



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	Torsemide Tablets 5 mg, 10 mg, 20 mg and 100 mg
Active substance	Torsemide
Intended Uses	Torsemide Tablet is indicated for the treatment of edema associated with congestive heart failure, renal disease, or hepatic disease.
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	
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety
Known Clinical Effects:	Adverse effects associated with therapeutic use include dizziness, headache, nausea, drowsiness, thirst, effects on hearing, and gastrointestinal disturbances. May cause kidney effects.
Section 3: Composition/Information on Ingredients	
Components	CAS No.
Torsemide	56211-40-6
Lactose Monohydrate	63-42-3
Microcrystalline Cellulose	9004-34-6
Crospovidone	94800-10-9
povidone USP	9003-39-8
Magnesium Stearate	557-04-0
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.



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

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	
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	Carbon dioxide, carbon monoxide, oxides of nitrogen
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	



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

Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
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	<ul style="list-style-type: none"> 5mg - white to off white, oval shaped, scored tablets, debossed with '56' on scored side and 'H' on the opposite side. Supplied in Bottles of 100 Tablets NDC 31722-529-01 Bottles of 500 Tablets NDC 31722-529-05 10mg - white to off white, oval shaped, scored tablets, debossed with '57' on scored side and 'H' on the opposite side. Supplied in Bottles of 100 Tablets NDC 31722-530-01 Bottles of 500 Tablets NDC 31722-530-05 20mg - white to off white, oval shaped, scored tablets, debossed with '59' on scored side and 'H' on the opposite side. Supplied in Bottles of 100 Tablets NDC 31722-531-01 Bottles of 500 Tablets NDC 31722-531-05 100mg - white to off white, oval shaped, scored tablets, debossed with '60' on scored side and 'H' on the opposite side. Supplied in Bottles of 100 Tablets NDC 31722-532-01 Bottles of 500 Tablets NDC 31722-532-05



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

Section 10: Stability and Reactivity

Stable under recommended storage conditions

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

No overall increase in tumor incidence was found when torsemide was given to rats and mice throughout their lives at doses up to 9 mg/kg/day (rats) and 32 mg/kg/day (mice). On a body-weight basis, these doses are 27 to 96 times a human dose of 20 mg; on a body-surface-area basis, they are 5 to 8 times this dose. In the rat study, the high-dose female group demonstrated renal tubular injury, interstitial inflammation, and a statistically significant increase in renal adenomas and carcinomas. The tumor incidence in this group was, however, not much higher than the incidence sometimes seen in historical controls. Similar signs of chronic non-neoplastic renal injury have been reported in high-dose animal studies of other diuretics such as furosemide and hydrochlorothiazide.

No mutagenic activity was detected in any of a variety of in vivo and in vitro tests of torsemide and its major human metabolite. The tests included the Ames test in bacteria (with and without metabolic activation), tests for chromosome aberrations and sister-chromatid exchanges in human lymphocytes, tests for various nuclear anomalies in cells found in hamster and murine bone marrow, tests for unscheduled DNA synthesis in mice and rats, and others.

In doses up to 25 mg/kg/day (75 times a human dose of 20 mg on a body-weight basis; 13 times this dose on a body-surface-area basis), torsemide had no adverse effect on the reproductive performance of male or female rats.

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



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

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.