

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material Lisinopril Tablets, USP
2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg & 40 mg Tablets

Manufacturer Lupin Limited
Mumbai 400 098 INDIA

Distributor Lupin Pharmaceuticals, Inc.
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Baltimore, MD 21202
United States
Tel. 001-410-576-2000
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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS	Quantity
Lisinopril	76547-98-3	2.5, 5, 10, 20, 30 or 40 mg/ Tablet
Non-hazardous ingredients	-----	q.s.

3. HAZARDOUS IDENTIFICATION

Fire and Explosion Assume that this product is capable of sustaining combustion.

Health Exposure might occur via skin; eyes; ingestion; inhalation.
May cause sensitisation by inhalation or skin contact.

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

4. FIRST AID MEASURES

Ingestion	Never attempt to 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

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.
Drug Interactions	<p>Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with lisinopril.</p> <p>Non-steroidal Anti-inflammatory Agents: In some patients with compromised renal function who are being treated with non-steroidal anti-inflammatory drugs, the coadministration of lisinopril may result in further deterioration of renal function.</p> <p>Other Agents: Lisinopril has been used concomitantly with nitrates and/or digoxin without evidence of clinically significant adverse interactions. This included post myocardial infarction patients who were receiving intravenous or transdermal nitroglycerin. No clinically important pharmacokinetic interactions occurred when lisinopril was used concomitantly with propranolol or hydrochlorothiazide. The presence of food in the stomach does not alter the bioavailability of lisinopril.</p>
Antidotes	No specific antidote exists.

5. FIRE-FIGHTING MEASURES

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. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

- 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

- 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 20°-25°C (68°-77° F) [see USP Controlled Room Temperature]. Protect from moisture, freezing and excessive heat.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL & CHEMICAL PROPERTIES

- Physical Form**
- 2.5 mg : White to off-white, round, biconvex uncoated tablet
 - 5 mg : Pink coloured, round, biconvex uncoated tablet
 - 10 mg : Pink coloured, round, biconvex uncoated tablet
 - 20 mg : Pink coloured, round, biconvex uncoated tablet
 - 30 mg : Red coloured, round, biconvex uncoated tablet
 - 40 mg : Yellow coloured, round, biconvex uncoated tablet

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity:	Not expected to be toxic following ingestion of maximum daily dose.
Inhalation Toxicity:	Can produce respiratory irritation. Adverse effects might occur following inhalation.
Skin Effects:	Irritation might occur following direct contact.
Eye Effects:	Irritation might occur following direct contact with eyes.
Gastrointestinal Reactions:	Pancreatitis, hepatitis (hepatocellular or cholestatic jaundice), vomiting, gastritis, dyspepsia, heartburn, gastrointestinal cramps, constipation, flatulence, dry mouth.
Hypersensitivity Reactions:	Lisinopril is contraindicated in patients who are hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor and in patients with hereditary or idiopathic angioedema.
Genetic Toxicity:	Not expected to be genotoxic based on animal studies.
Carcinogenicity:	<p>Not expected to be carcinogenic based on animal studies.</p> <p>There was no evidence of a tumorigenic effect when lisinopril was administered for 105 weeks to male and female rats at doses up to 90 mg/kg/day.</p> <p>There was no evidence of carcinogenicity when lisinopril was administered for 92 weeks to (male and female) mice at doses up to 135 mg/kg/day.</p> <p>Lisinopril was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. It was also negative in a forward mutation assay using Chinese hamster lung cells.</p> <p>There were no adverse effects on reproductive performance in male and female rats treated with up to 300 mg/kg/day of lisinopril.</p>
Reproductive Effects:	When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, lisinopril should be discontinued as soon as possible.
Over Dosage:	The most likely manifestation of overdosage would be hypotension, for which the usual treatment would be intravenous infusion of normal saline solution. Lisinopril can be removed by hemodialysis.

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.