

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Cefprozil For Oral Suspension USP 125 mg/5 mL and 250 mg/5 mL
Manufacturer	Lupin Limited Mandideep 462 046 INDIA
Distributor	Lupin Pharmaceuticals, Inc. Naples, FL 34108, United States

Section 2: Hazard(s) Identification

Fire and Explosion

Expected to be non-combustible.

Health

Cefprozil is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

BEFORE THERAPY WITH CEFPROZIL IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFPROZIL, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-SENSITIVITY AMONG β -LACTAM ANTIBIOTICS HAS BEEN CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO CEFPROZIL OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefprozil, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

Environment

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Ingredients	CAS No.	Ingredients	CAS No.
Cefprozil USP	92665-29-7	Colloidal silicon dioxide	7631-86-9
Aspartame	22839-47-0	Glycine	56-40-6
Anhydrous citric acid	77-92-9	Sodium carboxymethylcellulose	9004-32-4
Microcrystalline Cellulose NF	9004-34-6	Sodium benzoate	532-32-1
Sodium chloride	7647-14-5	Sucrose	57-50-1

*The exact percentage composition of this mixture has been withheld as a trade secret.

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

Single 5000 mg/kg oral doses of cefprozil caused no mortality or signs of toxicity in adult, weanling, or neonatal rats, or adult mice. A single oral dose of 3000 mg/kg caused diarrhea and loss of appetite in cynomolgus monkeys, but no mortality.

Cefprozil is eliminated primarily by the kidneys. In case of severe overdosage, especially in patients with compromised renal function, hemodialysis will aid in the removal of cefprozil from the body.

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

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

Handling	No special control measures are required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	Store dry powder at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Store constituted suspension in refrigerator. Discard after 14 days. Preserve in tight containers.

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

Physical Form

Cefprozil for oral suspension, USP is a pink coloured powder, forming pink coloured suspension with characteristic odour on constitution.

Cefprozil for Oral Suspension, USP 250 mg/5 mL is available as follows:

50 mL Bottle	NDC 68180-273-01
75 mL Bottle	NDC 68180-273-02
100 mL Bottle	NDC 68180-273-03

All powder formulations for oral suspension contain cefprozil in a bubble-gum flavored mixture.

Reconstitution Directions for Oral Suspension:

Prepare the suspension at the time of dispensing; for ease in preparation, add water in two portions and shake well after each aliquot.

Total Amount of Water Required for Reconstitution

Bottle Size	Final Concentration 250 mg/5 mL
50 mL	41 mL
75 mL	61 mL
100 mL	78 mL

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long term *in vivo* studies have not been performed to evaluate the carcinogenic potential of cefprozil.

Cefprozil was not found to be mutagenic in either the Ames *Salmonella* or *E. coli* WP2 *uvrA* reversion assays or the Chinese hamster ovary cell HGPRT forward gene mutation assay and it did not induce chromosomal abnormalities in Chinese hamster ovary cells or unscheduled DNA synthesis in rat hepatocytes *in vitro*. Chromosomal aberrations were not observed in bone marrow cells from rats dosed orally with over 30 times the highest recommended human dose based upon mg/m².

Impairment of fertility was not observed in male or female rats given oral doses of cefprozil up to 18.5 times the highest recommended human dose based upon mg/m².

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

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

Section 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

Section 15: Regulatory Information

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

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 MSDS.