LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Ramipril Capsules USP** 2.5 mg, 5 mg, and 10 mg
Manufacturer	**Lupin Limited** **MADE IN INDIA**
Distributor	Lupin Pharmaceuticals, Inc. Naples FL, 34108 United States

Section 2: Hazard(s) Identification

Fire and Explosion

Expected to be non-combustible.

Health

Ramipril is contraindicated in patients who are hypersensitive to this product or any other ACE inhibitor (e.g., a patient who has experienced angioedema during therapy with any other ACE inhibitor).
Ramipril capsules are contraindicated in combination with a neprilysin inhibitor (e.g., sacubitril). Do not administer ramipril capsules within 36 hours of switching to or from sacubitril/valsartan, a neprilysin inhibitor.
Do not co-administer ramipril with aliskiren:

- in patients with diabetes.

Suspected of damaging fertility or the unborn child

Environment

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

Section 3: Composition/Information on Ingredients

Ingredients	CAS Number
Ramipril USP	87333-19-5
Meglumine USP	6284-40-8
Pregelatinized Maize Starch NF	9005-25-8

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

Ingestion

If conscious, wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Call a physician immediately.

Inhalation	Move individual to fresh air. If not breathing, provide artificial respiration seek medical attention.
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 irritation develops and persists.
Eye Contact	In case of eye contact, remove contact lens and Flush eye immediately 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.

Single oral doses of ramipril in rats and mice of 10 g/kg to 11 g/kg resulted in significant lethality. In dogs, oral doses as high as 1 g/kg induced only mild gastrointestinal distress. Limited data on human overdosage are available. The most likely clinical manifestations would be symptoms attributable to hypotension.

Laboratory determinations of serum levels of ramipril and its metabolites are not widely available, and such determinations have, in any event, no established role in the management of ramipril overdose.

No data are available to suggest physiological maneuvers (e.g., maneuvers to change the pH of the urine) that might accelerate elimination of ramipril and its metabolites. Similarly, it is not known which, if any, of these substances can be effectively removed from the body by hemodialysis.

Angiotensin II could presumably serve as a specific antagonist-antidote in the setting of ramipril overdose, but angiotensin II is essentially unavailable outside of scattered research facilities. Because the hypotensive effect of ramipril is achieved through vasodilation and effective hypovolemia, it is reasonable to treat ramipril overdose by infusion of normal saline solution.

Section 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.
Special Firefighting Procedures	Wear self-contained breathing apparatus and protective clothing.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Personal Precautions	Wear protective clothing, gloves and eye/face protection.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Use absorbent/adsorbent material to solidify liquids. Do not vacuum. Remove sources of ignition.

Section 7: Handling and Storage

Handling	No special control measures are 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° to 25°C (68° to 77°F) in properly labeled containers.

Section 8: Exposure Controls/Personal Protection

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

OEL TWA-8 Hr: 25µg/m3.

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Ramipril capsules USP are available in 2.5 mg, 5 mg, and 10 mg hard gelatin capsules. Descriptions of Ramipril capsules USP are summarized below.
Ramipril capsules USP, 2.5 mg are: Size “4” capsules with orange cap, imprinted with ‘LUPIN’ in black ink and orange body imprinted with ‘RAMIPRIL 2.5 mg’ in black ink, containing white to off-white powder.

NDC 68180-589-10 bottles of 90
NDC 68180-589-01 bottles of 100
NDC 68180-589-02 bottles of 500

Ramipril capsules USP, 5 mg are: Size “4” capsules with red cap, imprinted with ‘LUPIN’ in black ink and red body imprinted with ‘RAMIPRIL 5 mg’ in black ink, containing white to off-white powder.

NDC 68180-590-10 bottles of 90
NDC 68180-590-01 bottles of 100
NDC 68180-590-02 bottles of 500

Ramipril capsules USP, 10 mg are: Size “4” capsules with light blue cap, imprinted with ‘LUPIN’ in black ink and light blue body imprinted with ‘RAMIPRIL 10 mg’ in black ink, containing white to off-white powder.

NDC 68180-591-10 bottles of 90
NDC 68180-591-01 bottles of 100
NDC 68180-591-02 bottles of 500

Section 10: Stability and Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport

Section 11: Toxicological Information

TWA-8 Hr: 25µg/m3.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No evidence of a tumorigenic effect was found when ramipril was given by gavage to rats for up to 24 months at doses of up to 500 mg/kg/day or to mice for up to 18 months at doses of up to 1000 mg/kg/day. (For either species, these doses are about 200 times the maximum recommended human dose when compared on the basis of body surface area).

No mutagenic activity was detected in the Ames test in bacteria, the micronucleus test in mice, unscheduled DNA synthesis in a human cell line, or a forward gene-mutation assay in a Chinese hamster ovary cell line. Several metabolites and degradation products of ramipril were also negative in the Ames test. A study in rats with dosages as great as 500 mg/kg/day did not produce adverse effects on fertility.

No teratogenic effects of ramipril were seen in studies of pregnant rats, rabbits, and cynomolgus monkeys. On a body surface area basis, the doses used were up to approximately 400 times (in rats and monkeys) and 2 times (in rabbits) the recommended human dose.

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.