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Package Insert

SARANTO 100

(Losartan Potassium Tablets 100 mg)

Rx Only

NAME OF DRUG PRODUCT:

Losartan Potassium Tablets 100 mg)

(TRADE) NAME OF PRODUCT:

SARANTO 100

STRENGTH: 100 mg

PHARMACEUTICAL DOSAGE FORM: Tablet.

QUALITATIVE AND QUANTITATIVE COMPOSITIONS:

Losartan Potassium Tablets 100 mg

Each film-coated tablet contains Losartan Potassium Ph.Eur. 100 mg.

PRODUCT DESCRIPTION:

Losartan Potassium Tablets 100 mg: White to off-white, oval shaped, biconvex film-coated tablets debossed with 'E' on one side and '47' on the other side.

CLINICAL PARTICULARS:

Pharmacodynamics/Pharmacokinetics

Pharmacodynamics:

Losartan inhibits systolic and diastolic pressor responses to angiotensin II infusions. At peak, 100 mg of losartan potassium inhibits these responses by approximately 85%; 24 hours after single and multiple – dose administration, inhibition is about 26-39%.

During losartan administration, removal of angiotensin II negative feedback on rennin secretion leads to increased plasma rennin activity. Increases in plasma rennin activity lead to increases in angiotensin II in plasma. During chronic (6 weeks) treatment of hypertensive patients with 100 mg/day losartan, approximately 2-3 fold increases of plasma angiotensin II were observed at time of peak plasma drug concentrations. In some patients, greater increases were observed particularly during short term (2 weeks) treatment. However, antihypertensive activity and suppression of plasma aldosterone concentration were apparent at 2 and 6 weeks, indicating effective angiotensin II receptor blockade. After discontinuation of losartan, plasma renin activity and angiotension II levels declined to untreated levels within 3 days. Since losartan is a specific antagonist of the angiotensin II receptor type AT1, it does not inhibit ACE (kininase II), the enzyme that degrades bradykinin. Plasma concentrations of losartan and its active metabolite and the antihypertensive effect of losartan increase with increasing dose. Since losartan and its active metabolite are both angiotensin II receptor antagonists, they both contribute to the antihypertensive effect. Losartan has no effect on autonomic reflexes and no sustained effect on plasma norepinephrine. Losartan potassium, administered in doses of upto 150 mg once daily, did not cause clinically important changes in fasting triglycerides, total cholesterol or HDL-cholesterol in patients with hypertension. The same doses of losartan had no effect on fasting glucose levels. Generally losartan caused a decrease in serum uric acid (usually <0.4 mg/dL) which has persistent in chronic therapy.

Pharmacokinetic properties

Absorption

Following oral administration, Losartan is well absorbed and undergoes first-pass metabolism, forming an active carboxylic acid metabolite and other inactive metabolites. The systemic bioavailability of Losartan tablets is approximately 33%. Mean peak concentrations of Losartan and its active metabolite are reached in 1 hour and in 3-4 hours, respectively.

Distribution

Both Losartan and its active metabolite are 99% bound to plasma proteins, primarily albumin. The volume of distribution of Losartan is 34 litres.

Biotransformation

About 14% of an intravenously or orally administered dose of Losartan is converted to its active metabolite. Following oral and intravenous administration of ¹⁴C-labelled Losartan Potassium, circulating plasma radioactivity primarily is attributed to Losartan and its active metabolite. In addition to the active metabolite, inactive metabolites are formed, including two major metabolites formed by hydroxylation of the butyl side chain and a minor metabolite, an N-2 tetrazole glucuronide.

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 the urine, and about 6% of the dose is excreted in the urine as active metabolite. The pharmacokinetics of Losartan and its active metabolite are linear with oral Losartan Potassium doses up to 200 mg.

Following oral administration, plasma concentrations of Losartan and its active metabolite decline polyexponentially with a terminal half-life of about 2 hours and 6-9 hours,

respectively. During once daily dosing with 100 mg, neither Losartan nor its active metabolite accumulates significantly in plasma.

Indication

Hypertension

Losartan Potassium is indicated for the treatment of hypertension.

Hypertensive patients with Left Ventricular Hypertrophy

Losartan Potassium 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

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 Potassium reduces the rate of progression of neuropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.

Recommended Dose

The starting and maintenance dose is 50 mg once daily for most patients.

Mode of Administration

Losartan Potassium may be administered with or without food.

Losartan Potassium may be administered with other antihypertensive agents.

Hypertension

The usual starting and maintenance dose is 50 mg once daily for most patients. The maximal antihypertensive effect is attained 3-6 weeks after initiation of therapy. Some patients may receive an additional benefit by increasing the dose to 100 mg once daily.

For patients with intravascular volume depletion (eg., those treated with high dose diuretics), a starting dose of 25 mg once daily should be considered. (see Precautions)

No initial dosage adjustment is necessary for elderly patients or for patients with renal impairment, including patients on dialysis. A lower dose should be considered for patients with a history of hepatic impairment. (see Precautions)

Hypertensive Patients with Left Ventricular Hypertrophy

The usual starting dose is 50 mg of Losartan Potassium tablets once daily. A low dose of hydrochlorothiazide should be added and/or the dose of Losartan potassium should be increased to 100 mg once daily based on blood pressure response.

Renal Protection in Type 2 Diabetic Patients with Proteinuria and Hypertension

The usual starting dose is 50 mg once daily. The dose may be increased to 100 mg daily based on blood pressure response. Losartan Potassium 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., sulfonylureas, glitazones and glucosidase inhibitors)

Contraindication

Concomitant use of (active ingredient of ARB) with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/ min/1.73 m²)

Losartan Potassium is contraindicated in pregnancy and in patients who are hypersensitive to any component of this product.

Warning and Precautions

Hypersensitivity:

Angioedema.

Losartan Potassium in patients with haemodynamically significant obstructive valvular disease or cardiomyopathy.

Hypotension and electrolyte/fluid im-balance

In patients who are intravascularly volume depleted (e.g. those treated with high-dose diuretics), symptomatic hypotension may occur. These conditions should be corrected prior to administration of Losartan Potassium or a lower starting dose should be used. In patients who are intravascularly volume-depleted, these conditions should be corrected prior to administration of Losartan Potassium. Electrolyte imbalances are common in patients with renal impairment, with or without diabetes, and should be addressed.

Liver function impairment

Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of losartan in cirrhotic patients, a lower dose should be considered for patients with a history of hepatic impairment.

Renal function impairment

As a consequence of inhibiting the renin angiotensin system, changes in renal function including renal failure have been reported in susceptible individuals; these changes in renal function may be reversible upon discontinuation of therapy.

Other drugs that effect 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

A/s: 210 x 300 mm ■ Black Booklet Size: 35 x 60 mm

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		SARANTO Tablets	Leaflet	P1541923	05.03.2026 & 02.50 pm
		Country	Version No.	Reason Of Issue	Reviewed / Approved by
		Malaysia U3	00	Submission	
Team Leader	Kiran.k	Dimensions (mm)	No Of Colours: 01		
Initiator	Arun	A/s: 210 x 300 mm	41923		
Artist	Designers Ashok	Pharma Code: 41923			
Additional Information:					
Supersede item Code: P1514418					

solitary kidney.

Race (Black patients):

Losartan Potassium may reduce the risk of stroke in black patients with hypertension and left ventricular hypertrophy.

Interaction with other Medicaments

ACE inhibitors: The use of (active ingredient of ARB) with an ACE inhibitor may increase the risk of hyperkalaemia, hypotension, and syncope, particularly in patients with atherosclerotic disease or heart failure, or in diabetics who have end–organ damage. Such combinations should be reserved for selected cases with close monitoring of renal function.

No drug interactions occur with hydrochlorothiazide, digoxin, warfarin, cimetidine, ketoconazole, erythromycin and phenobarbital (phenobarbitone). Rifampicin and fluconazole reduce levels of active metabolite.

As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium.

As with other drugs which affect the excretion of sodium, lithium excretion may be reduced. Therefore, serum lithium levels should be monitored carefully if lithium salts are to be co-administered with angiotensin II receptor antagonists.

Non-steroidal anti-inflammatory drugs (NSAIDs) including selective cyclooxygenase-2 inhibitors (COX-2 inhibitors) may reduce the effect of diuretics and other antihypertensive drugs. 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 cyclooxygenase-2 inhibitors, the co-administration of angiotensin II receptor antagonists may result in a further deterioration of renal function. These effects are usually reversible.

Pregnancy and Lactation

Pregnancy

When used pregnancy during the second and third trimesters, drugs that act directly on the renin angiotensin system can cause injury and even death in the developing foetus. When pregnancy is detected, Losartan Potassium Tablets should be discontinued as soon as possible.

Lactation

It is not known whether losartan is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Side Effects

Dizziness may occur. In addition, dose-related orthostatic effects may be seen.

The most common drug-related side effects were dizziness, asthenia/fatigue and vertigo. Losartan Potassium was generally well tolerated in type 2 diabetic patients with nephropathy. The most common drug-related side effects were asthenia/fatigue, dizziness, hypotension and hyperkalaemia.

The following adverse reactions may occur:

Hypersensitivity: Anaphylactic reactions, angioedema including swelling of the larynx and glottis causing airway obstruction and/or swelling of the face, lips, pharynx, and/or tongue occur rarely in patients treated with Losartan; some of these patients previously experienced angioedema with other drugs including ACE inhibitors. Vasculitis, including Henoch-Schonlein purpura, may occur rarely.

Gastro-intestinal: Hepatitis (rarely), diarrhoea, and liver function abnormalities.

Haematologic: Anaemia, thrombocytopenia.

Musculoskeletal: Myalgia, arthralgia.

Nervous system/Psychiatric: Migraine.

Respiratory: Cough.

Skin: Urticaria, pruritus, erythroderma, photosensitivity.

Symptoms and Treatment of Overdose

The most likely manifestation of overdosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension may occur, supportive treatment should be instituted. Neither Losartan nor the active metabolite can be removed by haemodialysis.

Shelf life

36 months.

Storage Condition

Store at temperature below 30°C.

Nature and contents of container

Blister pack of 30's (3 x 10's) and 100's (10 x 10's).

Manufactured by:



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