



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	Stavudine Capsules USP, 15 mg, 20 mg, 30 mg and 40 mg
Active substance	Stavudine
Intended Uses	Stavudine Capsules in combination with other antiretroviral agents is indicated for the treatment of HIV-I infection
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:	May damage the unborn child. Suspected of causing cancer. Suspected of causing genetic defects Obtain special instructions before use.
Known Clinical Effects:	May cause effects on central nervous system, liver, and kidney. nausea, Adverse effects associated with therapeutic use include vomiting, headache, dizziness, allergic skin rash, diarrhea, abdominal pain, muscle pain, numbness, sleep disturbances, changes in blood chemistry, sensory/motor nerve injury (peripheral neuropathy).
Section 3: Composition/Information on Ingredients	
Components	CAS No.
Stavudine	3056-17-5
Lactose Monohydrate	63-42-3
Anhydrous Lactose	63-42-3
Microcrystalline Cellulose	9004-34-6
Sodium starch Glycolate	9063-38-1
Magnesium Stearate	557-04-0
Hard gelatin capsules	Mixture
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.



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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.
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.



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Storage Conditions	Stavudine capsules, USP should be stored in tightly closed containers at 25°C (77°F). Excursions between 15°C and 30°C (59°F and 86°F) are permitted (see USP Controlled Room Temperature).
Section 8: Exposure Controls/Personal Protection	
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	Capsules
Odour	Not available
pH	Not available
Description & Availability	<ul style="list-style-type: none">15 mg: Dark orange/ Light orange, size '4' hard gelatin capsules, imprinted with 'H' on cap and '63' on body filled with Off white powder. They are available as follows Bottles of 60 Capsules NDC 31722-515-60 Bottles of 100 Capsules NDC 31722-515-01 Bottles of 1000 Capsules NDC 31722-515-1020 mg: Dark orange/ Dark orange, size '3.' hard gelatin capsules, imprinted with 'H' on cap and '64' on body filled with Off white powder. They are available as follows Bottles of 60 Capsules NDC 31722-516-60 Bottles of 100 Capsules NDC 31722-516-01 Bottles of 1000 Capsules NDC 31722-516-10



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- 30 mg: Light orange/ Light orange, size '2' hard gelatin capsules, imprinted with 'H' on cap and '62' on body filled with Off white powder. They are available as follows
Bottles of 60 Capsules NDC 31722-517-60
Bottles of 100 Capsules NDC 31722-517-01
Bottles of 500 Capsules NDC 31722-517-05
- 40 mg: Dark orange/ Dark orange, size '1' hard gelatin capsules, imprinted with 'H' on cap and '61' on body filled with Off white powder. They are available as follows
Bottles of 60 Capsules NDC 31722-518-60
Bottles of 100 Capsules NDC 31722-518-01
Bottles of 500 Capsules NDC 31722-518-05

Section 10: Stability and Reactivity

Stable under recommended storage conditions

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

In 2-year carcinogenicity studies in mice and rats, Stavudine was non carcinogenic at doses which produced exposures (AUC) 39 and 168 times, respectively, human exposure at the recommended clinical dose. Benign and malignant liver tumors in mice and rats and malignant urinary bladder tumors in male rats occurred at levels of exposure 250 (mice) and 732 (rats) times human exposure at the recommended clinical dose.

Stavudine was not mutagenic in the Ames, E. coli reverse mutation, or the CHO/HGPRT mammalian cell forward gene mutation assays, with and without metabolic activation. Stavudine produced positive results in the in vitro human lymphocyte clastogenesis and mouse fibroblast assays, and in the in vivo mouse micronucleus test. In the in vitro assays, Stavudine elevated the frequency of chromosome aberrations in human lymphocytes (concentrations of 25 to 250 mcg/mL, without metabolic activation) and increased the frequency of transformed foci in mouse fibroblast cells (concentrations of 25 to 2500 mcg/mL, with and without metabolic activation). In the in vivo micronucleus assay, Stavudine was clastogenic in bone marrow cells following oral Stavudine administration to mice at dosages of 600 to 2000 mg/kg/day for 3 days.

No evidence of impaired fertility was seen in rats with exposures (based on C_{max}) up to 216 times that observed following a clinical dosage of 1 mg/kg/day.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations



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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

<u>IATA/ICAO - Not Regulated</u>	
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

<u>IMDG - Not Regulated</u>	
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

<u>DOT - Not Regulated</u>	
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.