

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 and 40 mg
Manufacturer	Lupin Limited, 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
Lisinopril USP	83915-83-7

3. HAZARD IDENTIFICATION

Fire and Explosion	Assume that this product is capable of sustaining combustion.
Health	Lisinopril tablets are 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.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST AID MEASURES

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.
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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

OVERDOSAGE	<p>Following a single oral dose of 20 g/kg no lethality occurred in rats, and death occurred in one of 20 mice receiving the same dose. The most likely manifestation of overdosage would be hypotension, for which the usual treatment would be intravenous infusion of normal saline solution.</p> <p>Lisinopril can be removed by hemodialysis.</p>
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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 precautions are necessary when handling packed product. In case of accident, avoid breathing dust from crushed tablets. Avoid contact with skin and eyes. Wash hands after use.

Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Protect from moisture, freezing and excessive heat. Dispense in a tight container.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL AND CHEMICALS PROPERTIES

Physical Form

Lisinopril Tablets, USP are available as:

2.5 mg tablet is a white to off-white, round, biconvex, uncoated tablet with "LUPIN" debossed on one side and "2.5" on other side. They are available as follows:

Bottles of 90	NDC 68180-512-09
Bottles of 100	NDC 68180-512-01
Bottles of 500	NDC 68180-512-02
Bottles of 1000	NDC 68180-512-03

5 mg tablet is a pink coloured, round, biconvex, uncoated tablet with "5" debossed on one side and breakline on other side. They are available as follows:

Bottles of 90	NDC 68180-513-09
Bottles of 100	NDC 68180-513-01
Bottles of 500	NDC 68180-513-02
Bottles of 1000	NDC 68180-513-03
Bottles of 5000	NDC 68180-513-05

10 mg tablet is a pink coloured, round, biconvex, uncoated tablet with "LUPIN" debossed on one side and "10" on other side. They are available as follows:

Bottles of 90	NDC 68180-514-09
Bottles of 100	NDC 68180-514-01
Bottles of 500	NDC 68180-514-02
Bottles of 1000	NDC 68180-514-03
Bottles of 5000	NDC 68180-514-05

20 mg tablet is a pink coloured, round, biconvex, uncoated tablet with "LUPIN" debossed on one side and "20" on other side. They are available as follows:

Bottles of 90	NDC 68180-515-09
Bottles of 100	NDC 68180-515-01
Bottles of 500	NDC 68180-515-02
Bottles of 1000	NDC 68180-515-03
Bottles of 5000	NDC 68180-515-05

30 mg tablet is a red coloured, round, biconvex, uncoated tablet with "LUPIN" debossed on one side and "30" on other side. They are available as follows:

Bottles of 90	NDC 68180-516-09
Bottles of 100	NDC 68180-516-01
Bottles of 500	NDC 68180-516-02
Bottles of 1000	NDC 68180-516-03

40 mg tablet is a yellow coloured, round, biconvex, uncoated tablet with "LUPIN" debossed on one side and "40" on other side. They are available as follows:

Bottles of 90	NDC 68180-517-09
Bottles of 100	NDC 68180-517-01
Bottles of 500	NDC 68180-517-02
Bottles of 1000	NDC 68180-517-03
Bottles of 2000	NDC 68180-517-04

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility

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 (about 56 or 9 times* the maximum recommended daily human dose, based on body weight and body surface area, respectively). 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 (about 84 times* the maximum recommended daily human dose). This dose was 6.8 times the maximum human dose based on body surface area in mice.

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. Lisinopril did not produce single strand DNA breaks in an in vitro alkaline elution rat hepatocyte

assay. In addition, lisinopril did not produce increases in chromosomal aberrations in an in vitro test in Chinese hamster ovary cells or in an in vivo study in mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with up to 300 mg/kg/day of lisinopril. This dose is 188 times and 30 times the maximum human dose when based on mg/kg and mg/m², respectively.

*Calculations assume a human weight of 50 kg and human body surface area of 1.62 m².

12. ECOLOGICAL INFORMATION

No information available.

13. DISPOSAL CONSIDERATION

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

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

15. REGULATORY INFORMATION

No information available.

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.