EMERGENCY OVERVIEW
Each Losartan potassium tablets intended for oral administration contains 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

Identification of the product

Product name: Losartan Potassium Tablets, USP

Formula: C_{22}H_{22}ClKN_{6}O

Chemical Name: 2-butyl-4-chloro-1-[p-(1H-tetrazol-5-ylphenyl) benzyl]imidazole-5-methanol monopotassium salt.

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

Recommended use / Therapeutic Category Losartan potassium is an angiotensin II receptor (type AT_{1}) antagonist.
**Safety Data Sheet**  
**LOSARTAN POTASSIUM TABLETS, USP**

<table>
<thead>
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| **Restriction on Use / Contraindications:** | Losartan potassium tablets are contraindicated in patients who are hypersensitive to any component of this product. |

### Section 2. Hazard(s) 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, 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
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, 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 hyperkalemia.

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.

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 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.

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 3. Composition / information on ingredients**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principle Component :</strong></td>
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<td></td>
</tr>
<tr>
<td>Losartan Potassium</td>
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<td>124750-99-8</td>
</tr>
<tr>
<td><strong>Inactive Ingredients :</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colloidal Silica Anhydrous</td>
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<td>99439-28-8</td>
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<tr>
<td>Hydroxypropyl Cellulose (Low Substituted)</td>
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<td>9004-64-2</td>
</tr>
<tr>
<td>Hypromellose</td>
<td>Not Found</td>
<td>9004-65-3</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>Not Found</td>
<td>64044-51-5</td>
</tr>
</tbody>
</table>
## 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

### Flash point
Not Found

### Auto-Ignition Temperature:
Not Found

### Upper Flammable Limit:
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.
## Safety Data Sheet
LOSARTAN POTASSIUM TABLETS, USP

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### 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

#### Storage
Store at 20° to 25°C (68° to 77°F) Keep container tightly closed. Protect from light.

#### Incompatibilities:
No Data available.

### 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

#### 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.

| Strength: 25mg | Pack Size: 30, 90, 1000 and 10,000 Tablets per bottle |
| Strength: 50mg | Pack Size: 90, 100, 1000 and 10,000 Tablets per bottle |
| Strength: 100mg | Pack Size: 90, 100, 1000 and 5000 Tablets per bottle | Revision No.: 02 |

Solubility in water | No Data Available |
Boiling point | No Data Available |
Evaporation rate | No Data Available |
Reactivity in water | No Data Available |
% Volatile by volume | No Data Available |
Odour | Odourless |
Melting Point | No Data Available |
Vapour density | No Data Available |
Evaporation rate | No Data Available |
Specific gravity | No Data Available |
Vapour pressure | 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 10. Stability and Reactivity

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 |

Section 11. Toxicological information

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. |
Other | Not available. |

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration
Dispose the waste in accordance with all applicable Federal, State and local laws.

**Section 14. Transport Information**

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

**Section 15. Regulatory Information**

Generic Medicine. Approved by USFDA & the ANDA Number is 078243

**Section 16. Other information**

None

**Date of issue:** 28/05/2015  
**Supersedes edition of:** 01

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.