

Material Safety data sheet

LOSARTAN POTASSIUM TABLETS, USP

Losartan potassium 25 mg, tablets **Pack Size:** 30 , 90 , 1,000 and 10,000 Tablets per bottle

Losartan potassium 50 mg tablets **Pack Size:** 30 , 90 , 1,000 and 10,000 Tablets per bottle

Losartan potassium 100 mg tablets **Pack Size:** 30 , 90 , 1,000 and 5,000 Tablets per bottle

Revision No.: 00

EMERGENCY OVERVIEW

LOSARTAN POTASSIUM TABLETS contain Losartan Potassium and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name:	Losartan Potassium Tablets
Formula:	C ₂₂ H ₂₂ ClKN ₆ O
Chemical Name:	2-butyl-4-chloro-1-[p-(<i>o</i> -1 <i>H</i> -tetrazol-5-yl)phenyl]benzyl]imidazole-5-methanol monopotassium salt.
Therapeutic Category	Losartan potassium is an angiotensin II receptor (type AT ₁) antagonist

Manufacturer / supplier identification

Company:	Cadila Healthcare Ltd. Ahmedabad, India
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Losartan Potassium	Not Found	124750-99-8
Colloidal Silica Anhydrous	Not Found	99439-28-8
Hydroxypropyl Cellulose (Low Substituted)	Not Found	9004-64-2
Hypromellose	Not Found	9004-65-3
Lactose Monohydrate	Not Found	64044-51-5
Magnesium Stearate	Not Found	557-04-0
Maize Starch	Not Found	9005-25-8
Microcrystalline Cellulose	Not Found	9004-34-6
Polyethylene Glycol	Not Found	25322-68-3
Sodium Starch Glycolate	Not Found	9063-38-1

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Component	Exposure Limit	CAS No.
Talc	Not Found	14807-96-6
Titanium Dioxide.	Not Found	13463-67-7

Section 3. Health Hazards Information

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 ≥ 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, syncope

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: Anemia

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, paresthesia, 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

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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.

Contraindications

Losartan potassium tablets are contraindicated in patients who are 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 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 fetuses 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 fetuses, and serial ultrasound examinations should be performed to assess the intra-amniotic environment.

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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 hyperkalemia. 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.

Losartan potassium has been shown to produce adverse effects in rat fetuses and neonates, including decreased body weight, delayed physical and behavioral 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.

Pregnancy Category

Pregnancy Categories C (first trimester) and D (second and third trimesters)

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.

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Section 5. Fire – fighting measures

Flash point	Not Found	Upper Flammable Limit:	Not Found
Auto-Ignition Temperature:	Not Found	Lower Flammable Limit:	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	Fire and Explosion Hazard	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.
Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.		

Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20° to 25°C (68° to 77°F) Keep container tightly closed. Protect from light.
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.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and 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.

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Section 8. Physical and chemical properties

Appearance	Losartan Potassium Tablets USP, 25 mg are white to off-white, capsule-shaped, film-coated tablets debossed with the logo of “Z” on one side and “2” on other side		
	Losartan Potassium Tablets USP, 50 mg are white to off-white, capsule-shaped, film-coated tablets debossed with the logo of “Z16” on one side and plain on other side.		
	Losartan Potassium Tablets USP, 100 mg are white to off-white, capsule-shaped, film-coated tablets debossed with the logo of “Z18” on one side and plain on other side		
Odour	Odourless	Melting Point	No Data Available
Solubility in water	No Data Available	Vapour density	No Data Available
Boiling point	No Data Available	Evaporation rate	No Data Available
Evaporation rate	No Data Available	Specific gravity	No Data Available
Reactivity in water	No Data Available	Vapour pressure	No Data Available
% Volatile by volume	No Data Available		
Other information	Losartan potassium is off-white to creamish-yellow powder with a molecular weight of 461.01. It is soluble in water. Oxidation of the 5-hydroxymethyl group on the imidazole ring results in the active metabolite of losartan.		

Section 9. Physical Hazards

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	Hazardous Reaction	No data available.
Incompatibilities	No data available.		

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Section 10. Toxicological information

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.

other Not Available

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 22/01/10

Supersedes edition of: New Addition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.