



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Losartan Potassium Tablets USP, 25 mg, 50 mg and 100 mg
Manufacturer	Hetero Labs Limited Unit V Unit V, APIIC Formulation SEZ, Survey. No 439, 440, 441 & 458, Polepally Village, Jadcherla (Mandal), MahaboobNagar (District). Pin-509301, Telangana, India
Distributor	Camber Pharmaceuticals, Inc., Piscatway, NJ 08854

Section 2: Hazard(s) Identification

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Dose and Administration

Adult Hypertensive Patients:

Losartan potassium tablets may be administered with other antihypertensive agents, and with or without food.

Dosing must be individualized. The usual starting dose of losartan potassium tablets is 50 mg once daily, with 25 mg used in patients with possible depletion of intravascular volume and patients with a history of hepatic impairment. Losartan potassium tablets can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg.

Pediatric Hypertensive Patients \geq 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.

Adverse Effects

Body as a Whole: Facial edema, fever, orthostatic effects, Cardiovascular: Angina pectoris, second degree AV block, CVA, hypotension, myocardial infarction, arrhythmias including atrial fibrillation, palpitation, sinus bradycardia, tachycardia, ventricular tachycardia, ventricular fibrillation

Digestive: Anorexia, constipation, dental pain, dry mouth, flatulence, gastritis, vomiting

Hematologic: Anaemia



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Metabolic: Gout

Musculoskeletal: Arm pain, hip pain, joint swelling, knee pain, musculoskeletal pain, shoulder pain, stiffness, arthralgia,

arthritis, fibromyalgia, muscle weakness

Nervous System/Psychiatric: Anxiety, anxiety disorder, ataxia, confusion, depression, dream abnormality, hypesthesia, decreased libido, memory impairment, migraine, nervousness, paraesthesia, peripheral neuropathy, panic disorder, sleep disorder, somnolence, tremor, vertigo

Respiratory: Dyspnea, bronchitis, pharyngeal discomfort, epistaxis, rhinitis, respiratory congestion

Skin: Alopecia, dermatitis, dry skin, ecchymosis, erythema, flushing, photosensitivity, pruritus, rash, sweating, urticaria

Special Senses: Blurred vision, burning/stinging in the eye, conjunctivitis, taste perversion, tinnitus, decrease in visual acuity

Urogenital: Impotence, nocturia, urinary frequency, urinary tract infection

Over Dose Effect

Significant lethality was observed in mice and rats after oral administration of 1000 mg/kg and 2000 mg/kg, respectively, about 44 and 170 times the maximum recommended human dose on a mg/m² basis.

Limited data are available in regard to overdosage 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.

Medical Conditions

In the unusual case that there is no appropriate alternative to therapy with drugs affecting the renin-angiotensin system for a particular patient, apprise the mother of the potential risk to the fetus. Perform serial ultrasound examinations to assess the intra-amniotic environment.

If oligohydramnios is observed, discontinue losartan potassium, unless it is considered life-saving for the mother. Fetal testing may be appropriate, based on the week of pregnancy. Patients and physicians should be aware,



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however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Closely observe infants with histories of in utero exposure to losartan potassium for hypotension, oliguria, and hyperkalaemia.

Losartan potassium has been shown to produce adverse effects in rat fetuses and neonates, including decreased body weight, delayed physical and behavioural development, mortality and renal toxicity. With the exception of neonatal weight gain (which was affected at doses as low as 10 mg/kg/day), doses associated with these effects exceeded 25 mg/kg/day (approximately three times the maximum recommended human dose of 100 mg on a mg/m² basis). These findings are attributed to drug exposure in late gestation and during lactation. Significant levels of losartan and its active metabolite were shown to be present in rat fetal plasma during late gestation and in rat milk.

Hypotension — Volume-Depleted Patients:

In patients who are intravascularly volume-depleted (e.g., those treated with diuretics), symptomatic hypotension may occur after initiation of therapy with losartan potassium tablets. These conditions should be corrected prior to administration of losartan potassium tablets, or a lower starting dose should be used.

Contraindications

Losartan potassium tablets are contraindicated in patients where hypersensitive to any component of this product.

Pregnancy Comments

Fetal/Neonatal Morbidity and Mortality:

Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature in patients who were taking angiotensin converting enzyme inhibitors. When pregnancy is detected, losartan potassium tablets should be discontinued as soon as possible.

The use of drugs that act directly on the renin-angiotensin system during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or



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irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to exposure to the drug.

These adverse effects do not appear to have resulted from intrauterine drug exposure that has been limited to the first trimester.

Mothers whose embryos and foetuses are exposed to an angiotensin II receptor antagonist only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should have the patient discontinue the use of losartan potassium tablets as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to an angiotensin II receptor antagonist will be found. In these rare cases, the mothers should be apprised of the potential hazards to their foetuses, and serial ultrasound examinations should be performed to assess the intra-amniotic environment.

If oligohydramnios is observed, losartan potassium tablets should be discontinued unless it is considered life-saving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of in utero exposure to an angiotensin II receptor antagonist should be closely observed for hypotension, oliguria, and hyperkalaemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function.



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Pregnancy Category	<p>Losartan potassium has been shown to produce adverse effects in rat fetuses and neonates, including decreased bodyweight, delayed physical and behavioral development, mortality and renal toxicity. With the exception of neonatal weight gain (which was affected at doses as low as 10mg/kg/day), doses associated with these effects exceeded 25 mg/kg/day (approximately three times the maximum recommended human dose of 100 mg on a mg/m² basis). These findings are attributed to drug exposure in late gestation and during lactation. Significant levels of losartan and its active metabolite were shown to be present in rat fetal plasma during late gestation and in rat milk.</p> <p>Pregnancy Categories C (first trimester) and D (second and Third trimesters)</p>
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Section 3: Composition/Information on Ingredients

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Ingredients	Losartan potassium
CAS	[124750-99-8]

Section 4: First-Aid Measures

Section 4, First-aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
Overdose Treatment	If symptomatic hypotension should occur, supportive treatment should be instituted. Neither losartan nor its active metabolite can be removed by hemodialysis.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.
Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire



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fighter should use self- contained breathing equipment and protective clothing.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Spill Response

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7: Handling and Storage

Section 7, Handling and storage

Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Keep container tightly closed. Protect from light.

Incompatibilities:

No Data available.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Respiratory Protection

Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection

Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection

Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing

Protective clothing is not normally necessary, however it is good practice to use apron.

Engineering Control

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9: Physical and Chemical Properties

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Physical Form

Losartan Potassium Tablets USP, 25 mg

Losartan potassium tablets USP, 25 mg are white to off-white, film coated, oval shaped tablets debossed with 'l' on one side and '5' on the other side.

Bottles of 30 Tablets (NDC 31722-700-30)

Bottles of 60 Tablets (NDC 31722-700-60)

Bottles of 90 Tablets (NDC 31722-700-90)

Bottles of 500 Tablets (NDC 31722-700-05)

Bottles of 1000 Tablets (NDC 31722-700-10)

Losartan Potassium Tablets USP, 50 mg

Losartan potassium tablets USP, 50 mg are white to off-white, film coated, oval shaped tablets debossed with 'l' on one side and '6' on the other side with score line.

Bottles of 30 Tablets (NDC 31722-701-30)

Bottles of 60 Tablets (NDC 31722-701-60)

Bottles of 90 Tablets (NDC 31722-701-90)

Bottles of 500 Tablets (NDC 31722-701-05)

Bottles of 1000 Tablets (NDC 31722-701-10)

Losartan Potassium Tablets USP, 100 mg

Losartan potassium tablets USP, 100 mg are white to off-white, film coated, tear drop shaped tablets debossed with 'H' on one side and '145' on the other side.

Bottles of 30 Tablets (NDC 31722-702-30)

Bottles of 60 Tablets (NDC 31722-702-60)

Bottles of 90 Tablets (NDC 31722-702-90)

Bottles of 500 Tablets (NDC 31722-702-05)

Bottles of 1000 Tablets (NDC 31722-702-10)

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Condition to avoid

Avoid exposure to extreme heat, light and moisture.

Stable

Stable under recommended storage conditions.

Section 11: Toxicological Information

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General

Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ

Refer contraindication and adverse effect.



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Other	Not available.
Section 12: Ecological Information	
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Do not allow product to enter drinking water supplies, waste water or soil	
Section 13: Disposal Considerations	
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Dispose the waste in accordance with all applicable Federal, State and local laws.	
Section 14: Transport Information	
Section 14: Transport Information	
The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).	
Section 15: Regulatory Information	
Section 15: Regulatory Information	
Generic Medicine. Approved by USFDA & the ANDA Number is 203835	
Section 16: Other Information	
Section 16: Other Information	
The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.	
Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.	