SWISS PHARMA

Module 1- Administrative information and prescribing information

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

1.3.1 Summary Product Characteristics (SPC)

1 NAME OF THE MEDICINAL PRODUCT

LOSARMAX-50 (Losartan Potassium Tablets 50 mg), 50 mg per Tablets, film coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains	
Losartan Potassium USP	50 mg
Excipients	Q.S.

Kindly refer section 6.1 for full list of Excipients.

3 PHARMACEUTICAL FORM

White coloured oval shaped biconvex film coated tablet with break line on one side & plain on other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Losartan is indicated for the treatment of hypertension. Losartan is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy.

4.2 Posology and method of administration

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. 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. No initial dosage adjustment is necessary for the elderly patients or for patient with renal impairment, including patients on dialysis. A lower dose should be considered for patients with a history of hepatic impairment. Losartan may be administered with other antihypertensive agents of a different class. Losartan may be administered with or without food.

4.3 Contraindications

Losartan is contraindicated inpatients who are hypertensive to any component of this products.

4.4 Special warnings and precautions for use

Women of child bearing age should ensure adequate contraception.

Losartan contra-indication in pregnancy and should be used with care, if at all, during breast-feeding. Losartan should be used with caution in patients with bilateral renal artery stenosis or stenosis of an artery to a single kidney, aortic valve stenosis or hypertrophic obstructive cardiomyopathy. Symptomatic hypotension may occur

after initiation of losartan. Reduced doses must be considered in patients with hepatic impairment.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations containing any of the following medications, depending on the amount present, may also interact with Losartan:

Non-steroidal anti-inflammatory drugs (NSAIDs) may antagonize the anti-hypertensive effect of Losartan.

Concurrent use with sympathomimetics may reduce the anti-hypertensive effects of Losartan.

Potassium-sparing diuretics, potassium containing medication or potassium supplements used concurrently with Losartan may result in hyperkalaemia since reduction of aldosterone production induced by Losartan may lead to elevation of serum potassium

4.6 Pregnancy and lactation

Pregnancy:

Losartan should be discontinued as soon as possible, when pregnancy is suspected.

Losartan should not be used in pregnancy as teratogenicity has been shown in experimental animals.

Lactation:

Safety has not been established.

4.7 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.

4.8 Undesirable effects

The following side-effects may occur:

Blood and lymphatic system disorders: Symptomatic anaemia, neutropenic

Nervous system disorders: Headache, Dizziness, Insomnia, Migraine

Cardiac disorders: Palpitations, tachycardia

Vascular disorders: Hypotension

Respiratory, thoracic and mediastinal disorders: Cough, nasal congestion, pharayngitis, upper respiratory infection, Sinus disorder

Gastrointestinal disorder: Diarrhoea, Dyspepsia, nausea, acute pancreatitis, abdominal pain, taste disturbances, complete taste loss

Hepato-biliary disorders: Severe acute hepatotoxicity, cholestasis

Skin and subcutaneous tissue disorders: Urticaria, rash, atypical cutaneous lymphoid infiltrates. Angioedema (involving swelling of the face, lips and/or tongue) has been reported in patients treated with losartan

Muscukoskeletal, connective tissue and bone disorders: Back pain, Muscle cramps, leg pain, Myalgia.

Renal and urinary disorders: Impaired renal function.
General disorders and administrative site conditions: Fatigue, Chest pain, oedema/swelling, asthenia.

4.9 Overdose

Limited data are available in regard to overdose in humans. The most likely manifestation of overdosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Angiotensin II antagonists, plain
ATC code: C09CA01
Losartan is a nonpeptide angiotensin II receptor antagonist with high affinity and selectivity for the AT1 receptor, without binding to or blocking other hormone receptors or ion channels important in cardiovascular regulation. Angiotensin II is a potent vasoconstrictor, a primary active hormone of the renin-angiotensin system, and a major determinant of pathophysiology of hypertension. Losartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by inhibiting the binding of angiotensin II to the AT1 receptor.

5.2 Pharmacokinetic properties

Following oral administration, bioavailability is approximately 33%. It undergoes first pass metabolism to form an active carboxylic acid metabolite, (Which has greater pharmacological activity than losartan) and some inactive metabolites. About 14% of an intravenously or orally administered dose is converted to its active metabolite. The mean peak concentrations of losartan and its active metabolite are reached in 1 hour and 3-4 hours, respectively.
Both losartan and carboxylic acid metabolite are greater than, or equal to 99% bound to plasma proteins. The distribution volume of losartan id 34 litres.
The terminal half-life of losartan is 2 hours and of its active metabolite is 6-9 hours.
Losartan is excreted in the urine, and in the faeces, as unchanged drug and metabolites. Following oral dosing, about 35% of the dose is excreted in the urine and about 60% in the faeces. Neither losartan nor the active metabolite can be removed by haemodialysis.
Plasma concentrations of losartan are not altered in patients with impaired renal function and a creatinine clearance above 10ml/min. Compared to patients with normal renal function, the AUC for losartan is approximately 2-fold greater in patients on haemodialysis.

5.3 Preclinical safety data

No In-House preclinical study has been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Micro Crystalline Cellulose
Starch
Polyvinyl pyrrolidone (P.V.P.K 30)
Magnesium stearate
Purified Talc
Fumed Silica
Croscarmellose sodium
Sodium Lauryl Sulphate
Hydroxypropyl methyl cellulose
Polyethylene Glycol 4000
Titanium Dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a dark, dry place, Not exceeding 30°C temp.

6.5 Nature and contents of container

3 x 10 Tablets Alu-Alu Pack

6.6 Special precautions for disposal and other handling

No Special Requirements

7. APPLICANT/ MANUFACTURER

MANUFACTURED BY:

SWISS PHARMA PVT. LTD.
3709, G.I.D.C. Phase IV, Vatva,
City: Ahmedabad –382445, Dist.: Ahmedabad
Gujarat State, India
www.swisspharma.in
Telephone No. +91 (079) 2584 2852, 2584 1418.
Email: exports@swisspharma.in