOSARTAN MACLEODS
It is important to tell your doctor:

- If you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body, or if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body – treatment with **LOSARTAN MACLEODS** could lead to low blood pressure. Your doctor will treat you first for the loss of fluid and salts from your body or start you on a lower dose of **LOSARTAN MACLEODS.**
- If you suffer from kidney disease with or without diabetes.
- If you have liver disease such as cirrhosis – your doctor may prescribe a lower starting dose of 25 mg.
- If you have congestive heart failure (disease of the heart with shortness of breath and swelling of the feet or legs due to fluid build) - treatment with **LOSARTAN MACLEODS** could lead to reduced volume of urine, high levels of urea in the blood and with acute kidney failure and or death.
- If you have narrowing of the blood vessels to both kidneys or to a single functioning kidney - **LOSARTAN MACLEODS** may increase the levels of urea and creatinine in the blood.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren, an ACE inhibitor (e.g. enalapril, lisinopril, ramipril).
- Inform your doctor immediately if you are taking any antibiotic medicines which belong to the group Fluoroquinolones. Use of ACE inhibitors / renin-angiotensin receptor blockers, including **LOSARTAN MACLEODS**, together with fluoroquinolones can cause damage to your kidneys.

Your doctor will prescribe regular blood tests to monitor the potassium levels in your blood.

Taking LOSARTAN MACLEODSs with food and drink
LOSARTAN MACLEODS can be taken with or without food.

LOSARTAN MACLEODS
50 mg /100 mg
PM03910301

335 mm

475 mm

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **LOSARTAN MACLEODS.**

You should not take LOSARTAN MACLEODS if you are pregnant, or breastfeeding or planning to become pregnant.
The use of **LOSARTAN MACLEODS** while you are pregnant or breastfeeding is not recommended. If you are pregnant or become pregnant while taking **LOSARTAN MACLEODS**, stop taking **LOSARTAN MACLEODS** and talk to your doctor as soon as possible.

Driving and using machinery
Some people may feel dizzy, sleepy and tired while taking **LOSARTAN MACLEODS**. Cautioned is advised when operating hazardous machinery, including motor vehicles until you are reasonably certain that **LOSARTAN MACLEODS** does not adversely affect you.

Important information about some of the ingredients of LOSARTAN MACLEODS
Tell your doctor if you have galactosaemia (a condition in which the body is unable to use the sugar galactose) or glucose / galactose malabsorption syndrome. **LOSARTAN MACLEODS** contains lactose and is unsuitable for patients with these disorders.

Taking other medicines with LOSARTAN MACLEODS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Inform your doctor if you are taking any of the following medicines:
- Medicines containing lithium (used for some types of psychiatric illnesses).
- Certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen, diclofenac and COX-2 inhibitors such as celecoxib.
- Medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing diuretic medicines ("water pills") (e.g. spironolactone, triamterene, amiloride) and heparin (blood thinner).
- Rifampicin (used for TB).
- Fluconazole (antifungal medicine).
- Blood pressure lowering medicine containing aliskiren, an ACE inhibitor (e.g. enalapril, lisinopril, ramipril).
- Medicines used to treat infections (antibiotic medicines) which belong to the group fluoroquinolones (e.g. levofloxacin, moxifloxacin, ciprofloxacin).

HOW TO TAKE LOSARTAN MACLEODS

Do not share medicines prescribed for you with any other person.
Always take **LOSARTAN MACLEODS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **LOSARTAN MACLEODS** is too strong or too weak talk to your doctor or pharmacist.

Take **LOSARTAN MACLEODS** every day, exactly as your doctor has instructed. Your doctor will decide on the appropriate dose of **LOSARTAN MACLEODS**, depending on your condition and whether you are taking other medicines. It is important to continue taking **LOSARTAN MACLEODS** for as long as your doctor prescribes it in order to maintain control of your blood pressure.
The usual dose of **LOSARTAN MACLEODS** is 50 mg taken per day to control blood pressure over the 24-hr period.
For convenience and to help you remember, try to take **LOSARTAN MACLEODS** at the same time each day.

Use in children
There is no experience with the use of losartan in children. Therefore, **LOSARTAN MACLEODS** should not be given to children.

Use in elderly
Most older patients require the same dose as younger patients.

If you take more LOSARTAN MACLEODS than you should
In case of an overdose, contact your doctor immediately so that medical attention may be given promptly.

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 LOSARTAN MACLEODS
Try to take **LOSARTAN MACLEODS** daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

POSSIBLE SIDE EFFECTS

LOSARTAN MACLEODS can have side-effects.

If any of the following happens, stop taking LOSARTAN MACLEODS and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of face, tongue, throat, hands, feet, lips or mouth which may cause difficulties in swallowing or breathing
- hives
- severe skin reactions that can include blistering of the skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **LOSARTAN MACLEODS**. 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:
- Chest pain.
- Angina.
- Changes in the way your heart beats, for example, if you notice it beating faster.
- Widespread reddening of the skin with skin peeling off in scales or layers (erythroderma).
- Less urine than is normal for you.

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

Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:
- Respiratory infections.
- Difficulty in sleeping (insomnia).
- Headache, dizziness, feeling sleepy or other sleep disorders, migraine.
- Altered sense of taste.
- Spinning sensation.
- Low blood pressure when standing up from sitting or lying down; this may make you feel faint or dizzy.
- Cough, inflamed throat, nasal congestion, sinus problems.
- Diarrhoea, nausea, vomiting, stomach pain/cramp, upset stomach.
- Rash, itching, hives.
- Back pain, muscle cramps, muscle pain, joint pain.
- Feeling weak, tired.
- An increased amount of potassium in your blood. If this is severe you may notice tiredness, weakness, an irregular heartbeat or pins and needles.
- A reduction in your red or white blood cells. You may notice tiredness, an infection or a fever.
- Changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu like symptoms, blood tests may reveal increased levels of the liver enzyme ALT in the blood.
- Inflammation of blood vessels.
- Thrombocytopenia (low blood platelet count) resulting in bleeding or bruising more easily than normal.

Not all the side effects reported for **LOSARTAN MACLEODS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LOSARTAN MACLEODS**, please consult your doctor, pharmacist or health care professional for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSING OF LOSARTAN MACLEODS

Store **LOSARTAN MACLEODS** in a dry place at or below 30 °C and protect from light. Keep the container tightly closed. Do not open the blister pack until you are ready to take the medicine.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Do not use this medicine after the month and year following EXPIRES/VERVAL on the carton.

PRESENTATION

HDPE container pack of 30 tablets: The tablets are packed in a white HDPE container with a white, child resistant with pulp and heat seal liner, polypropylene closure.
Cold formed aluminium blister pack of 10 tablets. Pack of 30s.
The HDPE container and blisters are packed in a pre-printed outer container.

IDENTIFICATION

For Losartan Macleods 50 mg
White to off white oval shaped biconvex film coated tablets having 'CL14' debossed on one side and break line on other side.

For Losartan Macleods 100 mg
White to off white oval shaped biconvex film coated tablets having 'CL17' debossed on one side and plain on other side.

REGISTRATION NUMBER

LOSARTAN MACLEODS 50 mg: 46/7.1.3/0205
LOSARTAN MACLEODS 100 mg: 46/7.1.3/0206

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East)
1 Cussonia Drive, Bassonia Rock,
Ext 12 Alberton, South Africa

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 6 August 2015

The date of the most recently revised patient information leaflet as approved by SAHPRA: 20 December 2019

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S3

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:

LOSARTAN MACLEODS 50 mg (filmbedekte tablet)
LOSARTAN MACLEODS 100 mg (filmbedekte tablet)

Lees die hele brosjure sorgvuldig voordat u begin om LOSARTAN MACLEODS te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **LOSARTAN MACLEODS** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome.

WAT LOSARTAN MACLEODS BEVAT

Elke filmbedekte tablet bevat:
Kaliumlosartaan 50 mg/100 mg.
Bevat laktose.
Die ander bestanddele is laktosemonohidraat, gedroogde mieliestysel, povidoon, metileenchloried, silikagelmpregneerde mikrokristalryne sellulose, kolloidale silikondioksied, magnesiumstearaat. Die filmbedekking bestaan uit hidroksipropielsellulose, hipromellose en titaandioksied.

WAARVOOR LOSARTAN MACLEODS GEBRUIK WORD

LOSARTAN MACLEODS is 'n angiotensien II reseptorantagonis wat bloeddruk verlaag.
U dokter het **LOSARTAN MACLEODS** aan u voorgeskryf omdat u aan hipertensie of hoë bloeddruk ly.

VOORDAT U LOSARTAN MACLEODS NEEM
Moenie LOSARTAN MACLEODS neem nie:
- As u allergies teen enige van die bestanddele is nie.
- As u voorheen aan angioödeem gely het (swelling van die gesig, lippe, mond, tong of keel of moeite met sluk of asemhaling) terwyl u 'n AOE-inhibeerder of angiotensienreseptorblokkeerder soos losartaan gebruik het.
- As u aan oorerflike of idiopatiese (onbekende oorsaak) tipe angioödeem ly.
- As u aan aortastenose, 'n vernouing van die aortaklep tussen die ventrikel (groot pompkamer van die hart) en die aorta (die hoofslagaar wat weg van die hart loop, ly.
- As u aan hipertrofiese obstruktiewe kardiomiopatie ly; 'n hartafwyking waartydens die wande van die ventrikels (benede hartkamers) verdik en styf word. Die verdikte spiere blokkeer die vloei van bloed uit die hart uit.
- As u aan 'n vernouing van die bloedvate na beide niere of na 'n enkel funksionerende nier ly.
- As u diuretika (waterpille) neem wat veroorsaak dat u liggaam kalium terughou, soos spironolaktoon, triamtereen en amiloried.
- As u aan porfirie ly.
- As u medisyne neem wat litium bevat.
- As u swanger is of dink dat u swanger mag wees.
- As u beplan om swanger te raak.
- As u borsvoed.
- Indien jy diabetes of ingekorte nierfunksie het en jy behandel word met 'n bloeddrukverlagende medisyne wat aliskiren bevat, 'n AOE inhibeerder (bv. enalapril, lisinopril, ramipril).
- Indien jy nierskade het en/of antibiotika neem wat aan die klas Fluorokinolone behoort (sien afdeling Neem van ander medisyne).

Neem spesiale sorg met LOSARTAN MACLEODS:
Dit is belangrik om u dokter in kennis te stel:
- As u aan oormatige braking en diarree ly wat tot 'n oormatige verlies aan vloeistof of sout lei, of as u diuretika ontvang (medisyne wat die hoeveelheid water wat deur u niere uitgeskei word, verhoog), of as u op 'n beperkte soutdieet is wat tot 'n uitermatige verlies aan vloeistof en sout in u liggaam lei - die behandeling met **LOSARTAN MACLEODS** kan tot lae bloeddruk lei. U dokter sal u eers behandel om die verlies aan vloeistof en sout in u liggaam reg te stel of u op 'n laer begindosis van **LOSARTAN MACLEODS** begin.
- As u aan 'n niersiekte met of sonder diabetes ly.
- As u aan 'n lewersiekte soos sirrose ly - u dokter mag u op 'n laer begindosis van 25 mg begin.
- As u aan kongestiewe hartversaking ly ('n slekte van die hart wat kortademheid, en swelling van die voete of bene weens die opbou van vloeistof veroorsaak) - behandeling met **LOSARTAN MACLEODS** kan tot 'n afname in die volume urien, hoë ureumvlakke in die bloed met akute nierversaking en selfs die dood lei.
- As u aan vernouing van die bloedvate na beide niere of na 'n enkel funksionerende nier ly - **LOSARTAN MACLEODS** kan die hoeveelheid ureum en kreatinien in die bloed verhoog.
- Indien jy diabetes of ingekorte nierfunksie het en jy behandel word met 'n bloeddrukverlagende middel wat aliskiren bevat, 'n AOE inhibeerder (bv. enalapril, lisinopril, ramipril).
- Stel onmiddellik jou dokter in kennis indien jy enige antibiotiese middels neem wat aan die groep Fluorokinolone behoort. Gebruik van AOE inhibeerders/renien-angiotensien-reseptorblokkeerders, insluitend **LOSARTAN MACLEODS**, tesame met fluorokinolone kan skade aan jou niere veroorsaak.

U dokter sal gereelde bloedtoetse voorskryf om die kaliumvlakke in u bloed te monitor.

Die neem van LOSARTAN MACLEODS saam met voedsel en vloeistof:
LOSARTAN MACLEODS kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding:

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies nader voordat u **LOSARTAN MACLEODS** neem.

U behoort nie LOSARTAN MACLEODS te neem as u swanger is of borsvoed of beplan om swanger te raak nie.
Die gebruik van **LOSARTAN MACLEODS** terwyl u swanger is of borsvoed word nie aanbeveel nie.
As u swanger is of swanger raak terwyl u **LOSARTAN MACLEODS** gebruik, moet u ophou om **LOSARTAN MACLEODS** te neem en so gou as moontlik u dokter raadpleeg.

Bestuur en die gebruik van masjinerie:
Sommige mense mag duiselig, slaperig en moeg voel terwyl hulle **LOSARTAN MACLEODS** neem. Sorg word aanbeveel wanneer gevaarlike masjinerie, insluitende motorvoertuie gebruik word tot tyd en wyl u redelik seker is dat **LOSARTAN MACLEODS** u nie nadelig affekteer nie.

Belangrike inligting oor sommige van die bestanddele van LOSARTAN MACLEODS
Stel u dokter in kennis as u aan galaktosemie ly ('n kondisie waarin die liggaam nie in staat is om die suiker galaktose te gebruik nie) of aan glukose / galaktose wanabsorpsiesindroom ly. **LOSARTAN MACLEODS** bevat laktose en is daarom ongeskik vir gebruik in pasiënte met hierdie afwykings.

Die neem van ander medisyne saam met LOSARTAN MACLEODS:

Stel altyd u professionele gesondheidswerker in kennis as u enige nader medisyne neem. (Dit sluit komplementêre en tradisionele medisyne in.

Stel u dokter in kennis as u enige van die volgende medisyne neem:
- Medisyne wat litium bevat (gebruik vir sommige psigiatriese siektes)
- Sekere tipes pynstillers wat nie-steroïed anti-inflammatoriese middels (NSAIM) genoem word, soos ibuprofen, diklofenak en COX-2 inhibeerders soos selekoksib.
- Medisyne wat die hoeveelheid kalium in u bloed verhoog. Dit sluit kaliumsuppleme of soutvervangers wat kalium bevat, kaliumsparende diuretiese medisyne (waterpille) (bv. spironolaktoon, triamtereen, amiloried) en heparien (bloedverdunner) in.
- Rifampisien (gebruik vir TB).
- Flukonasool (swamwerende medisyne).
- Bloeddrukverlagende medisyne wat aliskiren bevat, 'n AOE inhibeerder (bv. enalapril, lisinopril, ramipril).
- Medisyne wat gebruik word om infeksies te behandel (antibiotiese middels) wat aan die groep fluorokinolone behoort (bv. levofloksasien, moksifloksasien, siprofloksasien).

HOE OM LOSARTAN MACLEODS TE NEEM

Moenie medisyne wat vir u voorgeskryf is met enigiemand anders deel nie.
Neem **LOSARTAN MACLEODS** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is.
As u van mening is dat die effek van **LOSARTAN MACLEODS** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

Neem **LOSARTAN MACLEODS** elke dag, presies soos deur u dokter voorgeskryf. U dokter sal, afhangende van u kondisie op die toepaslike dosis van **LOSARTAN MACLEODS** besluit. Om beheer van u bloeddruk te behou is dit belangrik om **LOSARTAN MACLEODS** te neem vir solank u dokter dit voorgeskryf het.
Die normale dosis van **LOSARTAN MACLEODS** is 50 mg per dag om u bloeddruk oor die 24-uur periode te beheer.
Vir gemak en om u te help onthou moet u probeer om **LOSARTAN MACLEODS** op dieselfde tyd elke dag te neem.

Gebruik in kinders
Daar bestaan geen ondervinding met die gebruik van losartaan in kinders nie. Daarom behoort **LOSARTAN MACLEODS** nie aan kinders toegedien te word nie.

Gebruik in bejaardes
Die meeste bejaarde pasiënte benodig dieselfde dosis as jonger pasiënte.

As u teveel LOSARTAN MACLEODS neem
In geval van 'n oordosis, raadpleeg onmiddellik u dokter sodat mediese aandag onmiddellik geskenk kan word.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

As u vergeet om LOSARTAN MACLEODS te neem
Probeer om **LOSARTAN MACLEODS** daagliks soos voorgeskryf te neem. Moenie 'n ekstra dosis neem as u vergeet om dit te neem nie. Gaan voort met u normale skedule.

MOONTLIKE NEWE-EFFEKTE

LOSARTAN MACLEODS kan newe-effekte hê.
As die volgende gebeur, moet u ophou om LOSARTAN MACLEODS te neem en onmiddellik u dokter in kennis stel, of gaan na die ongevalle-afdeling van u naaste hospitaal:
- Swelling van die gesig, tong, keel, hande, lippe of mond wat moeite met sluk en asemhaling kan veroorsaak.
- Urtikarie.
- Erge velreaksies wat blaasvorming kan insluit.

Hierdie is almal baie ernstige newe-effekte. As u daaraan ly het u moontlik 'n ernstige allergiese reaksie teen **LOSARTAN MACLEODS**. U mag dringende mediese aandag of hospitalisering nodig.

Stel onmiddellik u dokter in kennis of gaan na die ongevalle afdeling van u naaste hospitaal as u enige van die volgende waarneem:
- Borspyn.
- Angina.
- Veranderinge in die manier waarop u hart klop, bv. as u opmerk dat dit vinniger klop.
- Wydverspreide rooi verkleuring van die vel met die vel wat in skilfers of lae afdop (eritrodermie).
- Minder urien as normaal.

Hierdie is almal ernstige newe-effekte. U het moontlik dringende mediese hulp nodig.

Stel u dokter in kennis as u enige van die volgende newe-effekte waarneem, as hulle u kwel of as hulle nie wil verdwyn nie:
- Lugweginfeksies.
- Moeite met slaap (slaaploosheid).
- Hoofpyn, duiseligheid, slaperigheid of slaapafwykings, migraine.
- Smaakafwyking.
- Draaigevoel.
- Lae bloeddruk met opstaan vanuit 'n sittende of lêende posisie. Dit mag u flou of duiselig laat voel.
- Hoes, keelontsteking, verstopte neus, sinusprobleme.
- Diarree, naarheid, braking, maagpyn/-kramp, omgekrapte maag.
- Uitslag, jeuk, urtikarie.
- Rugpyn, spierkrampe, spierpyn, gewrigspyn.
- Swakheid, moegheid.
- 'n Toename in die hoeveelheid kalium in u bloed. As dit erg is mag u moegheid, swakheid, ongereelde hartklop of spelde en naalde waarneem.
- 'n Afname in die aantal rooi- en witbloedselle. U mag moegheid, 'n infeksie of 'n koors waarneem.
- Verandering in u lewerfunksie, insluitende inflammasie van die lewer (hepatitis). U mag moegheid, geel verkleuring van u vel of oë en griepagtige simptome waarneem, bloedtoetse mag 'n toename in die vlakke van die lewerensiem ALT in die bloed aantoon.
- Inflammasie van die bloedvate.
- Trombositopenie ('n lae bloedplaaljietelling) wat tot meer gereelde bloeding en kneusing lei.

Nie al die newe-effekte wat vir **LOSARTAN MACLEODS** aangemeld is word in hierdie blaadjie gelys nie. As u algehele gesondheid agteruitgaan of u ondervind enige nadelige effekte terwyl u **LOSARTAN MACLEODS** neem, moet u asseblief u dokter, apteker of professionele gesondheidswerker vir advies raadpleeg. As u enige newe-effekte ondervind wat nie in hierdie blaadjie genoem word nie, moet u asseblief u dokter of apteker in kennis stel.

OPBERGING EN WEGDOEN VAN LOSARTAN MACLEODS:

Bewaar in 'n koel en droë plek by of benede 30 °C en beskerm teen lig. Hou die houer dig toe. Moenie die stolpverpakking oopmaak tot voor gebruik nie.
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Moenie die medisyne gebruik na die maand en jaar na EXPIRES/VERVAL op die karton.

AANBIEDING

HDPE houer met 30 tablette:
Die tablette word in 'n wit HDPE houer met 'n wit kinderweerstandbiedende polipropileen skroefdeksel met pulp en hittegeseelde voering verpak.
Kouevorm aluminium stolpstrokie met 10 tablette. Pakke van 30.
Die HDPE houer en stolpstrokies word in 'n voorafgedrukte buitenste houer verpak.

IDENTIFIKASIE

LOSARTAN MACLEODS 50 mg:
'n Wit tot byna-wit, ovaalvormige, bikonvekse, filmbedekte tablet met 'CL14' op die een kant gedruk en 'n breeklyn aan die ander kant.

LOSARTAN MACLEODS 100 mg:
'n Wit tot byna-wit, ovaalvormige, bikonvekse, filmbedekte tablet met 'CL17' op die een kant gedruk en skoon aan die ander kant.

REGISTRASIENOMMER

LOSARTAN MACLEODS 50 mg: 46/7.1.3/0205
LOSARTAN MACLEODS 100 mg: 47/7.1.3/0206

NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIEHOUER

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Suid Afrika

DATUM VAN PUBLIKASIE VAN DIE INLIGTINGSBROSJURE VIR PASIËNTE

Datum van registrasie: 6 Augustus 2015

Die datum van die mees onlangs hersiene pasiëntinligtingstuk soos deur SAHPRA goedgekeur: 20 Desember 2019

MASTER COPY

MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: LOSARTAN MACLEODS 50 mg / 100 mg	
2. Country: South Africa - Private Market	3. Packaging component: Package Insert & Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 335 (L) x 475 (W) mm
9. Design / Style: (Booklet type)	10. Item code No.: PM03910301
11. Artwork has been made: Actual Size	12. Pharma code No.: 31795 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. File Name : Y:\Losartan\SA- Private Market\Losartan P/ & PIL Common PM03910301.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
10/08/22	Vanita Rajool	10/08/22	13/08/22	20/08/22	22/8/22

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

QA 20/08/22

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03910301		

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