SAFETY DATA SHEETS

This SDS packet was issued with item:

078948568

N/A

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SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification	
Material	**Finasteride Tablets USP, 1 mg**
Manufacturer	**Hetero labs limited,** Unit III, 22-110, IDA Jeedimetla Hyderabad -500 055, India.
Distributor	**Camber Pharmaceuticals, Inc**, Piscatway, NJ 08854.

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification	
Fire and Explosion	Expected to be non-combustible.
Health	Hypersensitivity to any component of this medication. Pregnancy. Finasteride use is contraindicated in women when they are or may potentially be pregnant. Because of the ability of Type II 5α-reductase inhibitors to inhibit the conversion of testosterone to 5α-dihydrotestosterone (DHT), finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male fetus. *[See also Warnings and Precautions (5.3), Use in Specific Populations (8.1), How Supplied/Storage and Handling (16) and Patient Counseling Information (17.2).]* In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.
Environment	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**
Finasteride USP	98319-26-7

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	If swallowed, wash out mouth with water, provided Person is conscious.
Inhalation	Move to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.
Skin Contact	Immediately wash skin with soap and plenty of water for at least 15 minutes.
Eye Contact	Immediately flush eyes with copious amounts of Water for at least 15 minutes.

NOTES TO HEALTH PROFESSIONALS

OVERDOSAGE	In clinical studies, single doses of finasteride up to 400 mg and multiple doses of finasteride up to 80 mg/day for three months did not result in adverse reactions. Until further experience is obtained, no specific treatment for an overdose with finasteride can be recommended. Significant lethality was observed in male and female mice at single oral doses of 1500 mg/m^2 (500 mg/kg) and in female and male rats at single oral doses of 2360 mg/m^2 (400 mg/kg) and 5900 mg/m^2(1000 mg/kg), respectively.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Suitable Extinguishing Media	Water spray, foam, dry chemical powder or Carbon dioxide.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Moisten spillages with water. Ensure suitable personal protection (including respiratory protection) during removal of spillages.

Section 7: Handling and Storage

Section 7, Handling and storage

Handling	Do not breathe dust. Avoid contact with skin and eyes. Atmospheric levels should be controlled in compliance with the occupational exposure limit.
Storage	Store Finasteride tablets USP 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, Safety glasses with side shields for eye protection. Wash hands and arms thoroughly after handling.

Use a NIOSH approved respirator for toxic particulates with a TLV less than 0.05mg/m^3 (i.e approved for radionuclides). Fit testing with a fit test agent is recommended. Use positive pressure air supplied respirator if exposures are high.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form	Finasteride tablets USP, 1 mg Brown color, round film coated tablets, debossed with 'H' on one side and '36' on other side. NDC 31722-526-30 bottles of 30 NDC 31722-526-90 bottles of 90 NDC 31722-526-10 bottles of 1000

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

This product is stable under defined storage conditions.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility	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 respective systemic exposure in rats of 888 and 2192 times those observed in man receiving the recommended human dose of 1 mg/day. All exposure calculations were based on calculated $AUC_{(0 \text{ to } 24 \text{ hr})}$ for animals and mean $AUC_{(0 \text{ to } 24 \text{ hr})}$ for man (0.05 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 1824 times the human exposure (250 mg/kg/day). In mice at 184 times the human exposure, estimated (25 mg/kg/day) and in rats at 312 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 240 and 2800 times (20 mg/kg/day and 45 mg/kg/day, respectively), or in mice treated for 19 months at 18.4 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. 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 (1824 times the human exposure) as determined in the carcinogenicity studies.

In sexually mature male rabbits treated with finasteride at 4344 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 488 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 but is not relevant in man.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

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.