1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material: Zolpidem Tartrate Extended-Release Tablets USP CIV 6.25 mg and 12.5 mg

Manufacturer: Lupin Limited
Goa 403 722
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 | CAS | Quantity
---|---|---
Zolpidem Tartrate USP | 99294-93-6 | 6.25 mg or 12.5 mg

Zolpidem Tartrate is a DEA Class IV Controlled Substance.

3. HAZARDOUS IDENTIFICATION

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.

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.
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 at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL & 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:

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Package Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>68180-779-06</td>
<td>Bottle of 30</td>
</tr>
<tr>
<td>68180-779-01</td>
<td>Bottle of 100</td>
</tr>
<tr>
<td>68180-779-02</td>
<td>Bottle of 500</td>
</tr>
<tr>
<td>68180-779-03</td>
<td>Bottle of 1000</td>
</tr>
<tr>
<td>68180-779-13</td>
<td>Box containing 5 X 10 unit dose blisters</td>
</tr>
</tbody>
</table>

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:
10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

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/m² basis. In rats, these doses are approximately 4, 18, and 80 times the MRHD on a mg/m² 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/m² basis. There was no impairment of fertility at any dose tested.

12. ECOLOGICAL INFORMATION

No information available

NDC Number Package Configuration
68180-780-06 Bottle of 30
68180-780-01 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.
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

**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

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.