



# 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	
<b>Product information</b>	
<b>Product Name</b>	Finasteride Tablets USP, 5 mg
<b>Active substance</b>	Finasteride
<b>Intended Uses</b>	Finasteride Tablets USP is indicated for the treatment of benign prostatic hyperplasia (BPH) in men with an enlarged prostate.
<b>Company Details</b>	
<b>Manufacturer</b>	Hetero labs limited, Unit III, 22 - 110, industrial development Area, Jeedimetla, Hyderabad -500 055.
<b>Distributor</b>	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Precautionary Statements</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Avoid release to the environment. Collect spillage.
<b>Effects of Overexposure</b>	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause increased severity of adverse effects. Individuals with underlying renal disease may be at risk for acute renal failure.
<b>Hazard Statements</b>	May be harmful if swallowed.
<b>Potential Health hazards</b>	<b>Inhalation:</b> Not expected to be an inhalation hazard in final pharmaceutical form. <b>Eye Contact:</b> Not expected to be a hazard to the eye in final pharmaceutical form. <b>Skin Contact:</b> Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. <b>Ingestion:</b> May be harmful if ingested. Ingestion may cause headache, nausea, diarrhea and abdominal discomfort.
Section 3: Composition/Information on Ingredients	
<b>Components</b>	<b>CAS No.</b>
Finasteride	98319-26-7
Lactose monohydrate	63-42-3
Microcrystalline Cellulose	9004-34-6
Pregelatinized Starch	9005-84-9
Sodium starch Glycolate	9063-38-1
Docusate Sodium	577-11-7
Magnesium Stearate	557-04-0
Opadry Blue	Not Assigned



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## Section 4: First-Aid Measures

<b>General</b>	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.
<b>Inhalation</b>	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.
<b>Eye contact</b>	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.
<b>Skin contact</b>	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.
<b>Ingestion</b>	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

<b>Extinguishing Media</b>	Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area
<b>Protection of Firefighters</b>	Wear full protective clothing and self-contained breathing apparatus.
<b>Hazardous Combustion Products</b>	Carbon dioxide, carbon monoxide, oxides of nitrogen
<b>Other information</b>	Decontaminate protective clothing and equipment before reuse.

## Section 6: Accidental Release Measures

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.

## Section 7: Handling and Storage

<b>Handling Precautions</b>	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.
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<b>Container</b>	Store in the original primary packaging as provided.
<b>Requirements</b>	
<b>Storage Conditions</b>	Store at 20° to 25° C (68° to 77°F) [see USP Controlled Room Temperature].
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Engineering Controls</b>	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.
<b>Respiratory Protection</b>	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.
<b>Personal Protection</b>	If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves
<b>Recommended Facilities</b>	Eye wash, washing facilities
<b>Section 9: Physical and Chemical Properties</b>	
<b>General Information</b>	
<b>Appearance</b>	
<b>Physical State</b>	Solid
<b>Form</b>	Tablets
<b>Odour</b>	Not available
<b>pH</b>	Not available
<b>Description &amp; Availability</b>	<ul style="list-style-type: none"><li>5 mg - blue color, round film coated tablets, debossed with 'H' on one side '37' on other side. They are supplied as follows Bottles of 30 Tablets      NDC 31722-525-30 Bottles of 100 Tablets      NDC 31722-525-01 Bottles of 1000 Tablets      NDC 31722-525-10 Bottles of 90 Tablets      NDC 31722-525-90 Bottles of 500 Tablets      NDC 31722-525-05</li></ul>
<b>Section 10: Stability and Reactivity</b>	
Stable under recommended storage conditions	
<b>Section 11: Toxicological Information</b>	
<b>Carcinogenesis, Mutagenesis, Impairment of Fertility</b>	
No evidence of a tumorigenic effect was observed in a 24-month study in Sprague-Dawley rats receiving doses of finasteride up to 160 mg/kg/day in males and 320 mg/kg/day in females. These doses produced	



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respective systemic exposure in rats of 111 and 274 times those observed in man receiving the recommended human dose of 5 mg/day. All exposure calculations were based on calculated AUC(0 to 24 hr) for animals and mean AUC(0 to 24 hr) for man (0.4 mcg•hr/mL).

In a 19-month carcinogenicity study in CD-1 mice, a statistically significant ( $p \leq 0.05$ ) increase in the incidence of testicular Leydig cell adenomas was observed at 228 times the human exposure (250 mg/kg/day). In mice at 23 times the human exposure, estimated (25 mg/kg/day) and in rats at 39 times the human exposure (40 mg/kg/day) an increase in the incidence of Leydig cell hyperplasia was observed. A positive correlation between the proliferative changes in the Leydig cells and an increase in serum LH levels (2- to 3-fold above control) has been demonstrated in both rodent species treated with high doses of finasteride. No drug-related Leydig cell changes were seen in either rats or dogs treated with finasteride for 1 year at 30 and 350 times (20 mg/kg/day and 45 mg/kg/day, respectively) or in mice treated for 19 months at 2.3 times the human exposure, estimated (2.5 mg/kg/day).

No evidence of mutagenicity was observed in an in vitro bacterial mutagenesis assay, a mammalian cell mutagenesis assay, or in an in vitro alkaline elution assay. In an in vitro chromosome aberration assay, using Chinese hamster ovary cells, there was a slight increase in chromosome aberrations. These concentrations correspond to 4000 to 5000 times the peak plasma levels in man given a total dose of 5 mg. In an in vivo chromosome aberration assay in mice, no treatment-related increase in chromosome aberration was observed with finasteride at the maximum tolerated dose of 250 mg/kg/day (228 times the human exposure) as determined in the carcinogenicity studies.

In sexually mature male rabbits treated with finasteride at 543 times the human exposure (80 mg/kg/day) for up to 12 weeks, no effect on fertility, sperm count, or ejaculate volume was seen. In sexually mature male rats treated with 61 times the human exposure (80 mg/kg/day), there were no significant effects on fertility after 6 or 12 weeks of treatment; however, when treatment was continued for up to 24 or 30 weeks, there was an apparent decrease in fertility, fecundity and an associated significant decrease in the weights of the seminal vesicles and prostate. All these effects were reversible within 6 weeks of discontinuation of treatment. No drug-related effect on testes or on mating performance has been seen in rats or rabbits. This decrease in fertility in finasteride-treated rats is secondary to its effect on accessory sex organs (prostate and seminal vesicles) resulting in failure to form a seminal plug. The seminal plug is essential for normal fertility in rats and is not relevant in man.

## Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

### Waste treatment methods

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