MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material
Ramipril Capsules USP
1.25 mg, 2.5 mg, 5 mg, and 10 mg

Manufacturer
Lupin Limited
Goa 403 722
INDIA.

Distributor
Lupin Pharmaceuticals, Inc.
Harborplace Tower, 21st 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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramipril USP</td>
<td>87333-19-5</td>
<td>1.25 mg, 2.5 mg, 5 mg, and 10 mg</td>
</tr>
</tbody>
</table>

3. HAZARD 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).

Do not co-administer aliskiren with ramipril in patients with diabetes.

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

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

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
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.
5. FIRE FIGHTING MEASURE

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° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in light-resistant, tight container with child-resistant closure.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form

Ramipril Capsules USP are available in 1.25 mg, 2.5 mg, 5 mg, and 10 mg hard gelatin capsules. Descriptions of Ramipril Capsules USP are summarized below.

Ramipril Capsules USP, 1.25 mg are: Size “4” capsules with yellow cap, imprinted with ‘LUPIN’ in black ink and yellow body imprinted with ‘RAMIPRIL 1.25 mg’ in black ink, containing white to off-white powder.

<table>
<thead>
<tr>
<th>NDC</th>
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<tbody>
<tr>
<td>68180-588-09</td>
<td>bottles of 90</td>
</tr>
<tr>
<td>68180-588-01</td>
<td>bottles of 100</td>
</tr>
<tr>
<td>68180-588-02</td>
<td>bottles of 500</td>
</tr>
</tbody>
</table>

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.

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<td>68180-589-02</td>
<td>bottles of 500</td>
</tr>
</tbody>
</table>

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.

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<tr>
<td>68180-590-02</td>
<td>bottles of 500</td>
</tr>
</tbody>
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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.

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<tr>
<td>68180-591-02</td>
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10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.
11. TOXICOLOGICAL INFORMATION

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.

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

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 |
15. REGULATORY INFORMATION

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

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.