

**Safety Data Sheet**  
**BROMOCRIPTINE MESYLATE TABLETS, USP**

**Strength:** 2.5 mg.

**Pack Size:** 30/100 Tablets per bottle

**Revision No.:** 02

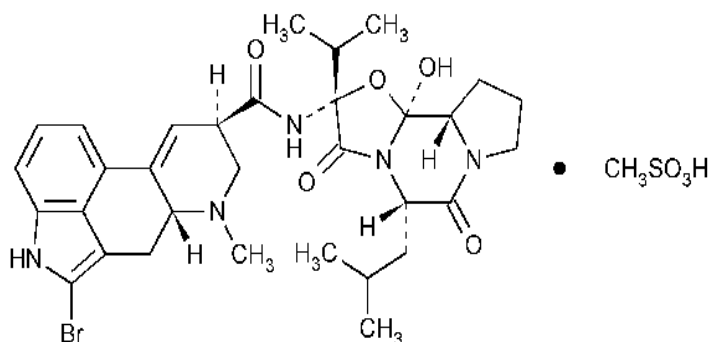
**EMERGENCY OVERVIEW**

Each Bromocriptine mesylate tablet USP, 2.5 mg intended for oral administration contains bromocriptine mesylate equivalent to 2.5 mg of bromocriptine and excipients considered nontoxic and nonhazardous in small quantities and under conditions of normal occupational exposure.

**Section 1. Identification**

**Identification of the product**

- Product name:** Bromocriptine Mesylate
- Formula:**  $C_{32}H_{40}BrN_5O_5 \cdot CH_4SO_3$
- Chemical Name:** Ergotaman-3',6',18-trione, 2-bromo-12'-hydroxy-2'-(1-methylethyl)-5'-(2-methylpropyl)-, (5' $\alpha$ )-mono-methanesulfonate (salt).



**Manufacturer / supplier identification**

- Company:** Cadila Healthcare Ltd. Ahmedabad, India
- Address:** Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.  
Dist. Ahmedabad – 382210. State: Gujarat. India
- Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319
- Emergency Telephone No.** Tel.: +91 79 6868100
- Recommended use /  
Therapeutic Category** Antiparkinsonion.

Strength: 2.5 mg.

Pack Size: 30/100 Tablets per bottle

Revision No.: 02

**Restriction on Use /  
Contraindications:**

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 In patients being treated for hyperprolactinemia bromocriptine mesylate tablets should be withdrawn when pregnancy is diagnosed.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become pregnant, a decision should be made as to whether the therapy continues to be medically necessary or can be withdrawn. If it is continued, the drug should be withdrawn in those who may experience hypertensive disorders of pregnancy (including eclampsia, preeclampsia, or pregnancy-induced hypertension) unless withdrawal of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

**Section 2. Hazard(s) Information**

**Dose and  
Administration**

**General:**

It is recommended that bromocriptine mesylate tablets be taken with food.

**Hyperprolactinemic Indications:**

½ tab to 1 tab if 2.5 mg. additional 2½ mg tablet may be Added to the treatment regimen as tolerated

**Acromegaly:**

½ tab to 1 tab if 2.5 mg bromocriptine mesylate tablet on retiring (with food) for 3 days. An additional ½ to 1 tablet should be added to the treatment regimen as tolerated every 3-7 days until the patient obtains optimal therapeutic benefit.

**Parkinson's Disease:**

½ tab to 1 tab if 2.5 mg tablet twice daily with meals.

**Adverse Effects**

**Hyperprolactinemic Indications:**

nausea (49%), headache (19%), dizziness (17%), fatigue (7%), lightheadedness (5%), vomiting (5%), abdominal cramps (4%), nasal congestion (3%), constipation (3%), diarrhea (3%) and drowsiness (3%).

**Acromegaly:**

nausea (18%), constipation (14%), postural/ orthostatic hypotension (6%), anorexia (4%), dry mouth/nasal stuffiness (4%),

**Safety Data Sheet**  
**BROMOCRIPTINE MESYLATE TABLETS, USP**

**Strength:** 2.5 mg.

**Pack Size:** 30/100 Tablets per bottle

**Revision No.:** 02

---

indigestion/dyspepsia (4%), digital vasospasm (3%), drowsiness/tiredness (3%) and vomiting (2%).

**Parkinson's Disease:**

nausea, abnormal involuntary movements, hallucinations, confusion, "on-off" phenomenon, dizziness, drowsiness, faintness/ fainting, vomiting, asthenia, abdominal discomfort, visual disturbance, ataxia, insomnia, depression, hypotension, shortness of breath, constipation, and vertigo.

**Over Dose Effect**

The most commonly reported signs and symptoms associated with acute bromocriptine mesylate tablets 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. However, one death occurred in a patient who committed suicide with an unknown quantity of bromocriptine mesylate and chloroquine.

**Medical Conditions**

Since hyperprolactinemia with amenorrhea/galactorrhea and infertility has been found in patients with pituitary tumors, a complete evaluation of the pituitary is indicated before treatment with bromocriptine mesylate.

If pregnancy occurs during bromocriptine administration, careful observation of these patients is mandatory. Prolactin-secreting adenomas may expand and compression of the optic or other cranial nerves may occur, emergency pituitary surgery becoming necessary. In most cases, the compression resolves following delivery. Reinitiation of bromocriptine treatment has been reported to produce improvement in the visual fields of patients in whom nerve compression has occurred during pregnancy. The safety of bromocriptine treatment during pregnancy to the mother and fetus has not been established.

Bromocriptine mesylate has been associated with somnolence, and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported. Patients must be informed of this and advised not to drive or operate machines during treatment with bromocriptine. Patients who have experienced somnolence and/or an episode of sudden sleep onset must not drive or operate machines. Furthermore, a reduction of dosage or termination of therapy may be considered.

**Safety Data Sheet**  
**BROMOCRIPTINE MESYLATE TABLETS, USP**

**Strength:** 2.5 mg.

**Pack Size:** 30/100 Tablets per bottle

**Revision No.:** 02

**Contraindications**

Uncontrolled hypertension and sensitivity to any ergot alkaloids. In patients being treated for hyperprolactinemia bromocriptine mesylate tablets should be withdrawn when pregnancy is diagnosed. In the event that bromocriptine mesylate tablets are reinstated to control a rapidly expanding macroadenoma and a patient experiences a hypertensive disorder of pregnancy, the benefit of continuing bromocriptine mesylate tablets must be weighed against the possible risk of its use during a hypertensive disorder of pregnancy. When bromocriptine mesylate tablets are 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 mesylate tablets are considered to be medically contraindicated.

**Pregnancy Comments**

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 Category**

**B**

**Section 3. Composition / information on ingredients**

<b>Component</b>	<b>Exposure Limit</b>	<b>CAS No.</b>
<b>Principle Component :</b>		
Bromocriptine Mesylate	Not Found	25614-03-3
<b>Inactive Ingredients :</b>		
Butylated hydroxyanisole	Not Found	25013-16-5
Colloidal silicon dioxide	Not Found	7631-86-9
Lactose monohydrate	Not Found	63-42-3

**Safety Data Sheet**  
**BROMOCRYPTINE MESYLATE TABLETS, USP**

**Strength:** 2.5 mg.

**Pack Size:** 30/100 Tablets per bottle

**Revision No.:** 02

---

Magnesium stearate	Not Found	557-04-0
Maleic acid	Not Found	110-16-7
Povidone	Not Found	9003-39-8

**Section 4. First - aid measures**

**General** Remove from exposure. Remove contaminated Clothing. Person developing 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**

**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. 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.

Strength: 2.5 mg.

Pack Size: 30/100 Tablets per bottle

Revision No.: 02

---

**Section 6. Accidental Release Measures**

**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.

**Section 7. Handling and Storage**

**Storage**                   Store at 20° to 25°C (68° to 77°F) [See USP Controller Room Temperature]. Dispense in a tight, light-resistant container.

**Incompatibilities:**       No Data available.

**Section 8. Exposure controls / personal protection**

**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.

**Engineering Control**       Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

**Safety Data Sheet**  
**BROMOCRIPTINE MESYLATE TABLETS, USP**

**Strength:** 2.5 mg.

**Pack Size:** 30/100 Tablets per bottle

**Revision No.:** 02

**Section 9. Physical and chemical properties**

**Appearance** Bromocriptine mesylate, USP is white or slightly colored, fine crystalline powder and odorless or having a weak, characteristic odor.

<b>Solubility in water</b>	No Data Available	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>% Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
		<b>Vapour pressure</b>	No Data Available

**Other information** No Data Available

**Section 10. Stability and Reactivity**

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal ambient and anticipated storage and handling conditions.
---------------------------	---	---------------	--

<b>Decomposition Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
-------------------------------	-------------------	---------------------------	--------------------

**Incompatibilities:** No Data available.

**Section 11. Toxicological information**

**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 tablet.

**Other** No Data available.

**Section 12. Ecological information**

Do not allow product to enter drinking water supplies, waste water or soil

**Section 13. Disposal Consideration**

Dispose the waste in accordance with all applicable Federal, State

**Safety Data Sheet**  
**BROMOCRYPTINE MESYLATE TABLETS, USP**

**Strength:** 2.5 mg.

**Pack Size:** 30/100 Tablets per bottle

**Revision No.:** 02

---

and local laws.

**Section 14. Transport Information**

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

**Section 15. Regulatory Information**

Generic Medicine. Approved by USFDA & the ANDA Number is 78741

**Section 16. Other information**

None

**Date of issue:** 28/05/2015

**Supersedes edition of:** 01

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.