MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material — **Quinapril Tablets, USP**
5 mg, 10 mg, 20 mg and 40 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
Quinapril Hydrochloride USP	82586-55-8	5 mg, 10 mg, 20 mg and 40 mg

3. HAZARD IDENTIFICATION

Fire and Explosion — Assume that this product is capable of sustaining combustion.

Health — Quinapril is contraindicated in patients who are hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an ACE inhibitor.

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

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

OVERDOSAGE

Doses of 1440 to 4280 mg/kg of quinapril cause significant lethality in mice and rats.

No specific information is available on the treatment of overdosage with quinapril. The most likely clinical manifestation would be symptoms attributable to severe hypotension.

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

No data are available to suggest physiological maneuvers (eg, maneuvers to change pH of the urine) that might accelerate elimination of quinapril and its metabolites.

Hemodialysis and peritoneal dialysis have little effect on the elimination of quinapril and quinaprilat. Angiotensin II could presumably serve as a specific antagonist-antidote in the setting of quinapril overdose, but angiotensin II is essentially unavailable outside of scattered research facilities. Because the hypotensive effect of quinapril is achieved through vasodilation and effective hypovolemia, it is reasonable to treat quinapril 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. 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 light.

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

Quinapril tablets USP are supplied as follows:

5-mg tablets: Yellow colored, oval shaped, film-coated tablets, debossed with 'L' & 'U' on either side of the breakline on one side and 'F01' on the other side.

NDC 68180-556-09 bottles of 90 tablets

10-mg tablets: Yellow colored, circular shaped, film-coated tablets, debossed with 'LU' on one side and 'F02' on the other side.

NDC 68180-557-09 bottles of 90 tablets
NDC 68180-557-03 bottles of 1000 tablets

20-mg tablets: Yellow colored, round shaped, film-coated tablets, debossed with 'LU' on one side and 'F03' on the other side.

NDC 68180-558-09 bottles of 90 tablets
NDC 68180-558-03 bottles of 1000 tablets

40-mg tablets: Yellow colored, elliptical shaped, film-coated biconvex tablets, debossed with 'LU' on one side and 'F04' on the other side.

NDC 68180-559-09 bottles of 90 tablets
NDC 68180-559-03 bottles of 1000 tablets

Dispense in well-closed containers as defined in the USP.

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility

Quinapril hydrochloride was not carcinogenic in mice or rats when given in doses up to 75 or 100 mg/kg/day (50 to 60 times the maximum human daily dose, respectively, on an mg/kg basis and 3.8 to 10 times the maximum human daily dose when based on an mg/m2 basis) for 104 weeks. Female rats given the highest dose level had an increased incidence of mesenteric lymph node hemangiomas and

skin/subcutaneous lipomas. Neither quinapril nor quinaprilat were mutagenic in the Ames bacterial assay with or without metabolic activation. Quinapril was also negative in the following genetic toxicology studies: *in vitro* mammalian cell point mutation, sister chromatid exchange in cultured mammalian cells, micronucleus test with mice, *in vitro* chromosome aberration with V79 cultured lung cells, and in an *in vivo* cytogenetic study with rat bone marrow. There were no adverse effects on fertility or reproduction in rats at doses up to 100 mg/kg/day (60 and 10 times the maximum daily human dose when based on mg/kg and mg/m^2, respectively).

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.