LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	**Zolpidem Tartrate Extended-Release Tablets USP C_{IV} 6.25 mg and 12.5 mg**
Manufacturer	**Lupin Limited** Goa – 403 722 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	Assume that this product is capable of sustaining combustion.
Health	Zolpidem tartrate extended-release tablets are contraindicated in patients with known hypersensitivity to zolpidem. Observed reactions include anaphylaxis and angioedema.
Environment	No information is available about the potential of this product to produce adverse environmental effects. Zolpidem Tartrate is a DEA Class IV Controlled Substance

Section 3: Composition/Information on Ingredients

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Ingredients	CAS Number
Zolpidem Tartrate USP	99294-93-6
Lactose Monohydrate NF	10039-26-6
Microcrystalline cellulose NF	9004-34-6
Hypromellose USP	9004-65-3
Sodium Starch Glycolate	9063-38-1
Potassium Bitartrate USP	868-14-4
Magnesium stearate NF	557-04-0
Colloidal Silicon Dioxide NF	7631-86-9

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

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 with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

NOTES TO HEALTH PROFESSIONALS

OVERDOSAGE

In post marketing experience of overdose with zolpidem tartrate alone, or in combination with CNS-depressant agents, impairment of consciousness ranging from somnolence to coma, cardiovascular and/or respiratory compromise and fatal outcomes have been reported.

General symptomatic and supportive measures should be used along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. Zolpidem's sedative hypnotic effect was shown to be reduced by flumazenil and therefore may be useful; however, flumazenil administration may contribute to the appearance of neurological symptoms (convulsions). As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate signs should be monitored and general supportive measures employed. Hypotension and CNS depression should be monitored and treated by appropriate medical intervention. Sedating drugs should be withheld following zolpidem overdosage, even if excitation occurs. The value of dialysis in the treatment of overdosage has not been determined, although hemodialysis studies in patients with renal failure receiving therapeutic doses have demonstrated that zolpidem is not dialyzable.

As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may wish to consider contacting a poison control center for up-to-date information on the management of hypnotic drug product overdosage.

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 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 at 25°C (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 Properties

Section 9, Physical and chemical properties

Physical Form

Zolpidem tartrate extended-release tablets USP, 6.25 mg are composed of two layers* and are pink colored, round, biconvex, film-coated tablets debossed with “E61” on one side and “LU” on the other side and supplied as:

NDC Number	Package Configuration
68180-779-06	Bottle of 30
68180-779-04	Bottle of 100
68180-779-02	Bottle of 500
68180-779-03	Bottle of 1000
68180-779-13	Box containing 5 X 10-unit dose blisters

Zolpidem tartrate extended-release tablets USP, 12.5 mg are composed of two layers* and are blue colored, round, biconvex, film-coated tablets debossed with “E62” on one side and “LU” on the other side and supplied as:

NDC Number	Package Configuration
68180-780-06	Bottle of 30
68180-780-04	Bottle of 100
68180-780-02	Bottle of 500
68180-780-03	Bottle of 1000
68180-780-13	Box containing 5 X 10-unit dose blisters

*Layers are covered by the coating and are indistinguishable.

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

Carcinogenesis
Zolpidem was administered to mice and rats for 2 years at oral doses of 4, 18, and 80 mg base/kg. In mice, these doses are approximately 2, 9, and 40 times the maximum recommended human dose (MRHD) of 12.5 mg/day (10 mg zolpidem base) on mg/m^2 basis. In rats, these doses are approximately 4, 18, and 80 times the MRHD on a mg/m^2 basis. No evidence of carcinogenic potential was observed in mice. In rats, renal tumors (lipoma, liposarcoma) were seen at the mid- and high doses.

Mutagenesis
Zolpidem was negative in *in vitro* (bacterial reverse mutation, mouse lymphoma, and chromosomal aberration) and *in vivo* (mouse micronucleus) genetic toxicology assays.

Impairment of Fertility
Oral administration of zolpidem (doses of 4, 20, and 100 mg base/kg/day) to rats prior to and during mating, and continuing in females through postpartum day 25, resulted in irregular estrus cycles and prolonged precoital intervals at the highest dose tested. The no-effect dose for these findings is approximately 20 times the MRHD on a mg/m^2 basis. There was no impairment of fertility at any dose tested.

Section 12: Ecological Information

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No information available.

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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No information available.

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.