



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	
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Material	Tetrabenazine Tablets, 12.5 mg and 25 mg
Manufacturer	Hetero Labs Limited, Unit V, Polepally, Jadcherla Mahaboob Nagar-509 301, India.
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Section 2, Hazard(s) identification	
Hazard statement Environment	Harmful by ingestion. Harmful if swallowed No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Section 3, Composition/information on ingredients	
Ingredients	CAS
Tetrabenazine	58-46-8
Section 4: First-Aid Measures	
Section 4, First-aid measures	
General advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation	If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician.
Skin Contact	Wash off with soap and plenty of water. Consult a physician.
Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Section 5: Fire-Fighting Measures	
Section 5, Fire-fighting measures	
Fire and Explosion Hazards	Not available
Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Protection of Firefighters	Wear self-contained breathing apparatus for firefighting if necessary.



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Section 6: Accidental Release Measures

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Personal Precautions	Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.
Environmental Precautions	Do not let product enter drains.
Clean-up Methods	Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

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Handling	Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Storage	Store Entecavir Tablets Store at 20 to 25°C (68 to 77° F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

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

Section 9, Physical and chemical properties

Physical Form	Tetrabenazine Tablets, 12.5 mg White to off white, round, flat bevel edged tablets, debossed with 'H' on one side and ' T5' on the other side. Bottle of 56 Tablets (NDC 31722-821-56) Bottle of 112 Tablets (NDC 31722-821-11) Tetrabenazine Tablets, 25 mg Yellowish-buff, round, flat bevel edged tablets, debossed with 'H' on one side and ' T6' with score line on other side. Bottle of 56 Tablets (NDC 31722-822-56) Bottle of 112 Tablets (NDC 31722-822-11)
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Section 10: Stability and Reactivity

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Stable under recommended storage conditions.

Section 11: Toxicological Information

Acute toxicity : LD50 Oral - mouse - 550 mg/kg

Skin corrosion/irritation : no data available



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Serious eye damage/eye irritation : no data available
Respiratory or skin sensitization : no data available
Germ cell mutagenicity : no data available
Carcinogenicity : IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity : Reproductive toxicity - rat – Subcutaneous
Effects on Fertility: Other measures of fertility
Specific target organ toxicity - single exposure (GHS) : no data available
Specific target organ toxicity - repeated exposure (GHS) : no data available
Aspiration hazard : no data available

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Product

Observe all federal, state, and local environmental regulations.

Contaminated packaging

Dispose of as unused product.

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



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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 SDS.