

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Ethacrynic Acid Tablets, USP 25 mg
Manufacturer	Lupin Limited Nagpur 441 108 INDIA
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

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Fire and Explosion	Expected to be non-combustible.
Health	All diuretics, including ethacrynic acid, are contraindicated in anuria. If increasing electrolyte imbalance, azotemia, and/or oliguria occur during treatment of severe, progressive renal disease, the diuretic should be discontinued. In a few patients this diuretic has produced severe, watery diarrhea. If this occurs, it should be discontinued and not used again. Until further experience in infants is accumulated, therapy with oral and parenteral ethacrynic acid is contraindicated. Hypersensitivity to any component of this product.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	CAS
Ethacrynic Acid USP	58-54-8

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
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Inhalation

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Skin Contact

Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

Eye Contact

Flush eye(s) immediately with plenty of water. If irritation occurs or persists, 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

Overdosage may lead to excessive diuresis with electrolyte depletion and dehydration.

In the event of overdosage, symptomatic and supportive measures should be employed. Emesis should be induced, or gastric lavage performed. Correct dehydration, electrolyte imbalance, hepatic coma, and hypotension by established procedures. If required, give oxygen or artificial respiration for respiratory impairment.

In the mouse, the oral LD₅₀ of ethacrynic acid is 627 mg/kg and the intravenous LD₅₀ of ethacrynate sodium is 175 mg/kg.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures**Fire and Explosion Hazards**

Not applicable

Extinguishing Media

Use carbon dioxide, dry chemical, or water spray.

Special Firefighting Procedures

During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Hazardous Combustion Products

May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

Section 6: Accidental Release Measures

Section 6, Accidental release measures**Personal Precautions**

Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Clean-up Methods

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Section 7: Handling and Storage

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Handling	Avoid generating airborne dust. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.
Storage	Store in a tightly closed container at 20°C to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

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

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form	Ethacrynic acid tablets USP, 25 mg, are white capsule shaped, scored tablets, and debossed 'L' & 'U' separated with scoreline on one side and 'E67' on the other side. They are supplied as follows: NDC 68180-159-01 in bottles of 100 Tablets.
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Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no evidence of a tumorigenic effect in a 79-week oral chronic toxicity study in rats at doses up to 45 times the human dose.

Ethacrynic acid had no effect on fertility in a two-litter study in rats or a two-generation study in mice at 10 times the human dose.

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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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

Section 15: Regulatory Information

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

Section 16: Other Information

Section 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 SDS.