

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

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| Material | Losartan Potassium Tablets USP 25 mg, 50 mg, 100 mg |
| Manufacturer | Lupin Limited Goa 403 722 INDIA |
| Distributor | Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 st Floor 111, South Calvert Street Baltimore, MD 21202 United States Tel. 001-410-576-2000 Fax 001-410-576-2221 |

2. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients | CAS | Quantity |
|---------------------------|-------------|----------------------|
| Losartan Potassium | 124750-99-8 | 25 mg, 50 mg, 100 mg |
| Non-hazardous ingredients | ----- | q.s. |

3. HAZARDOUS IDENTIFICATION

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| Fire and Explosion | Assume that this product is capable of sustaining combustion. |
| Health | Losartan potassium tablets are contraindicated in patients who are hypersensitive to any component of this product. |
| Environment | No information is available about the potential of this product to produce adverse environmental effects. |

4. FIRST AID MEASURES

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| Ingestion | If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention. |
| Inhalation | Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance. |
| Skin Contact | Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs. |
| Eye Contact | Flush eyes with plenty of water. Get medical attention. |

NOTES TO HEALTH PROFESSIONALS

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.

Neither losartan nor its active metabolite can be removed by hemodialysis.

5. FIRE-FIGHTING MEASURES

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| Fire and Explosion Hazards | Assume that this product is capable of sustaining combustion. |
| Extinguishing Media | Water spray, carbon dioxide, dry chemical powder or appropriate foam. |
| Special Firefighting Procedures | For single units (packages): No special requirements needed. |
| Hazardous Combustion Products | Hazardous combustion or decomposition products are expected when the product is exposed to fire. |

6. ACCIDENTAL RELEASE MEASURES

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| Personal Precautions | Wear protective clothing and equipment consistent with the degree of hazard. |
| Environmental Precautions | For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. |
| Clean-up Methods | Collect and place it in a suitable, properly labeled container for recovery or disposal. |

7. HANDLING AND STORAGE

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| Handling | No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. |
| Storage | Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Keep container tightly closed. Protect from light. |

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL & CHEMICAL PROPERTIES

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| Physical Form | <p>Losartan Potassium Tablets USP, 25 mg are white, capsule shaped, biconvex film-coated tablets, debossed with 'LU' on one side and 'P21' on the other side. They are supplied as follows:</p> <p>NDC 68180-210-06 – Bottles of 30 NDC 68180-210-09 – Bottles of 90 NDC 68180-210-01 – Bottles of 100 NDC 68180-210-03 – Bottles of 1000</p> <p>Losartan Potassium Tablets USP, 50 mg are white, capsule shaped, biconvex film-coated tablets, debossed with 'LU' on one side and 'P22' on the other side. They are supplied as follows:</p> <p>NDC 68180-211-06 – Bottles of 30 NDC 68180-211-09 – Bottles of 90 NDC 68180-211-01 – Bottles of 100 NDC 68180-211-03 – Bottles of 1000</p> |
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Losartan Potassium Tablets USP, 100 mg are white, capsule shaped, biconvex film-coated tablets, debossed with 'LU' on one side and 'P23' on the other side. They are supplied as follows:

NDC 68180-212-06 – Bottles of 30
NDC 68180-212-09 – Bottles of 90
NDC 68180-212-01 – Bottles of 100
NDC 68180-212-03 – Bottles of 1000

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Losartan potassium was not carcinogenic when administered at maximally tolerated dosages to rats and mice for 105 and 92 weeks, respectively. Female rats given the highest dose (270 mg/kg/day) had a slightly higher incidence of pancreatic acinar adenoma. The maximally tolerated dosages (270 mg/kg/day in rats, 200 mg/kg/day in mice) provided systemic exposures for losartan and its pharmacologically active metabolite that were approximately 160- and 90-times (rats) and 30- and 15-times (mice) the exposure of a 50 kg human given 100 mg per day.

Losartan potassium was negative in the microbial mutagenesis and V-79 mammalian cell mutagenesis assays and in the *in vitro* alkaline elution and *in vitro* and *in vivo* chromosomal aberration assays. In addition, the active metabolite showed no evidence of genotoxicity in the microbial mutagenesis, *in vitro* alkaline elution, and *in vitro* chromosomal aberration assays.

Fertility and reproductive performance were not affected in studies with male rats given oral doses of losartan potassium up to approximately 150 mg/kg/day. The administration of toxic dosage levels in females (300/200 mg/kg/day) was associated with a significant ($p < 0.05$) decrease in the number of corpora lutea/female, implants/female, and live fetuses/female at C-section. At 100 mg/kg/day only a decrease in the number of corpora lutea/female was observed. The relationship of these findings to drug treatment is uncertain since there was no effect at these dosage levels on implants/pregnant female, percent post-implantation loss, or live animals/litter at parturition. In nonpregnant rats dosed at 135 mg/kg/day for 7 days, systemic exposure (AUCs) for losartan and its active metabolite were approximately 66 and 26 times the exposure achieved in man at the maximum recommended human daily dosage (100 mg).

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATION

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

14. TRANSPORT INFORMATION

The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, or ground transport purposes.

15. REGULATORY INFORMATION

No information found.

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.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.