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LOSARTAN POTASSIUM + AMLODIPINE

AMLOZAAR

50 mg / 5 mg

Film-Coated Tablet

ANGIOTENSIN II RECEPTOR BLOCKER/
CALCIUM CHANNEL BLOCKER

PRODUCT NAME :
Amlozaar

DOSAGE FORM AND STRENGTH :
Losartan Potassium 50 mg and Amlodipine 5 mg Tablets

PHARMACOLOGIC CATEGORY: Angiotensin II Receptor Blocker/ Calcium Channel Blocker

PRODUCT DESCRIPTION :
Yellow coloured, circular, biconvex, film-coated tablets with **MICRO** engraved on both surfaces.

FORMULATION/COMPOSITION :
Each film-coated tablet contains
Losartan Potassium USP ..... 50 mg
Amlodipine Besilate BP
equivalent to Amlodipine ..... 5 mg

PHARMACOKINETICS :
Losartan:
The oral bioavailability is about 30%. The peak plasma concentration close to 800 nanograms per mL is reached within one hour after oral intake of 100 mg. The peak of the active metabolite is 2 times that of Losartan & appears between 2 and 4 hours after dosing & contributes to the late phase of the activity. The curve of plasma concentrations does not seem unaffected by food intake. The binding of Losartan and its active metabolite to plasma proteins (mainly albumin) is 99%. The plasma half life of Losartan is about 2 hours and that of its metabolites is between 6 & 9 hours. Losartan is metabolized by the liver into an active metabolite-5 carboxylic acid which is subsequently degraded. About 30 to 40% of the orally administered dose is recovered in the urine as unchanged drug & active metabolite. About 50 to 60% of orally administered dose is recovered in the feces.
Amlodipine:
After oral administration of the therapeutic doses, Amlodipine is totally absorbed. The absolute bioavailability of Amlodipine ranges from 64 to 80%. The plasma peak is delayed, occurring 6 to 12 hours after dosing. The terminal elimination half life is about 35 to 50 hours & is consistent with once daily dosing. Steady state plasma levels are reached after 7 to 8 days of consecutive dosing. Amlodipine is almost entirely metabolized to inactive metabolites. 10% of the parent compound & 60% of metabolites are excreted in urine *In vitro* studies have shown that circulating Amlodipine is bound to 97.5% of plasma proteins.

INDICATIONS :
For the treatment of mild to moderate hypertension in patients whose blood pressure is not adequately controlled on either monotherapy.

DOSAGE AND MODEL ROUTE OF ADMINISTRATION :
The recommended dosage is one tablet once a day or as directed by the physician.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S) :
Losartan and Amlodipine are contraindicated in patients with known hypersensitivity to Amlodipine and Losartan Potassium. It is also contraindicated in pregnant women (in their 2nd and 3rd trimester) and nursing mothers.

Rarely, patients with coronary arterial obstruction develop a high frequency of angina and myocardial infarction. The mechanism of this effect has not been elucidated.

PREGNANCY AND LACTATION :
Losartan
Pregnancy: The use of losartan is not recommended during the first trimester of pregnancy. The use of losartan is contra-indicated during the 2nd and 3rd trimester of pregnancy.
Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with Angiotensin II Receptor Inhibitors (AIIRAs), similar risks may exist for this class of medicinal products. Unless continued AIIRA therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with losartan should be stopped immediately and, if appropriate, alternative therapy should be started.
Exposure to AIIRA therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, and hyperkalaemia).
Should exposure to losartan have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Lactation: Because no information is available regarding the use of losartan during breastfeeding, losartan is not recommended and alternative treatments with better established safety profiles during breastfeeding are preferable, especially while nursing a newborn or preterm infant.
Amlodipine: Although some Dihydropyridines compounds have been found to be teratogenic in animals, data it he rat and rabbit for amlodipine provide no evidence for a teratogenic effect. There is, however, no clinical experience with the preparation in pregnancy. Accordingly, amlodipine should not be administered during pregnancy or to women of childbearing potential unless effective contraception is used.
Lactation: Although some Dihydropyridines compounds have been found to be teratogenic in animals, data in the rat and rabbit for amlodipine provide no evidence for a teratogenic effect. There is, however, no clinical experience with the preparation in lactation. Accordingly, amlodipine should not be administered during lactation

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INTERACTIONS :
No significant interactions are observed when Amlodipine is co-administered with thiazide diuretics, beta blockers, ACE (angiotensin-converting enzyme) inhibitors, and nitrates, anti-inflammatory drugs, antibiotics & oral hypoglycemic. Cimetidine does not alter the pharmacokinetics of Amlodipine. Amlodipine did not alter plasma levels of digoxin, phenytoin, warfarin & indometacin (INN).

ADVERSE EFFECTS :
Losartan and Amlodipine are well tolerated. The most commonly observed adverse effects were diarrhea, dyspepsia, myalgia, oedema, dizziness, insomnia & headache.

OVERDOSAGE AND TREATMENT :
Losartan:
Symptoms of intoxication
Limited data are available with regard to overdose in humans. The most likely manifestation of overdose would be hypotension and tachycardia. Bradycardia could occur from parasympathetic (vagal) stimulation.
Treatment of intoxication
If symptomatic hypotension should occur, supportive treatment should be instituted. Measures are depending on the time of medicinal product intake and kind and severity of symptoms. Stabilization of the cardiovascular system should be given priority. After oral intake, the administration of a sufficient dose of activated charcoal is indicated. Afterwards, close monitoring of the vital parameters should be performed. Vital parameters should be corrected if necessary. Neither losartan nor the active metabolite can be removed by hemodialysis.
Amlodipine: Available data suggest that gross over dosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome have been reported. Administration of activated charcoal to healthy volunteers immediately or up to two hours after ingestion of amlodipine 10mg has been shown to significantly decrease amlodipine absorption.
In humans, experience with intentional overdose is limited. Gastric lavage may be worthwhile in some cases. Clinically significant hypotension due to amlodipine over dosage calls for active cardiovascular support including frequent monitoring of cardiac and respiratory function, elevation of extremities, and attention to circulating fluid volume and urine output. A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

STORAGE CONDITION :
Store at temperatures not exceeding 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE :
Losartan Potassium 50 mg and Amlodipine 5 mg Tablet (Amlozaar)
Packed in Alu/Alu Blister pack by 10's (Box of 30's and 100's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE) :
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER :
Marketing Authorization Holder
Brown & Burk Philippines Inc
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.,
Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER :
MICRO LABS LIMITED
92, SIPCOT, HOSUR – 635 126,
TAMIL NADU, INDIA

CAUTION STATEMENT :
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT :
FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER :
DRP-6349

DATE OF FIRST AUTHORIZATION :
25 May, 2015

DATE OF REVISION OF PACKAGE INSERT :
May 2020

EXG-ML01I-1211/A

Size: 120 (L) x 240 (H) mm
Folding size: 30 x 120 mm
Carton size: 53 x 25 x 130 mm