# Material Safety data sheet

**BROMOCRIPTINE MESYLATE CAPSULES USP**

**Strength:** 5 mg **Pack Size:** 30/100 Capsules per bottle **Revision No.:** 00

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**EMERGENCY OVERVIEW**

BROMOCRIPTINE MESYLATE CAPSULES USP contains BROMOCRIPTINE MESYLATE and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

## Section 1. Identification of the substance

**Identification of the product**

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| **Product name:** | BROMOCRIPTINE MESYLATE CAPSULES USP |
| **Formula:** | $C_{32}H_{40}BrN_5O_5.CH_4SO_3$ |
| **Chemical Name:** | Ergotaman-3′,6′,18-trione,2-bromo-12′-hydroxy-2′-(1-methylethyl)-5′-(2-methylpropyl)-, (5′α)-mono-methanesulfonate (salt). |
| **Therapeutic Category** | Dopamine Receptor Agonist |

**Manufacturer / supplier identification**

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|---|---|
| **Company:** | **Cadila Healthcare Ltd. Ahmedabad, India** |
| **Contact for information:** | Tel.: +91 79 26868100 Fax: +91 79 26862365 |
| **Emergency telephone No.** | Tel.: +91 79 26868100 |

## Section 2. Composition / information on ingredients

| Component | Exposure Limit | CAS No. |
|---|---|---|
| **Principle Component :** | | |
| BROMOCRIPTINE MESYLATE. | Not Found | 22260-51-1 |
| **Inactive Ingredients :** | | |
| Colloidal silicon dioxide | Not Found | 7631-86-9 |
| D & C Red #28 | Not Found | |
| FD & C Blue # 1 | Not Found | |
| FD & C Yellow # 6 | Not Found | |
| Lactose monohydrate | Not Found | 63-42-3 |
| Magnesium stearate | Not Found | 557-04-0 |
| Maleic Acid | Not Found | 110-16-7 |
| Titanium dioxide | Not Found | 13463-67-7 |

## Section 3. Health Hazards Information

Dose and Administration

**General:**
It is recommended that bromocriptine mesylate tablets and capsules be taken with food. Patients should be evaluated frequently during dose escalation to determine the lowest dosage that produces a therapeutic response.

**Hyperprolactinemic Indications:**
The initial dosage of bromocriptine mesylate tablets in adults is ½ to one 2½ mg scored tablet daily. An additional 2½ mg tablet may be added to the treatment regimen as tolerated every 2-7 days until an optimal therapeutic response is achieved. The therapeutic dosage ranged from 2.5-15 mg daily in adults studied clinically.

**Parkinson's Disease:**
The basic principle of bromocriptine mesylate therapy is to initiate treatment at a low dosage and, on an individual basis, increase the daily dosage slowly until a maximum therapeutic response is achieved. The dosage of levodopa during this introductory period should be maintained, if possible. The initial dose of bromocriptine is ½ of a 2½ mg tablet twice daily with meals

Adverse Effects

- Symptomatic hypotension
- Blurred vision
- Headache, dizziness, nausea, vomiting, fatigue, syncope , diarrhea and cramps. Decreases in blood pressure
- Long-term treatment (6-36 months) with bromocriptine mesylate tablets and capsules in doses ranging from 20-100 mg/day has been associated with pulmonary infiltrates, pleural effusion and thickening of the pleura in a few patients

Over Dose Effect

The most commonly reported signs and symptoms associated with acute bromocriptine mesylate overdose are: nausea, vomiting, constipation, diaphoresis, dizziness, pallor, severe hypotension, malaise, confusion, lethargy, drowsiness, delusions, hallucinations, and repetitive yawning. The lethal dose has not been established and the drug has a very wide margin of safety.

Medical Conditions

**Hyperprolactinemia-Associated Dysfunctions:**
Bromocriptine mesylate tablets and capsules are indicated for the treatment of dysfunctions associated with **hyperprolactinemia** including **amenorrhea** with or without **galactorrhea, infertility or hypogonadism.** Bromocriptine treatment is indicated in patients with **prolactin-secreting adenomas,** which may be the basic underlying endocrinopathy contributing to the above clinical presentations. **Reduction** in **tumor size** has been demonstrated in both male and female patients with macroadenomas. In cases where adenectomy is elected, a

course of bromocriptine mesylate tablets and/or capsules therapy may be used to reduce the tumor mass prior to surgery.

**Acromegaly:**

Bromocriptine mesylate tablets and capsules therapy is indicated in the treatment of acromegaly.

**Parkinson's Disease:**

Bromocriptine mesylate tablets or capsules are indicated in the treatment of the signs and symptoms of idiopathic or postencephalitic Parkinson's disease. As adjunctive treatment to levodopa (alone or with a peripheral decarboxylase inhibitor), bromocriptine therapy may provide additional therapeutic benefits in those patients who are currently maintained on optimal dosages of levodopa, those who are beginning to deteriorate (develop tolerance) to levodopa therapy, and those who are experiencing "end of dose failure" on levodopa therapy.

Contraindications

Uncontrolled hypertension and sensitivity to any ergot alkaloids. In patients being treated for hyperprolactinemia, bromocriptine mesylate tablets and capsules should be withdrawn when pregnancy is diagnosed In the event that bromocriptine is reinstituted to control a rapidly expanding macroadenoma and a patient experiences a hypertensive disorder of pregnancy, the benefit of continuing bromocriptine must be weighed against the possible risk of its use during a hypertensive disorder of pregnancy. When bromocriptine is being used to treat acromegaly, prolactinoma, or Parkinson's disease in patients who subsequently become pregnant, a decision should be made as to whether the therapy continues to be medically necessary or can be withdrawn. If it is continued, the drug should be withdrawn in those who may experience hypertensive disorders of pregnancy (including eclampsia, preeclampsia, or pregnancy-induced hypertension) unless withdrawal of bromocriptine is considered to be medically contraindicated.

The drug should not be used during the post-partum period in women with a history of coronary artery disease and other severe cardiovascular conditions unless withdrawal is considered medically contraindicated. If the drug is used in the post-partum period the patient should be observed with caution.

Pregnancy Comments

Administration of 10-30 mg/kg of bromocriptine to 2 strains of rats on days 6-15 post coitum (p.c.) as well as a single dose of 10 mg/kg on day 5 p.c. interfered with nidation. Three mg/kg given on days 6-15 were without effect on nidation, and did not produce any anomalies. In animals treated from day 8-15 p.c., i.e., after implantation, 30 mg/kg produced increased prenatal mortality in the form of increased incidence of embryonic resorption. One anomaly, aplasia of spinal vertebrae and ribs, was found in the group of 262 fetuses derived from the dams treated with 30 mg/kg bromocriptine. No fetotoxic effects were found in

offspring of dams treated during the peri- or post-natal period.

Two studies were conducted in rabbits (2 strains) to determine the potential to interfere with nidation. Dose levels of 100 or 300 mg/kg/day from day 1 to day 6 p.c. did not adversely affect nidation. The high dose was approximately 63 times the maximum human dose administered in controlled clinical trials (100 mg/day), based on body surface area. In New Zealand white rabbits some embryo mortality occurred at 300 mg/kg which was a reflection of overt maternal toxicity.
No teratological or embryo-toxic effects of bromocriptine were produced in any of 6 offspring from 6 monkeys at a dose level of 2 mg/kg.

Information concerning 1276 pregnancies in women taking bromocriptine has been collected. In the majority of cases, bromocriptine was discontinued within 8 weeks into pregnancy (mean 28.7 days), however, 8 patients received the drug continuously throughout pregnancy. The mean daily dose for all patients was 5.8 mg (range 1-40 mg).

Pregnancy Category ***B***

## Section 4. First aid measures

General: Remove from exposure. Remove contaminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention

Overdose Treatment: Treatment of overdose consists of removal of the drug by emesis (if conscious), gastric lavage, activated charcoal, or saline catharsis. Careful supervision and recording of fluid intake and output is essential. Hypotension should be treated by placing the patient in the Trendelenburg position and administering I.V. fluids. If satisfactory relief of hypotension cannot be achieved by using the above measures to their fullest extent, vasopressors should be considered..

## Section 5. Fire – fighting measures

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| **Flash point** | Not Found | **Upper Flammable Limit:** | Not Found |
| **Auto-Ignition Temperature:** | Not Found | **Lower Flammable Limit:** | Not Found |
| **Extinguishing Media** | Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material. | **Fire and Explosion Hazard** | This material is assumed to be combustible.<br>As with all dry powders it is advisable to ground mechanical equipment in contact with the dry |

material to dissipate the potential build up of static electricity.

**Fire Fighting Procedure** As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

## Section 6. Storage / Spill / Disposal Measures

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| Storage | Store at 20° to 25°C (68° to 77° F) [See USP Controlled Room Temperature]; in tight, light-resistant container. |
| Spill Response | Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site. |
| Disposal | Dispose the waste in accordance with all applicable Federal, State and local laws. |

## Section 7. Exposure controls and personal protection

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| Respiratory Protection | Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate. |
| Skin Protection | Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling. |
| Eye protection | Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses. |
| Protective Clothing | Protective clothing is not normally necessary, however it is good practice to use apron. |

## Section 8. Physical and chemical properties

**Appearance** Bromocriptine Mesylate Capsules USP, 5 mg are white to off-white powder filled in size "3" empty hard gelatin capsules with tan colored cap printed with "ZA 17" in black ink and white colored body printed with "5 mg" in black ink and are supplied as follows:

NDC 68382-110-06 in bottle of 30 capsules
NDC 68382-110-01 in bottle of 100 capsules

| | | | |
|---|---|---|---|
| **Solubility in water** | No Data Available | **Odour** | Odourless |
| **Boiling point** | No Data Available | **Melting Point** | No Data Available |
| **Evaporation rate** | No Data Available | **Vapour density** | No Data Available |

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|---|---|---|---|
| **Reactivity in water** | No Data Available | **Evaporation rate** | No Data Available |
| **Percentage Volatile by volume** | No Data Available | **Specific gravity** | No Data Available |
| **Vapour pressure** | No Data Available | | |
| **Other information** | Bromocriptine mesylate, USP is white or slightly colored, fine crystalline powder and odorless or having a weak, characteristic odor. | | |

## Section 9. Physical Hazards

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| **Condition to avoid** | Avoid exposure to extreme heat, light and moisture. | **Stable** | Stable under normal ambient and anticipated storage and handling conditions. |
| **Decomposition Products** | No Data Available | **Hazardous Reaction** | No data available. |
| **Incompatibilities** | No data available. | | |

## Section 10. Toxicological information

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| General | Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation. |
| Target organ | Eye contact, Skin contact and inhalation is not great risk as this product is capsules. |

## Section 11. Ecological information

No data available on Ecotoxicity

## Section 12. Other information

None

**Date of issue:** 19/11/2008 **Supersedes edition of:** New Edition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.