1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material
Cefprozil For Oral Suspension USP
125 mg/5 mL and 250 mg/5 mL

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
Fax. 001-410-576-2221

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients
Cefprozil USP
CAS
92665-29-7

3. HAZARD IDENTIFICATION

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

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.
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

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.

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 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.
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

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

Cefprozil for Oral Suspension, USP 125 mg/5 mL is available as follows:

- 50 mL Bottle NDC 68180-401-01
- 75 mL Bottle NDC 68180-401-02
- 100 mL Bottle NDC 68180-401-03

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

- 50 mL Bottle NDC 68180-402-01
- 75 mL Bottle NDC 68180-402-02
- 100 mL Bottle NDC 68180-402-03

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

<table>
<thead>
<tr>
<th>Bottle Size</th>
<th>Final Concentration 125 mg/5 mL</th>
<th>Final Concentration 250 mg/5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mL</td>
<td>36 mL</td>
<td>36 mL</td>
</tr>
<tr>
<td>75 mL</td>
<td>53 mL</td>
<td>53 mL</td>
</tr>
<tr>
<td>100 mL</td>
<td>70 mL</td>
<td>70 mL</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.
11. **TOXICOLOGICAL INFORMATION**

**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 urvA 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.

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
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.