SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	Eszopiclone Tablets 1 mg, 2 mg and 3 mg For the treatment of insomnia
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Fire and Explosion	Expected to be non-combustible
Health	Eszopiclone is contraindicated in patients with known hypersensitivity to eszopiclone. Hypersensitivity reactions include anaphylaxis and angioedema.
Environment	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Eszopiclone	138729-47-2
Croscarmellose Sodium	74811-65-7
Colloidal Silicon Dioxide	112926-00-8
Anhydrous Dibasic Calcium Phosphate	7757-93-9
Lactose Monohydrate	64044-51-5
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6
Opadry-Blue	NA
Opadry II white	NA
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 centre. 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	In clinical trials with eszopiclone, one case of overdose with up to 36 mg of eszopiclone was reported in which the subject fully recovered. Since commercial marketing began, spontaneous cases of eszopiclone overdoses up to 270 mg (90 times the maximum recommended dose of eszopiclone) have been reported, in which patients have recovered. Fatalities related to eszopiclone overdoses were reported only in combination with other CNS drugs or alcohol.
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 vapours 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 required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.	
Section 9: Physical and Chemical Properties	
Physical Form	Eszopiclone tablets USP, 3 mg are dark blue to blue, round, biconvex, film-coated tablets debossed with 'H' on one side and 'E16' on the other side. Bottles of 30 tablets NDC 31722-857-30 Bottles of 100 tablets NDC 31722-857-01 Eszopiclone tablets USP, 2 mg are white to off-white, round, biconvex, film-coated tablets debossed with 'H' on one side and 'E15' on the other side. Bottles of 30 tablets NDC 31722-856-30 Bottles of 100 tablets NDC 31722-856-01 Eszopiclone tablets USP, 1 mg are light blue, round, biconvex, film-coated tablets debossed with 'H' on one side and 'E14' on the other side. Bottles of 30 tablets NDC 31722-855-30 Bottles of 100 tablets NDC 31722-855-01 Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature].
Section 10: Stability and Reactivity	
Stable under recommended storage conditions.	
Section 11: Toxicological Information	
Toxicology - The oral LD50 of eszopiclone in rats is 980 mg/kg and 3200 mg/kg in rabbits.	
Carcinogenesis, Mutagenesis, Impairment of Fertility	
Carcinogenesis	In a carcinogenicity study in rats, oral administration of

	eszopiclone for 97 (males) or 104 (females) weeks resulted in no increases in tumours; plasma levels (AUC) of eszopiclone at the highest dose tested (16 mg/kg/day) are approximately 80 (females) and 20 (males) times those in humans at the maximum recommended human dose (MRHD) of 3 mg/day. However, in a 2 year carcinogenicity study in rats, oral administration of racemic zopiclone (1, 10, or 100 mg/kg/day) resulted in increases in mammary gland adenocarcinomas (females) and thyroid gland follicular cell adenomas and carcinomas (males) at the highest dose tested. Plasma levels of eszopiclone at this dose are approximately 150 (females) and 70 (males) times those in humans at the MRHD of eszopiclone. The mechanism for the increase in mammary adenocarcinomas is unknown. The increase in thyroid tumours is thought to be due to increased levels of TSH secondary to increased metabolism of circulating thyroid hormones, a mechanism not considered relevant to humans. In a 2-year carcinogenicity study in mice, oral administration of racemic zopiclone (1, 10, or 100 mg/kg/day) produced increases in pulmonary carcinomas and carcinomas plus adenomas (females) and skin fibromas and sarcomas (males) at the highest dose tested. The skin tumours were due to skin lesions induced by aggressive behaviour, a mechanism not relevant to humans. A carcinogenicity study of eszopiclone was conducted in mice at oral doses up to 100 mg/kg/day. Although this study did not reach a maximum tolerated dose, and was thus inadequate for overall assessment of carcinogenic potential, no increases in either pulmonary or skin tumours were seen at doses producing plasma levels of eszopiclone approximately 90 times those in humans at the MRHD of eszopiclone (and 12 times the exposure in the racemate

	study). Eszopiclone did not increase tumours in a p53 transgenic mouse bioassay at oral doses up to 300 mg/kg/day.
Mutagenesis	Eszopiclone was clastogenic in in vitro (mouse lymphoma and chromosomal aberration) assays in mammalian cells. Eszopiclone was negative in the in vitro bacterial gene mutation (Ames) assay and in an in vivo micronucleus assay. (S)-N-desmethyl zopiclone, a metabolite of eszopiclone, was positive in in vitro chromosomal aberration assays in mammalian cells. (S)-N-desmethyl zopiclone was negative in the in vitro bacterial gene mutation (Ames) assay and in an in vivo chromosomal aberration and micronucleus assay.

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

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Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

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