Section 1: Identification

<table>
<thead>
<tr>
<th>Material</th>
<th>Losartan Potassium Tablets USP 25 mg, 50 mg and 100 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Lupin Limited</td>
</tr>
<tr>
<td></td>
<td>MADE IN INDIA</td>
</tr>
<tr>
<td>Distributor</td>
<td>Lupin Pharmaceuticals, Inc.</td>
</tr>
<tr>
<td></td>
<td>111 South Calvert Street,</td>
</tr>
<tr>
<td></td>
<td>Harborplace Tower, 21st Floor,</td>
</tr>
<tr>
<td></td>
<td>Baltimore, Maryland 21202</td>
</tr>
<tr>
<td></td>
<td>United States</td>
</tr>
<tr>
<td></td>
<td>Tel. 001-410-576-2000</td>
</tr>
<tr>
<td></td>
<td>Fax. 001-410-576-2221</td>
</tr>
</tbody>
</table>

Section 2: Hazard(s) Identification

<table>
<thead>
<tr>
<th>Fire and Explosion</th>
<th>Expected to be non-combustible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>Losartan potassium tablets are contraindicated:</td>
</tr>
<tr>
<td></td>
<td>• In patients who are hypersensitive to any component of this product.</td>
</tr>
<tr>
<td></td>
<td>• For coadministration with aliskiren in patients with diabetes</td>
</tr>
<tr>
<td>Environment</td>
<td>No information is available about the potential of this product to produce adverse environmental effects</td>
</tr>
</tbody>
</table>

Section 3: Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Losartan Potassium USP</td>
<td>124750-99-8</td>
</tr>
</tbody>
</table>

Section 4: First-Aid Measures

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.</th>
</tr>
</thead>
</table>

Section 1, Identification

Material

Losartan Potassium Tablets USP 25 mg, 50 mg and 100 mg

Manufacturer

Lupin Limited
MADE IN INDIA

Distributor

Lupin Pharmaceuticals, Inc.
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Harborplace Tower, 21st Floor,
Baltimore, Maryland 21202
United States
Tel. 001-410-576-2000
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Section 2, Hazard(s) identification

Fire and Explosion

Expected to be non-combustible

Health

Losartan potassium tablets are contraindicated:
• In patients who are hypersensitive to any component of this product.
• For coadministration with aliskiren in patients with diabetes

Environment

No information is available about the potential of this product to produce adverse environmental effects

Section 3, Composition/information on ingredients

Ingredients

Losartan Potassium USP 124750-99-8

Section 4, First-aid measures

Ingestion

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
| **Inhalation**   | Remove to fresh air and keep patient at rest. Seek medical attention immediately. |
| **Skin Contact** | Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. |
| **Eye Contact**  | Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. |

**NOTES TO HEALTH PROFESSIONALS**

**Medical Treatment**
Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient’s airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient’s vital signs, blood gases, serum electrolytes, etc.

**OVERDOSAGE**
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.

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**Section 5: Fire-Fighting Measures**

**Fire and Explosion Hazards**
Not determined

**Extinguishing Media**
Use carbon dioxide, dry chemical, or water spray.

**Special Firefighting Procedures**
For single units (packages): No special requirements needed. During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Hazardous Combustion Products**
Formation of toxic gases is possible during heating or fire.

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**Section 6: Accidental Release Measures**

**Health and Safety Precautions**
Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Measures for Environmental Protections

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Cleaning / Collecting

Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage

Section 7, Handling and storage

Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

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

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form

Losartan potassium tablet USP is a white film-coated tablet supplied as follows:

<table>
<thead>
<tr>
<th>Losartan</th>
<th>Shape</th>
<th>Engraving</th>
<th>NDC 68180-xxxx-xx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>One side</td>
<td>Bottle/30</td>
</tr>
<tr>
<td>25 mg</td>
<td>Capsule</td>
<td>LU</td>
<td>P21</td>
</tr>
<tr>
<td>50 mg</td>
<td>Capsule</td>
<td>L and U on eitherside of breakline (Scored)</td>
<td>P22</td>
</tr>
<tr>
<td>100 mg</td>
<td>Capsule</td>
<td>LU</td>
<td>P23</td>
</tr>
</tbody>
</table>
Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 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).

Section 12: Ecological Information

Section 12: Ecological Information

No relevant studies identified.
**Section 13: Disposal Considerations**

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

**Section 14: Transport Information**

**IATA/ICAO - Not Regulated**
- IATA Proper shipping Name: N/A
- IATA UN/ID No: N/A
- IATA Hazard Class: N/A
- IATA Packaging Group: N/A
- IATA Label: N/A

**IMDG - Not Regulated**
- IMDG Proper shipping Name: N/A
- IMDG UN/ID No: N/A
- IMDG Hazard Class: N/A
- IMDG Flash Point: N/A
- IMDG Label: N/A

**DOT - Not Regulated**
- DOT Proper shipping Name: N/A
- DOT UN/ID No: N/A
- DOT Hazard Class: N/A
- DOT Flash Point: N/A
- DOT Packing Group: N/A
- DOT Label: N/A

**Section 15: Regulatory Information**

This Section Contains Information relevant to compliance with other Federal and/or state laws.

**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.

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 SDS.