HETERO LABS LIMITED

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SAFETY DATA SHEET

Section 1: Identification

Material	Atomoxetine Hydrochloride Capsule , 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg.
Recommended Use	Pharmaceutical
Recommended restrictions	None known
Manufacturer	**Hetero Labs Limited Unit III** 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	**Camber Pharmaceuticals, Inc., Piscataway, NJ 08854**

Section 2: Hazard's Identification

Physical Hazards	Not classified.
Health Hazards	Acute toxicity, oral — Category 4 Serious eye damage/eye irritation — Category 1 Specific target organ toxicity, single exposure — Category 3 Specific target organ toxicity, repeated exposure — Category 2 .
OSHA defined Hazards	Not classified.
Hazard statement	H302 Harmful if swallowed. H318 Causes serious eye damage. H336 May cause drowsiness or dizziness. H373 May cause damage to organs (Liver) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Wash thoroughly after handling. Do not breathe dust. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.
Response	Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
Hazard(s) not other wise Classified (HNOC)	None known.

Section 3: Composition/ Information on Ingredients

Ingredient	CAS No
Atomoxetine Hydrochloride	130018-87-0
Composition comments	Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

Section 4: First Aid Measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.
Skin Contact	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Eye contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Call a physician or poison control center immediately.
Ingestion	Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.
Most Important symptoms/effects, acute and delayed	Harmful if swallowed. Causes serious eye damage. May cause drowsiness or dizziness. May cause damage to organs (Liver) through prolonged or repeated exposure.
Indication of immediate medical attention and special treatment needed	An airway should be established. Monitoring of cardiac and vital signs is recommended, along with appropriate symptomatic and supportive measures. Gastric lavage may be indicated if performed soon after ingestion. Because atomoxetine is highly protein-bound, dialysis is not likely to be useful in the treatment of overdose.
General Information	The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

Section 5: Fire Fighting Measures

Suitable extinguishing media	Carbon dioxide, dry chemical or water.
Specific hazards arising from the chemical	Hazardous decomposition products formed under fire conditions.
Unsuitable extinguishing media	None known.
Special protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.

Section 6: Accidental Release measures

Personal precautions, protective equipment and emergency procedures	Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up Environmental precautions	Do not sweep. Vacuum material with appropriate dust collection filter in place. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

Section 7: Handling and Storage

Precautions for safe handling Hygiene measures	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.

Conditions for safe storage, including any incompatibilities	Keep container tightly closed in a dry and well-ventilated place.

Section 8: Exposure controls / Personal Protection

Appropriate engineering controls	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/ faceshield.
Skin and hand protection	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL.
Environmental exposure controls	A void release to the environment.
General hygiene considerations	Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material.

Section 9: Physical and chemical Properties

Appearance	
Physical state	Solid.
Form	Capsule.
Description	Atomoxetine capsules USP, 10 mg are white opaque / white opaque size 5 hard gelatin capsules imprinted with ‘I’ on cap and ‘105’ on body, filled with white to off-white granular powder. Bottles of 30 capsules NDC 31722-714-30 Atomoxetine capsules USP, 18 mg are yellow / white opaque size 4 hard gelatin capsules imprinted with ‘I’ on cap and ‘106’ on body, filled with white to off-white granular powder. Bottles of 30 capsules NDC 31722-715-30 Atomoxetine capsules USP, 25 mg are opaque blue / white opaque size 3 hard gelatin capsules imprinted with ‘I’ on cap and ‘107’ on body, filled with white to off-white granular powder. Bottles of 30 capsules NDC 31722-716-30 Atomoxetine capsules USP, 40 mg are blue opaque / blue opaque size 2 hard gelatin capsules imprinted with ‘I’ on cap and ‘108’ on body, filled with white granular powder. Bottles of 30 capsules NDC 31722-717-30

	Atomoxetine capsules USP, 60 mg are blue opaque / yellow size 2 hard gelatin capsules imprinted with 'I' on cap and '109' on body, filled with white to off-white granular powder. Bottles of 30 capsules NDC 31722-718-30 Atomoxetine capsules USP, 80 mg are brown opaque / white opaque size 2 hard gelatin capsules imprinted with 'I' on cap and '110' on body, filled white to off-white granular powder. Bottles of 30 capsules NDC 31722-719-30 Atomoxetine capsules USP,100 mg, are brown opaque / brown opaque size 1 hard gelatin capsules imprinted with 'I' on cap and '111' on body, filled with white to off-white granular powder. Bottles of 30 capsules NDC 31722-720-30
Storage	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 10: Stability and Reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.

Section 11:Toxicological Information

Specific target organ toxicity - single exposure	May cause drowsiness or dizziness. Tremors. Elevated blood pressure. Increased heart rate. (Atomoxetine hydrochloride)
Specific target organ toxicity - repeated exposure	Hepatotoxicity (increased liver weight, hepatocellular vacuolation, increased serum ALT) was reported in male rats given dietary concentrations greater than or equal to 0.01% for 3 or 12 months and in mice given 0.4% in diet for 3 months. No hepatoxicity was observed in dogs administered up to 16 mg/kg/day for 3 or 12 months. Clinical signs (pupillary light response, tremors, dilated pupils) were observed in dogs given less than 8 mg/kg/day for 1 year. Young rats administered up to 50 mg/kg/day from 10 days of age through adulthood matured physically and behaviorally with no major organ toxicity. (Atomoxetine hydrochloride)
Aspiration hazard	No aspiration toxicity classification(Atomoxetine hydrochloride)
Further information	The most commonly reported symptoms accompanying acute and chronic overdoses were gastrointestinal symptoms, somnolence, dizziness, tremor, and abnormal behavior. Hyperactivity and agitation have also been reported. Signs and symptoms consistent with mild to moderate sympathetic nervous system activation (e.g., tachycardia, blood pressure increased, mydriasis, dry mouth) were also observed. Most events were mild to moderate. (Atomoxetine hydrochloride)

Section 12: Ecological Information

Ecotoxicity	Very toxic to acquatic life with long lasting effects.
Mobility in soil	No data is available.
Other adverse effects	Not available.

Section 13: Disposal instructions

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 14: Transport Information

IATA

Proper shipping Name		Environmentally hazardous substance, solid, n.o.s. (Atomoxetine Hydrochloride)
IATA UN/ID No	:	UN3077
IATA Hazard Class	:	9
IATA Packaging Group	:	III
IATA Label	:	N/A

IMDG

IMDG Proper shipping Name	:	Environmentally hazardous substance, solid, n.o.s. (Atomoxetine Hydrochloride)
IMDG UN/ID No	:	UN3077
IMDG Hazard Class	:	9
IMDG Packaging Group	:	III
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT	:	Not regulated as dangerous goods.
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

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure).

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive

Section 16: Other Information

Section 16: Other Information

Issue Date: 18-03-2021

Version: 00

Revision note: New

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.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.