



SAFETY DATA SHEET

Section 1: Identification	
Material	Milnacipran Hydrochloride Tablets, 12.5 mg, 25 mg, 50 mg and 100 mg
Recommended use	Pharmaceutical product used as Selective serotonin and norepinephrine reuptake inhibitor (SNRI)
Manufacturer	Hetero Labs Limited Unit V, Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301 India
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	Toxic if swallowed or if inhaled Causes skin irritation Causes serious eye damage May cause an allergic skin reaction May cause respiratory irritation May cause damage to organs through prolonged or repeated exposure Very toxic to aquatic life Toxic to aquatic life with long lasting effects
Precautionary statements	Do not breathe dust/fume/gas/mist/vapors/spray Wash thoroughly after handling Do not eat, drink or smoke when using this product Use only outdoors or in a well-ventilated area Contaminated work clothing must not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves / eye protection / face protection. If swallowed: Immediately call a poison center/doctor. Specific treatment (see on this label). Rinse mouth. If on skin: Wash with plenty of water If inhaled: Remove person to fresh air and keep comfortable for breathing Call a poison center/doctor If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a poison center/doctor if you feel unwell. Get medical advice/attention if you feel unwell. Take off contaminated clothing and wash it before reuse.



	<p>If skin irritation or rash occurs: Get medical advice/attention. Collect spillage Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.</p>
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Other hazards	<p>Other hazards Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable. Classification according to (d)(1)(ii) of § 1910.1200 The SDS issuer does not object to the classifications provided by importers or manufacturers of precursor products. Hazards not otherwise classified There are no adverse physical or health effects known that are not covered by the hazard classes of the Hazard Communications Standard.</p>
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Section 3: Composition/Information on Ingredients

Ingredients	CAS
Milnacipran hydrochloride	101152-94-7
Microcrystalline Cellulose	9004-34-6
Carboxymethylcellulose calcium	9050-04-8
Colloidal Silicon Dioxide	7631-86-9
Povidone	9003-39-8
Talc	14807-96-6
Magnesium Stearate	557-04-0
Opadry Blue 200F505003	NA
Opadry White 200F280000	NA
Opadry Pink 200F540020	NA

Section 4: First-Aid Measures

After inhalation	<p>Supply fresh air or oxygen; call for doctor. In case of unconsciousness place patient stably in side position for transportation.</p>
After skin contact:	<p>Immediately wash with water and soap and rinse thoroughly.</p>
After eye contact:	<p>Rinse opened eye for several minutes under running water. Then consult a doctor.</p>



After swallowing:	Do not induce vomiting; immediately call for medical help.
Most important symptoms and effects, both acute and delayed	No further relevant information available.
Indication of any immediate medical attention and special treatment needed	No further relevant information available
Section 5: Fire-Fighting Measures	
Suitable extinguishing agents	Use firefighting measures that suit the environment. A solid water stream may be inefficient.
Special hazards arising from the substance or mixture	No further relevant information available
Advice for firefighters Protective equipment:	Mouth respiratory protective device.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	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
Methods and material for containment and cleaning up	Collect and place it in a suitable, properly labeled container for recovery or disposal
Protective Action Criteria for Chemicals	PAC-1: Substance is not listed. · PAC-2: Substance is not listed. PAC-3: Substance is not listed.
Section 7: Handling and Storage	
Storage	Store at 20° to 25°C (68 to 77°F) [see USP Controlled Room Temperature].
Section 8: Exposure Controls/Personal Protection	
Control parameters	
Components with limit values that require monitoring at the workplace:	Not required
Exposure controls	
Appropriate engineering controls	No further data
Personal protective equipment	



	unit dose tablets	NDC 31722-848-32
	Milnacipran hydrochloride tablets 100 mg are pink, oval, biconvex film-coated tablets debossed with 'H' on one side and 'M11' on the other side	
	Bottles of 60 tablets	NDC 31722-849-60
	Carton of 100 (10 x 10) unit dose tablets	NDC 31722-849-32
	Titration Pack: 4-Week Titration Pack NDC 31722-880-31 (Blister package containing 55 tablets: 5 x 12.5 mg tablets, 8 x 25 mg tablets, and 42 x 50 mg tablets.)	

Section 10: Stability and Reactivity

Reactivity	No further relevant information available
Chemical stability	
Thermal decomposition / conditions to be avoided	No decomposition if used according to specifications
Possibility of hazardous reactions	No dangerous reactions known
Conditions to avoid	No further relevant information available.
Incompatible materials	strong oxidizing agents
Hazardous decomposition products	carbon dioxide, carbon monoxide, hydrogen chloride gas, nitrogen oxides

Section 11: Toxicological Information

Information on toxicological effects			
Acute toxicity	LD/LC50 values that are relevant for classification		
	Oral	TDLO	10 mg/kg
		LD50	213 mg/kg (rat)
		Subcutaneous TDLO	60 mg/kg (rat)
		Intraperitoneal TDLO40	40 mg/kg (rat)
Primary irritant effect			
on the skin	Irritant to skin and mucous membranes		
on the eye	Strong irritant with the danger of severe eye injury		
Sensitization	Sensitization possible through skin contact.		
Additional toxicological information			
Interactive effects	No interactive effects between components are known		
Carcinogenic categories			



IARC (International Agency for Research on Cancer)	Substance is not listed
NTP (National Toxicology Program)	Substance is not listed.
OSHA-Ca (Occupational Safety & Health Administration)	Substance is not listed
Section 12: Ecological Information	
Toxicity	
Aquatic toxicity:	No further relevant information available.
Persistence and degradability	No further relevant information available.
Bioaccumulative potential	No further relevant information available.
Mobility in soil	No further relevant information available.
Results of PBT and vPvB assessment	
PBT	Not applicable
vPvB	Not applicable
Section 13: Disposal Considerations	
Waste treatment methods	
Recommendation:	Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Uncleaned packaging:	
Recommendation:	Disposal must be made according to official regulations
Section 14: Transport Information	
DOT, IMDG, IATA	Not regulated as a hazardous material
Section 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	No further relevant information available.
Sara	
Section 355 (extremely hazardous substances)	Substance is not listed.
Section 313 (Specific toxic chemical listings)	Substance is not listed.
TSCA (Toxic Substances Control Act)	Substance is not listed.
Hazardous Air Pollutants	Substance is not listed
Chemicals known to cause cancer:	Substance is not listed
Chemicals known to cause reproductive toxicity for females:	Substance is not listed



Chemicals known to cause reproductive toxicity for males:	Substance is not listed
Chemicals known to cause developmental toxicity:	Substance is not listed

Section 16: Other Information

Issue Date: 04-03-2026

Version: 00

Further information

Revision date: NA

Revision notes: NA

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