MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material

Perindopril Erbumine Tablets
2 mg, 4 mg and 8 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

Ingredients                    CAS   Quantity
Perindopril Erbumine          107133 - 36-8   2 mg, 4 mg and 8 mg
Non-hazardous ingredients     -----------   q.s.

3. HAZARDOUS IDENTIFICATION

Fire and Explosion

Assume that this product is capable of sustaining combustion.

Health

Perindopril erbumine tablets are contraindicated in patients known to be hypersensitive to this product or to any other ACE inhibitor. Perindopril erbumine tablets are also contraindicated in patients with a history of angioedema related to previous treatment with an ACE inhibitor.

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

In animals, doses of perindopril up to 2,500 mg/kg in mice, 3,000 mg/kg in rats and 1,600 mg/kg in dogs were non-lethal. Past experiences were scant but suggested that overdosage with other ACE inhibitors was also fairly well tolerated by humans. The most likely manifestation is hypotension, and treatment should be symptomatic and supportive. Therapy with the ACE inhibitor should be discontinued, and the patient should be observed. Dehydration, electrolyte imbalance and hypotension should be treated by established procedures.

However, of the reported cases of perindopril overdosage, one (dosage unknown) required assisted ventilation and the other developed hypothermia, circulatory arrest and died following ingestion of up to 180 mg of perindopril. The intervention for perindopril overdose may require vigorous support (see below).

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

No data are available to suggest physiological maneuvers (e.g., maneuvers to change the pH of the urine) that might accelerate elimination of perindopril and its metabolites. Perindopril can be removed by hemodialysis, with clearance of 52 mL/min for perindopril and 67 mL/min for perindoprilat.

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

**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]. Protect from moisture.

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

Perindopril Erbumine Tablets are supplied as below:

2 mg: White to off-white, round, biconvex tablets, debossed with ‘L’ and ‘U’ on either side of the breakline on one side and ‘C11’ on the other side.
Bottles of 100  NDC 68180-235-01

4 mg: White to off-white, capsule-shaped, biconvex tablets, debossed with ‘L’ and ‘U’ on either side of the breakline on one side and ‘C12’ on the other side.
Bottles of 100  NDC 68180-236-01

8 mg: White to off-white, round, biconvex tablets, debossed with ‘L’ and ‘U’ on either side of the breakline on one side and ‘C13’ on the other side.
Bottles of 100  NDC 68180-237-01

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenesis:

No evidence of carcinogenic effect was observed in studies in rats and mice when perindopril was administered at dosages up to 20 times (mg/kg) or 2 to 4 times (mg/m²) the maximum proposed clinical doses (16 mg/day) for 104 weeks.

Mutagenesis:

No genotoxic potential was detected for perindopril erbumine tablets, perindoprilat and other metabolites in various in vitro and in vivo investigations, including the Ames test, the Saccharomyces cerevisiae D4 test, cultured human lymphocytes, TK ± mouse lymphoma assay, mouse and rat micronucleus tests and Chinese hamster bone marrow assay.

Impairment of Fertility:

There was no meaningful effect on reproductive performance or fertility in the rat given up to 30 times (mg/kg) or 6 times (mg/m²) the proposed maximum clinical dosage of perindopril erbumine tablets during the period of spermatogenesis in males or oogenesis and gestation in females.
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.