1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

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

Manufacturer: Lupin Limited
Mumbai 400 098 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 mg/capsule,</td>
<td>87333-19-5</td>
<td>1.25 mg/capsule, 2.5 mg/capsule, 5 mg/capsule, 10 mg/capsule</td>
</tr>
<tr>
<td>Non-hazardous ingredients</td>
<td>---------</td>
<td>q.s.</td>
</tr>
</tbody>
</table>

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. Harmful if swallowed. Antihypertensive drug: Has blood pressure lowering properties.

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.

**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 might be expected to cause hypotension.

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.

**Antidotes**
Angiotensin II could presumably serve as a specific antagonist-antidote.

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

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
1.25 mg: Capsules with yellow cap and yellow body containing white to off-white powder
2.5 mg: Capsules with orange cap and orange body containing white to off-white powder
5 mg: Capsules with red cap and red body containing white to off-white powder
10 mg: Capsules with light blue cap and light blue body containing white to off-white powder

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.
11. TOXICOLOGICAL INFORMATION

**Oral Toxicity:** Not expected to be toxic following ingestion of recommended 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:** Hepatic failure, hepatitis, jaundice, pancreatitis, abdominal pain (sometimes with enzyme changes suggesting pancreatitis), anorexia, constipation, diarrhea, dry mouth, dyspepsia, dysphagia, gastroenteritis, hepatitis, increased salivation and taste disturbance.

**Cardiovascular:** Symptomatic hypotension, syncope and palpitations.

**Genetic Toxicity:** Not expected to be genotoxic based on animal studies.

**Carcinogenicity:** Two years carcinogenicity studies in rats and mice were negative.

**Reproductive Effects:** ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible. When ACE inhibitors have been used in second and third trimesters of pregnancy, there have been reports of neonatal hypotension, renal failure, skull hypoplasia and death.

**Pharmacological Effects:** This material inhibits angiotensin-converting enzyme. It is antihypertensive.

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.