PATIENT INFORMATION LEAFLET
(LOSA 50) LOSARTAN POTASSIUM USP 50 MG TABLETS
[Losartan Potassium]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

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1. WHAT LOSARTAN POTASSIUM TABLETS IS AND WHAT IT IS USED FOR

It contain active ingredient Losartan potassium, belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes. It is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. Nephropathy in Type 2 Diabetic Patients: It is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥300 mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, losartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end stage renal disease (need for dialysis or renal transplantation).

2. BEFORE YOU USE LOSARTAN POTASSIUM TABLETS

It is contraindicated in patient with known hypersensitivity to losartan or to any of excipients. It is also contra-indicated during pregnancy and lactation. Losartan Potassium should be discontinued as soon as possible, when pregnancy is suspected. Do not co-administer aliskiren with losartan in patients with diabetes. Do not take if any of the above apply to you. If you are not sure, talk to your physician, pharmacist or nurse before having losartan potassium tablets.

Take special care with losartan potassium tablets: Warnings and Precautions: Talk to your physician before taking Losartan potassium tablets. Hypotension volume-depleted patients: intravascularly volume-depleted (e.g., those treated with diuretics), symptomatic hypotension may occur after initiation of therapy with losartan. These conditions should be corrected prior to administration of losartan, or a lower starting dose should be used. Potassium Supplements: A patient receiving losartan should be told not to use potassium supplements or salt substitutes containing potassium without consulting the prescribing physician. Electrolyte Imbalance:

Electrolyte imbalances are common in patients with renal impairment, with or without diabetes, and should be addressed. In a clinical study conducted in type 2 diabetic patients with proteinuria, the incidence of hyperkalemia was higher in the group treated with losartan as compared to the placebo group; however, few patients discontinued therapy due to hyperkalemia. Impaired Hepatic Function: A lower dose should be considered for patients with impaired liver function. Impaired Renal Function: As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function have been reported in susceptible individuals treated with losartan; in some patients, these changes in renal function were 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 azotemia and (rarely) with acute renal failure and/or death. Similar outcomes have been reported with losartan. In studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen (BUN) have been reported. Similar effects have been reported with losartan; in some patients, these effects were reversible upon discontinuation of therapy. Pediatric Use: Limited pharmacokinetic data are available in hypertensive children above one month of age. Losartan is not recommended for use in children under 6 years old. It is not recommended in children with hepatic impairment. Geriatric Use: No overall differences in effectiveness or safety were observed in controlled clinical studies between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Using other medicines: Tell your physician if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines such as certain diuretics (amiloride, triamteren, spironolactone), or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with Losartan Potassium is not advisable. Take particular co-administered with losartan potassium: other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by class of drugs: tricyclic antidepressants, antipsychotics, baclofen, amifostine, non-steroidal anti-inflammatory drugs such as indomethacin, including Cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan. If patients are taking an ACE–inhibitor or aliskiren if your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function. Lithium containing medicines should not be taken in combination with losartan without close supervision by your physician. Special precautionary measures (e.g. blood tests) may be appropriate. **Using Losartan Potassium Tablets with food and drink:** It may be taken with or without food.

Pregnancy and breast-feeding: Before taking any medicine for advice consult to direction of **physician. Pregnancy:** It is contra-indicated pregnancy therefore it should not be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Use in breast-feeding:** Tell your physician if you are breast-feeding or about to start breast-feeding**.** It is not recommended for mothers who are breast-feeding, and your physician may choose another treatment for you if you wish to breast-feed, especially if your baby is a new-born or born prematurely.

Driving and using machines: No studies on the effects on the ability to drive and use machines have been performed. It is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your physician before attempting such activities.

Important information about some of the ingredients of Losartan potassium tablets contains Each film coated tablet contains lactose monohydrate, patients with rare hereditary problems of galactose intolerance, total-lactase deficiency or glucose-galactose malabsorption should not take this medicine. Talk to your physician.

3. HOW TO USE LOSARTAN POTASSIUM TABLETS

It should be taken as directed by physician. Take your normal dose immediately and continue taking your tablets at the usual time of day, do not take a double dose to make up for the missed dose. Do not change your usual dose without talking to physician. **Method of administration:** For oral use only. It may be taken with or without food or as directed by physician. It should be swallowed with a glass of water. **The usual recommended doses: Adult Hypertensive Patients:** Losartan may be administered with other antihypertensive agents, and with or without food. Dosing must be individualized. The usual starting dose is 50 mg once daily, with 25 mg used in patients with possible depletion of intravascular volume (e.g., patients treated with diuretics) and patients with a history of hepatic impairment. It can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg. If the antihypertensive effect measured at trough using once-a-day dosing is inadequate, a twice-a-day regimen at the same total daily dose or an increase in dose may give a more satisfactory response. The effect of losartan is substantially present within one week but in some studies the maximal effect occurred in 3-6 weeks**.** If blood pressure is not controlled by losartan potassium alone, a low dose of a diuretic may be added. Hydrochlorothiazide has been shown to have an additive effect. No initial dosage adjustment is necessary for elderly patients or for patients with renal impairment, including patients on dialysis.

Pediatric population use: Above one month of age: Limited pharmacokinetic data are available in hypertensive children above one month of age. Losartan is not recommended for use in children under 6 years old**. Children and adolescents aged 6-18 years old:** There are limited data on the efficacy and safety of Losartan Potassium children and adolescents aged 6-18 years old for the treatment of hypertension. **Pediatric Hypertensive Patients ≥6 years of age:** The usual recommended starting dose is 0.7 mg/kg once daily (up to 50 mg total) administered as a tablet or a suspension. Dosage should be adjusted according to blood pressure response. Doses above 1.4 mg/kg (or in excess of 100 mg) daily have not been studied in pediatric patients**.** It is not recommended in pediatric patients <6 years of age or in pediatric patients with glomerular filtration rate <30 mL/min/1.73 m^2. **Hypertensive Patients with Left Ventricular Hypertrophy:** The usual starting dose is 50 mg once daily. Hydrochlorothiazide 12.5 mg daily should be added and/or the dose of losartan potassium should be increased to 100 mg once daily followed by an increase in hydrochlorothiazide to 25 mg once daily based on blood pressure response. **Use in Elderly:** Although consideration should be given to initiating therapy with 25 mg in patients over 75 years of age, dosage adjustment is not usually necessary for the elderly**.**

If you more Losartan potassium tablets than you should: Limited data are available in regard to over dosage in humans. If you accidentally take too many tablets, contact your Physician immediately. The most likely manifestation of over dosage 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 its active metabolite can be removed by hemodialysis.

If you forget to Losartan potassium tablets: If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Following less frequent adverse effects have been reported. Dizziness, low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics), dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lyingor sitting position, debility, fatigue, too little sugar in the blood (hypoglycaemia), too much potassium in the blood (hyperkalaemia), changes in kidney function including kidney failure, reduced number of red blood cells (anaemia), increase in blood urea, serum creatinine and serum potassium in patients with heart failure. ***Uncommon:*** somnolence, headache, sleep disorders, feeling of increased heart rate (palpitations), severe chest pain (angina pectoris), shortness of breath (dyspnoea), abdominal pain, obstipation, diarrhoea, nausea, vomiting, hives (urticaria), itching (pruritus), rash, localised swelling (oedema), cough. ***Rare:*** Hypersensitivity, angioedema, inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura), numbness or tingling sensation (paraesthesia), fainting (syncope), very rapid and irregular heartbeat (atrial fibrillation), brain attack (stroke), inflammation of the liver (hepatitis), elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment. ***Not known:*** reduced number of thrombocytes, migraine,liver function abnormalities, muscle and joint pain, flu-like symptoms, back pain and urinary tract infection, increased sensitivity to the sun (photosensitivity), unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis), impotence, inflammation of the pancreas (pancreatitis), low levels of sodium in the blood (hyponatraemia), depression, generally feeling unwell (malaise), ringing, buzzing, roaring, or clicking in the ears (tinnitus) disturbed taste (dysgeusia).Side effects in children are similar to those seen in adults.

5. HOW TO STORE LOSARTAN POTASSIUM TABLETS

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. Do Not Freeze. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as losartan potassium USP. Excipients: Microcrystalline Cellulose (pH 102), Lactose Monohydrate,Croscarmellose Sodium, Magnesium Stearate, Colloidal Anhydrous Silica, Dichloromethane, Isopropyl Alcohol, Colour Erythrosine SC-SP-2006. Pack size: Pink coloured, round shaped, biconvex, film coated tablet, plain on both sides., tablets filled in Alu-Alu Blister Pack.10 Tablets are in Alu-Alu Blister Pack. Such 3 Alu-Alu blisters are packed in a printed carton along with packing insert

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