BEPSAR Tablets

(Losartan Potassium Tablet USP)

COMPOSITION:
Each film coated tablet contains:
Losartan Potassium USP ... 25mg or 50mg.
[USP Specs.]

PHARMACODYNAMICS:
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 Potassium prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan Potassium slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

PHARMACOKINETIC:
Absorption: Following oral administration, Losartan Potassium is well absorbed and undergoes first-pass metabolism, forming an active carboxylic acid metabolite and other inactive metabolites. The systemic bioavailability of Losartan Potassium tablets is approximately 33%. Mean peak concentrations of Losartan Potassium and its active metabolite are reached in 1 hour and in 3-4 hours, respectively.
Distribution: Both Losartan Potassium and its active metabolite are ≥ 99% bound to plasma proteins, primarily albumin. The volume of distribution of Losartan Potassium is 34 litres.
Elimination: Plasma clearance of Losartan Potassium and its active metabolite is about 600ml/min and 50ml/min, respectively. Renal clearance of Losartan Potassium and its active metabolite is about 74ml/min and 26ml/min, respectively. When Losartan Potassium 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.

THERAPEUTIC INDICATIONS:
Treatment of essential hypertension in adults and in children and adolescents 6-18 years of age.
Treatment of renal disease in adult patients with hypertension and type 2 diabetes mellitus with proteinuria ≥ 0.5g/day as part of an antihypertensive treatment.
Treatment of chronic heart failure in adult patients when treatment with Angiotensin-converting enzyme (ACE) inhibitors is not considered suitable due to incompatibility, especially cough or contra-indication.
Reduction in the risk of stroke in adult hypertensive patients with left ventricular hypertrophy documented by ECG.

CONTRA-INDICATIONS:
Hypersensitivity to the active substance or to any of the excipients of the product. 2nd and 3rd trimester of pregnancy. Also not recommended for mothers who are breastfeeding. Severe hepatic impairment. The concomitant use of Losartan Potassium with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60ml/min/1.73m^2).

DOSAGE AND ADMINISTRATION:
BEPSAR tablet should be swallowed with a glass of water and may be administered with or without food.
Hypertension: The usual starting dose is 25mg and maintenance dose is 50mg 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 100mg once daily (in the morning).
Hypertensive type II diabetic patients with proteinuria ≥ 0.5g/day: Initially the usual starting dose is 25mg once daily and then 50mg once daily. The dose may be increased to 100mg once daily based on blood pressure response from one month onwards after initiation of therapy. Losartan Potassium may be administered with other antihypertensive agents (e.g. diuretics, calcium channel blockers, α- or β-blockers, and centrally acting agents).
Heart Failure: The usual initial dose of losartan in patients with heart failure is 12.5mg once daily and increased at weekly intervals to max. 150mg once daily if tolerated.
Elderly: Over 75 years initially 25mg daily.

WARNINGS AND PRECAUTIONS:
Patients with angioedema and electrolyte imbalances should be closely monitored. It is not recommended for children with GFR < 30ml/min. Concomitant use of Losartan Potassium and ACE inhibitors (like Captopril, Lisinopriletc) has shown to impair renal function.

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Special caution is indicated in patients suffering from aortic and mitral valve stenosis. Excessive blood pressure decrease in patients with ischaemic cardiovascular and cerebrovascular disease could result in a myocardial infarction or stroke. Losartan Potassium is not recommended in patients with hyperaldosteronism.ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy. Special warning regarding excipients.Losartan Potassium contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactosemalabsorption should not take this medicine. **Effects on ability to drive and use machines:** No studies on the effects on the ability to drive and use machines have been performed. However, when driving vehicles or operating machinery it must be borne in mind that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy, in particular during initiation of treatment or when the dose is increased.

OVERDOSE:
In humans, the most likely manifestation of overdose would be hypotension and tachycardia. Bradycardia could occur from parasympathetic (vagal) stimulation.If symptomatic hypotension occur, supportive treatment should be instituted.

INTERACTION WITH OTHER MEDICINAL PRODUCTS:
Other antihypertensive agents may increase the hypotensive action of losartan. Concomitant use with other substances which may induce hypotension as an adverse reaction (like tricyclic antidepressants, antipsychotics, baclofen and amifostine) may increase the risk of hypotension.
As with other medicinal products that block angiotensin II or its effects, concomitant use of other medicinal products which retain potassium (e.g. potassium-sparing diuretics: amiloride, triamterene, spironolactone) or may increase potassium levels (e.g. heparin), potassium supplements or salt substitutes containing potassium may lead to increases in serum potassium. Co-medication is not advisable. Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with ACE inhibitors.

ADVERSE REACTIONS:
Adverse effects have been reported to be usually mild and transient and include dizziness and dose-related orthostatic hypotension. Impaired renal function and rarely, rash, angioedema and raised alanine aminotransferase may occur. Hyperkalemia and myalgia have been reported. Raised liver enzyme values occured rarely. Taste disturbances progressing to complete taste loss occur in patient receiving Losartan Potassium tablet for hypertension. Severe migraine has also been reported.

INSTRUCTIONS:
Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:
BEPSAR (Losartan Potassium) tablets 25mg & 50mg are available in a blister packs of 10'sx2.

بیپ سار گولیاں

(لوسارٹن پوٹاشیم)

اجزاءترکیب: بیپ سار (لوسارٹن پوٹاشیم) کی ہر فلم کوٹڈ گولی میں ۲۵ ملی گرام یا ۵۰ ملی گرام لوسارٹن پوٹاشیم شامل ہے۔

خوراک اور طریقہ استعمال: بیپ سار (لوسارٹن پوٹاشیم) بلند فشارِ خون میں استعمال کی جاتی ہے۔

اسکی عمومی خوراک ۲۵ ملی گرام یا ۵۰ ملی گرام روزانہ ہے۔ اگر ضروری ہو تو عمومی خوراک ۱۰۰ ملی گرام روزانہ تک بڑھائی جاسکتی ہے۔

۷۵ سال سے زائد عمر کے مریضوں کے لئے ابتدائی خوراک ۲۵ ملی گرام روزانہ تجویز کی جاتی ہے۔

ہدایات برائے استعمال: حاملہ خواتین اور دودھ پلانے والی مائیں اس دوا کا استعمال نہ کریں۔ بچوں میں دوا کا استعمال ممنوع ہے۔ ڈاکٹر کی ہدایت کے مطابق دوا استعمال کریں۔

احتیاط: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

طریقہ فراہمی: ۲۵ ملی گرام اور ۵۰ ملی گرام بیپ سار ۲ x ۱۰ گولیوں کے بلسٹر پیک میں فراہم کی جاتی ہیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.
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