MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material **Ethambutol Hydrochloride Tablets USP 100 mg and 400 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
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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS	Quantity
Ethambutol HCl	1070-11-7	100 mg/tablet ; 400 mg/tablet
Non-hazardous ingredients	----------	q.s.

3. HAZARDOUS IDENTIFICATION

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

Health Ethambutol hydrochloride is contraindicated in patients who are known to be hypersensitive to this drug. It is also contraindicated in patients with known optic neuritis unless clinical judgement determines that it may be used.

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

Treat according to locally accepted protocols.

Ethambutol may produce decreases in visual acuity which appear to be due to optic neuritis and to be related to dose and duration of treatment. The effects are generally reversible when administration of the drug is discontinued promptly. In rare cases recovery may be delayed for up to one year or more and effect may possibly be irreversible in these cases.

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

Protect from light and moisture.

Dispense in a tight, light-resistant container defined in as the USP using a child-resistant closure.

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

100 mg: Tablets are available as white to off-white, round, biconvex, film coated tablet debossed with 'LU' on one side and 'C31' on the other side.

They are supplied as follows:
NDC 68180-280-01 Bottles of 100's

400 mg: Tablets are available as white to off-white, round, biconvex, film coated tablet debossed with 'L' and 'U' on either side of the breakline on one side and 'C32' on other side.

They are supplied as follows:
NDC 68180-281-01 Bottles of 100's
NDC 68180-281-02 Bottles of 500's
NDC 68180-281-13 4 x 14's unit dose blisters

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity : As with any potent drug, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic, should be made during long term therapy.

Inhalation Toxicity: Can produce respiratory irritation. Adverse effects might occur following inhalation.

Skin Effects: Irritation might occur following direct contact.

Eye Effects: This drug may have adverse effects on vision, physical examination should include ophthalmoscopy, finger perimetry and testing of color discrimination. In patients with visual defects such as cataracts, recurrent inflammatory conditions of the eye, optic neuritis, and diabetic retinopathy, the evaluation of changes in visual acuity is more difficult, and care should be taken to be sure the variations in vision are not due to the underlying disease conditions. In such patients, consideration should be given to relationship between benefits expected and possible visual deterioration since evaluation of visual changes is difficult.

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

Reproductive Effects: The effects of combinations of ethambutol hydrochloride with other antituberculous drugs on the fetus is not known. While administration of this drug to pregnant human patients has produced no detectable effect upon the fetus, the possible teratogenic potential in women capable of bearing children should be weighed carefully against the benefits of therapy. There are published reports of five women who received the drug during pregnancy without apparent adverse effect upon the fetus.

Ethambutol is not recommended for use in children under thirteen years of age since safe conditions for use have not been established.

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.