

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	Cefuroxime Axetil Tablets USP 250 mg and 500 mg
Manufacturer	Lupin Limited Mandideep 462 046 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	Cefuroxime axetil is contraindicated in patients with a known hypersensitivity (e.g., anaphylaxis) to cefuroxime axetil or to other β -lactam antibacterial drugs (e.g., penicillins and cephalosporins).
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
Cefuroxime Axetil USP	64544-07-6

Section 4: First-Aid Measures

Section 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

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions or encephalopathy. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

Section 5: Fire-Fighting Measures

Section 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.

Section 6: Accidental Release Measures

Section 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.

Section 7: Handling and Storage

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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 the tablets at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature].
Replace cap securely after each opening.

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**

Cefuroxime axetil tablets USP, 250 mg of cefuroxime (as cefuroxime axetil), are white to off-white, capsule-shaped, film-coated tablets with "LUPIN" debossed on one side and "302" on the other side, supplied in bottles of 20 and 60.

20s Bottle NDC 68180-302-20

60s Bottle NDC 68180-302-60

Cefuroxime axetil tablets USP, 500 mg of cefuroxime (as cefuroxime axetil), are white to off-white, capsule-shaped, film-coated tablets with "LUPIN" debossed on one side and "303" on the other side, supplied in bottles of 20 and 60.

20s Bottle NDC 68180-303-20

60s Bottle NDC 68180-303-60

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**

Although lifetime studies in animals have not been performed to evaluate carcinogenic potential, no mutagenic activity was found for cefuroxime axetil in a battery of bacterial mutation tests. Positive results were obtained in an *in vitro* chromosome aberration assay; however, negative results were found in an *in vivo* micronucleus test at doses up to 1.5 g/kg. Fertility studies in rats (males dosed for 70 days prior to and through mating; females dosed 21 days prior to mating through lactation) at doses up to 1,000 mg/kg/day (9 times the MRHD based on body surface area) have revealed no adverse effects on fertility.

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.