SAFETY DATA SHEET

Section 1: Identification	
Material	Lurasidone Hydrochloride Tablets 20 mg, 40 mg, 60 mg, 80 mg and 120 mg
Recommended use	Pharmaceutical. Use only as directed.
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	• Known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone. • Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.). • Strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.).
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Lurasidone Hydrochloride	367514-88-3
Croscarmellose Sodium	74811-65-7
Hypromellose	9004-65-3
Magnesium Stearate	557-04-0
Mannitol	69-65-8
Opadry White	NA
Pregelatinized Starch	9005-25-8

Section 4: First-Aid Measures	
Ingestion	Flush out mouth with water, consult a physician immediately
Inhalation	In case of inhalation remove to fresh air and seek medical aid
Skin Contact	Remove immediately contaminated clothes, wash affected skin with plenty of water.
Eye Contact	In case of contact with eyes rinse thoroughly with plenty of water and get medical advice.

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	**Human Experience** In premarketing clinical studies, accidental or intentional overdosage of lurasidone hydrochloride was identified in one patient who ingested an estimated 560 mg of lurasidone hydrochloride. This patient recovered without sequelae. This patient resumed lurasidone hydrochloride treatment for an additional two months
	Management of Overdosage No specific antidotes for lurasidone hydrochloride are known. In managing overdose, provide supportive care, including close medical supervision and monitoring, and consider the possibility of multiple drug involvement. If an overdose occurs, consult a Certified Poison Control Center (1-800-222-1222 or www.poison.org). Cardiovascular monitoring should commence immediately, including continuous electrocardiographic monitoring for possible arrhythmias.If antiarrhythmic therapy is administered, disopyramide, procainamide,and quinidine carry a theoretical hazard of additive QT-prolonging effects when administered in patients with an acute overdose of lurasidone hydrochloride. Similarly, the alpha-blocking properties of bretylium might be additive to those of lurasidone hydrochloride,resulting in problematic hypotension. Hypotension and circulatory collapse should be treated with appropriate measures. Epinephrine and dopamine should not be used,or other sympathomimetics with beta-agonist activity, since beta stimulation may worsen hypotension in the setting of lurasidone hydrochloride-induced alpha blockade. In case of severe extrapyramidal symptoms, anticholinergic medication should be administered. Gastric lavage (after intubation if patient is unconscious) and administration of activated charcoal together with a laxative should be considered. The possibility of obtundation, seizures, or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis.

Section 5: Fire-Fighting Measures	
Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion
Extinguishing Media	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide
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	
Accidental release measures	
Personal Precautions	Avoid excessive contact and contact with eyes. Wear safety goggles or shield
Environmental Precautions	For large spills, take precautions to prevent entry into water ways, sewers, or surface drainage systems.
Clean-up Methods	This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.
Section 7: Handling and Storage	
Handling	No special control measures required for the normal 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	Tablet
Colour	White to off white,
Appearance	Lurasidone Hydrochloride Tablets 20 mg: White to off white, round, biconvex tablets, debossed with "L" on one side and "1" on the other side. 30s bottle NDC 31722-080-30 90s bottle NDC 31722-080-90 500s bottle NDC 31722-080-05

	Lurasidone Hydrochloride Tablets 40 mg: White to off white, round, biconvex tablets, debossed with "L" on one side and "2" on the other side. 30s bottle NDC 31722-081-30 90s bottle NDC 31722-081-90 500s bottle NDC 31722-081-05 Lurasidone Hydrochloride Tablets 60 mg: White to off white, oblong, biconvex tablets, debossed with "L" on one side and "3" on the other side. 30s bottle NDC 31722-082-30 90s bottle NDC 31722-082-90 500s bottle NDC 31722-082-05 Lurasidone Hydrochloride Tablets 80 mg: White to off white, oval, biconvex tablets, debossed with "L" on one side and "4" on the other side. 30s bottle NDC 31722-083-30 90s bottle NDC 31722-083-90 500s bottle NDC 31722-083-05 Lurasidone Hydrochloride Tablets 120 mg: White to off white, oval, biconvex tablets, debossed with "L" on one side and "5" on the other side. 30s bottle NDC 31722-084-30 90s bottle NDC 31722-084-90 500s bottle NDC 31722-084-05
Section 10: Stability and Reactivity	
Stable under recommended storage conditions.	
Section 11: Toxicological Information	
Carcinogenesis, Mutagenesis, Impairment of Fertility	
Carcinogenesis	Lurasidone increased incidences of malignant mammary gland tumors and pituitary gland adenomas in female mice orally dosed with 30, 100, 300, or 650 mg/kg/day. The lowest dose produced plasma levels (AUC) approximately equal to those in humans receiving the MRHD of 160 mg/day. No increases in tumors were seen in male mice up to the highest dose tested, which produced plasma levels (AUC) 14 times those in humans receiving the MRHD. Lurasidone increased the incidence of mammary gland carcinomas in female rats orally dosed at 12 and 36

	mg/kg/day: the lowest dose;3 mg/kg/day is the no-effect dose which produced plasma levels (AUC) 0.4 times those in humans receiving the MRHD. No increases in tumors were seen in male rats up to the highest dose tested, which produced plasma levels (AUC) 6 times those in humans receiving the MRHD. Proliferative and/or neoplastic changes in the mammary and pituitary glands of rodents have been observed following chronic administration of antipsychotic drugs and are considered to be prolactin-mediated.
Mutagenesis	Lurasidone did not cause mutation or chromosomal aberration when tested in vitro and in vivo test battery. Lurasidone was negative in the Ames gene mutation test, the Chinese Hamster Lung (CHL) cells, and in the in vivo mouse bone marrow micronucleus test up to 2000 mg/kg which is 61 times the MRHD of 160 mg/day based on mg/m2 body surface area.
Impairment of Fertility	Estrus cycle irregularities were seen in rats orally administered lurasidone at 1.5, 15 and 150 mg/kg/day for 15 consecutive days prior to mating, during the mating period, and through gestation day 7. No effect was seen at the lowest dose of 0.1 mg/kg which is approximately 0.006 times the MRHD of 160 mg/day based on mg/m^2. Fertility was reduced only at the highest dose, which was reversible after a 14 day drug-free period. The no- effect dose for reduced fertility was approximately equal to the MRHD based on mg/m^2. Lurasidone had no effect on fertility in male rats treated orally for 64 consecutive days prior to mating and during the mating period at doses up to 9 times the MRHD based on mg/m^2.

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

Issue Date : 15-11-2024

Version : 00

Further information

Revision date: NA

Revision note: NA.

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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