Section 1: Identification

Material: Cefdinir for Oral Suspension USP 125 mg/5 mL and 250 mg/5 mL

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

Fire and Explosion: Expected to be non-combustible.

Health: Cefdinir is contraindicated in patients with known allergy to the cephalosporin class of antibiotics

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

Section 3: Composition/Information on Ingredients

Ingredients: Cefdinir USP
CAS: 91832-40-5

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**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

Information on cefdinir overdosage in humans is not available. In acute rodent toxicity studies, a single oral 5600 mg/kg dose produced no adverse effects. Toxic signs and symptoms following overdosage with other β-lactam antibiotics have included nausea, vomiting, epigastric distress, diarrhea, and convulsions. Hemodialysis removes cefdinir from the body. This may be useful in the event of a serious toxic reaction from overdosage, particularly if renal function is compromised.

**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

### Section 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 dry powder and reconstituted suspension at 20° - 25°C (68°-77°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**

**HOW SUPPLIED**

Cefdinir for oral suspension USP, is an off-white to creamish powder formulation that, when reconstituted as directed, contains 125 mg cefdinir/5 mL or 250 mg cefdinir/5 mL. The reconstituted suspension has an off-white to creamish color and strawberry flavor. The powder is available as follows:

- **125 mg/5 mL:**
  - 60 mL bottles: NDC 68180-722-20
  - 100 mL bottles: NDC 68180-722-10

- **250 mg/5 mL:**
  - 60 mL bottles: NDC 68180-723-20
  - 100 mL bottles: NDC 68180-723-10
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

The carcinogenic potential of cefdinir has not been evaluated. No mutagenic effects were seen in the bacterial reverse mutation assay (Ames) or point mutation assay at the hypoxanthine-guanine phosphoribosyltransferase locus (HGPRT) in V79 Chinese hamster lung cells. No clastogenic effects were observed in vitro in the structural chromosome aberration assay in V79 Chinese hamster lung cells or in vivo in the micronucleus assay in mouse bone marrow. In rats, fertility and reproductive performance were not affected by cefdinir at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m²/day).

Section 12: Ecological Information

Section 12: Ecological Information

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

Section 14: Transport Information

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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.