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SAFETY DATA SHEET

Section 1: Identification

Material	**Duloxetine Delayed Release capsules USP 20mg, 30mg and 60mg**
Manufacturer	**Hetero Labs Limited Unit III** 22-110, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible.
Health	The use of Monoamine Oxidase Inhibitors (MAOIs) intended to treat psychiatric disorders with duloxetine or within 5 days of stopping treatment with duloxetine is contraindicated because of an increased risk of serotonin syndrome. The use of duloxetine within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated. Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs. Starting duloxetine in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome. In clinical trials, duloxetine use was associated with an increased risk of mydriasis; therefore, its use should be avoided in patients with uncontrolled narrow-angle glaucoma.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition / Information on Ingredients

Ingredients	Duloxetine Hydrochloride USP
CAS	136434-34-9

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 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	There is no specific antidote to duloxetine delayed-release capsules, but if serotonin syndrome ensues, specific treatment (such as with cyproheptadine and/or temperature control) may be considered. In case of acute overdose, treatment should consist of those general measures employed in the management of overdose with any drug. An adequate airway, oxygenation, and ventilation should be assured, and cardiac rhythm and vital signs should be monitored. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal may be useful in limiting absorption of duloxetine from the gastrointestinal tract. Administration of activated charcoal has been shown to decrease AUC and

	C_{max} by an average of one-third, although some subjects had a limited effect of activated charcoal. Due to the large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be beneficial. In managing overdose, the possibility of multiple drug involvement should be considered. A specific caution involves patients who are taking or have recently taken duloxetine delayed-release capsules and might ingest excessive quantities of a TCA. In such a case, decreased clearance of the parent tricyclic and/or its active metabolite may increase the possibility of clinically significant sequelae and extend the time needed for close medical observation *[see Warnings and Precautions (5.4) and Drug Interactions (7)]*. The physician should consider contacting a poison control center (1-800-222-1222 or www.poison.org) for additional information on the treatment of any overdose. Telephone numbers for certified poison control centers are listed in the *Physicians' Desk Reference* (PDR).
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 Fire fighting 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	
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 labelled container for recovery or disposal.

Section 7: Handling and Storage

General Requirements	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 20° to 25°C (68° to 77°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

Duloxetine Capsules Delayed release capsules USP 20mg

Duloxetine Delayed-release Capsules USP, 20 mg are Opaque green cap/Opaque green body size '4' hard gelatin capsule imprinted with 'H' on cap and '190' on body, filled with off white colored pellets. They are supplied as follows:

Duloxetine Delayed-release Capsules USP, 20 mg

Bottles of 30 Capsules (NDC 31722-168-30)
Bottles of 60 Capsules (NDC 31722-168-60)
Bottles of 100 Capsules (NDC 31722-168-01)
Bottles of 1000 Capsules (NDC 31722-168-10)
Blister Card of 7 Unit-Dose Capsules (31722-168-31)
Blister Pack of 105 (15x7) Unit-Dose Capsules (31722-168-32)

Duloxetine Capsules Delayed release capsules USP 30mg

Duloxetine Delayed-release Capsules USP, 30 mg are Opaque blue cap/ Opaque white body size '3' hard gelatin capsule imprinted with 'H' on cap and '191' on body, filled with off white colored pellets.

Duloxetine Delayed-release Capsules USP, 30 mg

Bottles of 30 Capsules (NDC 31722-169-30)
Bottles of 90 Capsules (NDC 31722-169-90)
Bottles of 100 Capsules (NDC 31722-169-01)
Bottles of 1000 Capsules (NDC 31722-169-10)

Blister Card of 7 Unit-Dose Capsules (31722-169-31)
Blister Pack of 105 (15x7) Unit-Dose Capsules (31722-169-32)

Duloxetine Capsules Delayed release capsules USP 60mg

Duloxetine Delayed-release Capsules USP, 60 mg Opaque blue cap/ Opaque green body size '1' hard gelatin capsule imprinted with 'H' on cap and '192' on body, filled with off white colored pellets.

Duloxetine Delayed-release Capsules USP, 60 mg

Bottles of 30 Capsules (NDC 31722-170-30)
Bottles of 100 Capsules (NDC 31722-170-01)
Bottles of 1000 Capsules (NDC 31722-170-10)
Blister Card of 10 Unit-Dose Capsules (31722-170-31)
Blister Pack of 90 (9x10) Unit-Dose Capsules (31722-170-32)

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Duloxetine was administered in the diet to mice and rats for 2 years.

In female mice receiving duloxetine at 140 mg/kg/day (11 times the maximum recommended human dose [MRHD, 60 mg/day] and 6 times the human dose of 120 mg/day on a mg/m^2 basis), there was an increased incidence of hepatocellular adenomas and carcinomas. The no-effect dose was 50 mg/kg/day (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis). Tumor incidence was not increased in male mice receiving duloxetine at doses up to 100 mg/kg/day (8 times the MRHD and 4 times the human dose of 120 mg/day on a mg/m^2 basis). In rats, dietary doses of duloxetine up to 27 mg/kg/day in females (4 times the MRHD and 2 times the human dose of 120 mg/day on a $mg/mg/m^2$ basis) and up to 36 mg/kg/day in males (6 times the MRHD and 3 times the human dose of 120 mg/day on a mg/m^2 basis) did not increase the incidence of tumors.

Mutagenesis

Duloxetine was not mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) and was not clastogenic in an *in vivo* chromosomal aberration test in mouse bone marrow cells.

Additionally, duloxetine was not genotoxic in an *in vitro* mammalian forward gene mutation assay in mouse lymphoma cells or in an *in vitro* unscheduled DNA synthesis (UDS) assay in primary rat hepatocytes, and did not induce sister chromatid exchange in Chinese hamster bone marrow *in vivo*.

Impairment of Fertility

Duloxetine administered orally to either male or female rats prior to and throughout mating at doses up to 45 mg/kg/day (7 times the maximum recommended human dose of 60 mg/day and 4 times the human dose of 120 mg/day on a mg/m^2 basis) did not alter mating or fertility.

Section 12: Ecological Information

Ecotoxicity	Not available.
BOD5 and COD	Not available.
Products of Biodegradation	Not available.
Toxicity of the Products of Biodegradation	The products of degradation are less toxic than the product itself.
Special Remarks on the Products of Biodegradation	Not available.

Section 13: Disposal Considerations

Waste Disposal	Waste must be disposed of in accordance with federal, state and local environmental control 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: 07-12-2021

Version: 00

Further information
Revision date: Nil
Revision note: Nil

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.

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