

SAFETY DATA SHEETS

This SDS packet was issued with item:

078933880

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078933881



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

Product information

Product Name	Hydralazine hydrochloride tablets USP, 10 mg, 25 mg, 50 mg and 100 mg
Active substance	Hydralazine hydrochloride
Intended Uses	Hydralazine Hydrochloride Tablets are used for the essential hypertension, alone or as an adjunct.

Company Details

Manufacturer	Hetero labs limited, Unit III, 22 - 110, industrial development Area, Jeedimetla, Hyderabad -500 055.
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Inhalation	Not expected to be an inhalation hazard in final pharmaceutical form.
Eye Contact	Not expected to be a hazard to the eye in final pharmaceutical form.
Skin Contact	Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.
Effects of Overdose	Sign & symptom of overdose include hypertension, tachycardia, headache, & generalized skin flushing.

Section 3: Composition/Information on Ingredients

Components	CAS No.
Hydralazine Hydrochloride, USP	2192-20-3
Anhydrous lactose, USP-NF	63-42-3
Microcrystalline Cellulose	9004-34-6
Sodium starch Glycolate	9063-38-1
Stearic acid	57-11-4
FD & C Yellow	2783-94-0

Section 4: First-Aid Measures

General	Check the vital functions-Unconscious: maintain adequate airway and respiration. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
Inhalation	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.



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Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Ingestion	If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. Rinse mouth with water-Immediately after ingestion: give lots of water to drink
Section 5: Fire-Fighting Measures	
Flammability	Flammable, Keep away from heat
Extinguishing Media	Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area
Protection of Firefighters	Wear full protective clothing and self-contained breathing apparatus.
Hazardous Combustion Products	Not applicable
Other information	Decontaminate protective clothing and equipment before reuse.
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 labeled container for recovery or disposal.
Section 7: Handling and Storage	
Handling Precautions	Avoid exposure and formation of dust and aerosols. When handling broken or crushed tablets or capsules, ensure worker exposure is below the recommended exposure limit. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Container Requirements	Store in the original primary packaging as provided.
Storage Conditions	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Section 8: Exposure Controls/Personal Protection	
Engineering Controls	Not required when handling tablets or containers. Ventilation should be matched to conditions.



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Respiratory Protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Personal Protection	If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves
Recommended Facilities	Eye wash, washing facilities

Section 9: Physical and Chemical Properties

General Information

Appearance	
Physical State	Solid
Form	Tablets
Odour	Not available
pH	Not available
Description & Availability	10mg - Orange, round, unscored tablets debossed with 'H' on one side and '38' on the other side. Supplied in Bottles of 100 Tablets NDC 31722-519-01 Bottles of 500 Tablets NDC 31722-519-05 Bottles of 1000 Tablets NDC 31722-519-10 25mg - Orange, round, unscored tablets debossed with 'H' on one side and '39' on the other side. Supplied in Bottles of 100 Tablets NDC 31722-520-01 Bottles of 500 Tablets NDC 31722-520-05 Bottles of 1000 Tablets NDC 31722-520-10 50mg - Orange, round, unscored tablets debossed with 'H' on one side and '40' on the other side. Supplied in Bottles of 100 Tablets NDC 31722-521-01 Bottles of 500 Tablets NDC 31722-521-05 Bottles of 1000 Tablets NDC 31722-521-10 100mg - Orange, round, unscored tablets debossed with 'H' on one side and '41' on the other side. Supplied in Bottles of 100 Tablets NDC 31722-522-01 Bottles of 500 Tablets NDC 31722-522-05

Section 10: Stability and Reactivity

Stable under recommended storage conditions



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Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a lifetime study in Swiss albino mice, there was a statistically significant increase in the incidence of lung tumors (adenomas and adenocarcinomas) of both male and female mice given hydralazine continuously in their drinking water at a dosage of about 250 mg/kg per day (about 80 times the maximum recommended human dose). In a 2-year carcinogenicity study of rats given hydralazine by gavage at dose levels of 15, 30, and 60 mg/kg/day (approximately 5 to 20 times the recommended human daily dosage), microscopic examination of the liver revealed a small, but statistically significant, increase in benign neoplastic nodules in male and female rats from the high-dose group and in female rats from the intermediate-dose group. Benign interstitial cell tumors of the testes were also significantly increased in male rats from the high-dose group. The tumors observed are common in aged rats and a significantly increased incidence was not observed until 18 months of treatment. hydralazine was shown to be mutagenic in bacterial systems (Gene Mutation and DNA Repair) and in one of two rat and one rabbit hepatocyte in vitro DNA repair studies. Additional in vivo and in vitro studies using lymphoma cells, germinal cells, and fibroblasts from mice, bone marrow cells from Chinese hamsters and fibroblasts from human cell lines did not demonstrate any mutagenic potential for hydralazine.

The extent to which these findings indicate a risk to man is uncertain. While long-term clinical observation has not suggested that human cancer is associated with hydralazine use, epidemiologic studies have so far been insufficient to arrive at any conclusions.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Waste treatment methods

Additional information	Wash clothing and equipment after handling
Ecology - waste materials	Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

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



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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

Section 16, Other information

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.