



# 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

<b>Section 1: Identification</b>	
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<b>Material</b>	<b>Nevirapine Tablets USP 200mg</b>
<b>Manufacturer</b>	<b>Hetero Labs Limited Unit III</b>
	22-110, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc., Piscatway, NJ 08854</b>
<b>Section 2: Hazard(s) Identification</b>	
<b>Section 2, Hazard(s) identification</b>	
<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Section 3, Composition/information on ingredients</b>	
<b>Ingredients</b>	Nevirapine Anhydrous
<b>CAS</b>	[129618-40-2]
<b>Section 4: First-Aid Measures</b>	
<b>Section 4, First-aid measures</b>	
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Inhalation</b>	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.
<b>Skin Contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye Contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Section 5: Fire-Fighting Measures</b>	
<b>Section 5, Fire-fighting measures</b>	
<b>Extinguishing Media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for fire-fighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard fire fighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>Section 6: Accidental Release Measures</b>	
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<b>Personal precautions,</b>	Keep unnecessary personnel away. Wear appropriate personal



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<b>protective equipment and emergency procedures</b>	protective equipment (See Section 8).
<b>Methods and materials for containment and cleaning up</b>	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## Section 7: Handling and Storage

<b>Section 7, Handling and storage</b>	Avoid contact with eyes, skin, and clothing. Avoid breathing dust.
<b>Precautions for safe handling</b>	Wash hands thoroughly after handling.
<b>STORAGE</b>	Nevirapine Tablets, USP should be stored at 25°C (77°F); excursions permitted to 15°to 30°C (59°to 86°F) [see USP Controlled Room Temperature]. Store in a safe place out of the reach of children.

## Section 8: Exposure Controls/Personal Protection

<b>Section 8, Exposure controls/personal protection</b>	None required for normal handling. Wash hands and arms thoroughly after handling.
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## Section 9: Physical and Chemical Properties

<b>Section 9, Physical and chemical properties</b>	
<b>Physical Form</b>	<b>Nevirapine Tablets USP 200mg</b> Off-white to pale yellow colored, capsule shaped, biconvex tablets debossed with 'H' on one side and '7' on other side with a break line on both sides Bottle of 60 Tablets (NDC 31722-505-60) Bottle of 100 Tablets (NDC 31722-505-01) Bottle of 500 Tablets (NDC 31722-505-05) Bottle of 1000 Tablets (NDC 31722-505-10)

## Section 10: Stability and Reactivity

<b>Section 10, Stability and reactivity</b>	Stable under recommended storage conditions.
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## Section 11: Toxicological Information

<b>Section 11, Toxicological Information</b>	
<b>Carcinogenesis, Mutagenesis, Impairment of Fertility</b>	Long-term carcinogenicity studies in mice and rats were carried out with nevirapine. Mice were dosed with 0, 50, 375 or 750 mg/kg/day for two years. Hepatocellular adenomas and carcinomas were increased at all doses in males and at the two high doses in females. In studies in which rats were administered nevirapine at doses of 0, 3.5, 17.5 or 35 mg/kg/day for two years, an increase in hepatocellular



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adenomas was seen in males at all doses and in females at the high dose. The systemic exposure (based on AUCs) at all doses in the two animal studies was lower than that measured in humans at the 200 mg twice daily dose. The mechanism of the carcinogenic potential is unknown. However, in genetic toxicology assays, nevirapine showed no evidence of mutagenic or clastogenic activity in a battery of *in vitro* and *in vivo* studies. These included microbial assays for gene mutation (Ames: Salmonella strains and *E. coli*), mammalian cell gene mutation assay (CHO/HGPRT), cytogenetic assays using a Chinese hamster ovary cell line and a mouse bone marrow micronucleus assay following oral administration. Given the lack of genotoxic activity of nevirapine, the relevance to humans of hepatocellular neoplasms in nevirapine-treated mice and rats is not known. In reproductive toxicology studies, evidence of impaired fertility was seen in female rats at doses providing systemic exposure, based on AUC, approximately equivalent to that provided with the recommended clinical dose of nevirapine.

## Section 12: Ecological Information

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<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Mobility in soil</b>	Product components are soluble in water and will slowly dissolve and disperse.
<b>Other adverse effects</b>	None

## Section 13: Disposal Considerations

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<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## Section 14: Transport Information

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<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMTA</b>	Not regulated as dangerous goods.

## Section 15: Regulatory Information

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This Section Contains Information relevant to compliance with other Federal and/or state laws.



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## Section 16: Other Information

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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.