



SAFETY DATA SHEET

Dutasteride Capsules

1. IDENTIFICATION

Manufacturer:

Ascent Pharmaceuticals Inc
550 S.Research Place
Central Islip, NY 11722
Product Name: Dutasteride capsules

Emergency Phone:

1-855-221-1622

Synonym(s): Not found.

Chemical Name: (5alpha,17beta)-N-(2,5-Bis(trifluoromethyl)phenyl)-3-oxo-4-azaandrost-1-ene-17-carboxamide.

Trade Name(s): Dutasteride capsules, 0.5 mg

Therapeutic Category: In treatment of benign prostatic hyperplasia.

Molecular formula and weight: C₂₇ H₃₀ F₆ N₂O₂

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions. Accidental ingestion of large amounts may be harmful.

Emergency Overview

Primary Physical and Health Hazards: Toxic, Reproductive Toxicity

CAUTION STATEMENT:

WARNING: Avoid contact during pregnancy/while nursing

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Label elements**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Dutasteride	[164656-23-9]	0.093 % (approx.)
Excipients	NA	99.907 % (approx.)

4. FIRST AID MEASURES

Inhalation: No emergency procedures necessary for intact Capsules. In case of accidental inhalation, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms appear.

Eye Contact: No emergency procedures necessary for intact Capsules. If exposure occurs to crushed or broken capsules immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact: No emergency procedures necessary for handling intact Capsules. If exposure occurs to crushed Capsules, wash with soap and water. Get medical attention if irritation develops. Take off contaminated clothing and wash before reuse.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately

Most important symptoms/effects, acute and delayed: The following adverse effects have been noted with therapeutic use of this material: decrease in ejaculatory volume; mild reduction in sperm count; breast enlargement and tenderness in males decrease in libido; symptoms of hypersensitivity (such as skin rash, hives, itching).



Indication of immediate medical attention and special treatment needed:

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information Centre.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5.FIRE-FIGHTING MEASURES

Extinguisher Media: Use foam or all-purpose dry chemicals to extinguish. This material is harmful to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any water way, sewer or drain.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Fire and Explosion Hazards: None known under normal conditions of product handling.

Hazardous Decomposition Products: gases hazardous to health may be formed.

6.ACCIDENTAL RELEASE MEASURES

The following are recommended for manufacturing or other situations where exposure may occur.

Personal Precautions: Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. For large spills, immediately contact emergency personnel. Keep unnecessary personnel away. Use suitable protective equipment.

Methods for cleaning up: Contain the source of spill if it is safe to do so. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water

7.HANDLING AND STORAGE

Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while

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nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.

Storage Conditions: Controlled Room Temperature: 20° to 25° C (68° to 77° F). Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limit Values

Material	Type	Value
Dutasteride (CAS 164653-23-9))	TWA	0.3 micrograms/ m ³

Capsules are not considered hazardous under normal handling procedures and the following are recommended for manufacturing or other situations where exposure may occur.

Engineering Controls: Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment:

Eye/Face Protection: Wear safety glasses with side shields wherever the potential exists for direct exposure to capsules.

Skin Protection: Use disposable chemical resistant gloves

Respiratory Protection: None required with normal handling of finished product. Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Additional Exposure Precautions: None required with normal handling of finished product. Use disposable outer garments or chemical resistant garments of equal or greater protection, when there is potential for direct contact with crushed or leaking capsules. Protect exposed skin. New or expectant mothers might be at greater risk from overexposure. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager.



9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Yellow oblong capsules containing clear liquid printed with 'AT131' with black ink.

Physical State: Solid (Capsule)

Boiling Point: Not available

Melting range: Dutasteride: 243.9°C-247.4°C

Specific Gravity: Not available

pH: Not available.

Evaporation Rate: Not available

Solubility: Not available

Vapor Density: Not available.

Vapor Pressure: Not available.

10. STABILITY AND REACTIVITY

Stability: The product is stable.

Incompatibilities: Strong oxidizing agents

Hazardous Polymerization: Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. TOXICOLOGICAL INFORMATION

Oral Rat: MLD: > 1500 mg/kg

Oral Mouse: MLD: > 2000 mg/kg

Dermal Rabbit MLD: > 2000 mg/kg

Listed as a Carcinogen by: NTP: No IARC: No OSHA: No

Irritancy Data: Skin/rabbit: not irritating
Eye/rabbit: Slight

Symptoms related to the physical, chemical, and toxicological characteristics: In males: Impotence. Decreased ejaculate. Decreased sexual desire. Swelling or tenderness of breasts. Skin rash.

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Skin sensitization: Based on available data, the classification criteria are not met.
Sensitization Buehler test Result: Negative Species: Guinea pig

Carcinogenicity: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

12.ECOLOGICAL INFORMATION

Eco-toxicity: No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.

Avoid release in to the environment

Runoff from fire control or dilution water may cause pollution.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste in accordance with all applicable Federal, State, or local regulations.

14.TRANSPORT INFORMATION

Regulatory Organizations:

DOT: Not Regulated

IATA: Not Regulated

15.REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Ascent and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.



U.S. Regulations

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 311/312 : Not on this list

OSHA Substance Specific – Not on this list

16.OTHER INFORMATION

SDS Sections Revised: New SDS

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute or product literature which may accompany the finished product.

GLOSSARY:

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

DOT = Department of Transportation

ECG = Electrocardiography

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/ International Air Transport Association

IMO = International Maritime Organization

MSDS = Material Safety Data Sheet

NA = Not Applicable

NIOSH = National Institute for Occupational Safety and Health

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

SARA = Superfund Amendments and Reauthorization Act

SSRI's = Selective serotonin reuptake inhibitor

TSCA = Toxic Substances Control Act

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