HETERO LABS LIMITED
"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http//www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Material	Ranolazine Extended-Release Tablets 500 mg and 1000 mg
Recommended use	Pharmaceutical product
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	Ranolazine is contraindicated in patients: • Taking strong inhibitors of CYP3A • Taking inducers of CYP3A • With liver cirrhosis
Environment	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Ranolazine	95635-55-5
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	High oral doses of ranolazine produce dose-related increases in Dizziness, nausea, and vomiting. High intravenous exposure also Produces diplopia, paraesthesia, confusion, and syncope. In addition to general supportive measures, continuous ECG monitoring may be warranted in the event of overdose. Severe tremor, unsteady gait/incoordination, dysphasia, and

	hallucinations have been reported in cases of overdose with ranolazine extended-release tablets. Since ranolazine is about 62% bound to plasma proteins, haemodialysis is unlikely to be effective in clearing ranolazine.
Section 5: Fire-Fighting Measures	
Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion
Extinguishing Media **Special Firefighting Procedures**	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide. 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	Avoid excessive contact and contact with eyes. Wear safety goggles or shield.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways 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 20-25°C (68°F)
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

Description	Ranolazine extended-release tablets are supplied in the following strengths: Ranolazine extended-release tablets, 500 mg are blue colored, oblong shaped film coated tablets debossed with 'R18' on one side and 'H' on the other side. Bottle of 60 tablets NDC 31722-668-60 Ranolazine extended-release tablets, 1000 mg are blue colored, oblong shaped film coated tablets debossed with 'R19' on one side and 'H' on the other side. Bottle of 60 tablets NDC 31722-669-60

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility	Ranolazine tested negative for genotoxic potential in the following Assays: Ames bacterial mutation assay, Saccharomyces assay for mitotic gene conversion, chromosomal aberrations assay in Chinese hamster ovary (CHO) cells, mammalian CHO/HGPRT gene mutation assay, and mouse and rat bone marrow micronucleus assays. There was no evidence of carcinogenic potential in mice or rats. The highest oral doses used in the carcinogenicity studies were 150 mg/kg/day for 21 months in rats (900 mg/m2/day) and 50 mg/kg/day for 24 months in mice (150 mg/m2/day). These maximally tolerated doses are 0.8 and 0.1 times, respectively, the daily maximum recommended human dose (MRHD) of 2000 mg on a surface area basis. A published study reported that ranolazine promoted tumour formation and progression to malignancy when given to transgenic APC (min/+) mice at a dose of 30 mg/kg twice daily. The clinical significance of this finding is unclear. In male and female rats, oral administration of ranolazine that produced exposures (AUC) approximately 3-fold or 5-fold higher, respectively, than the MRHD had no effect on fertility.

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: 02-07-2022

Version:00
Further information:

Revision date: New issue

Revision note: New issue

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.

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 MSDS.