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$_5$O$_{5}$CH$_4$SO$_3$
Chemical Name: Ergotaman-3´,6´,18-trione, 2-bromo-12´-hydroxy-2´-(1-methylethyl)-5´-(2-methylpropyl)-, (5´α)-mono-methanesulfonate (salt).

Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, 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

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 In patients being treated for hyperprolactinemia bromocriptine mesylate tablets should be withdrawn when pregnancy is diagnosed.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 reinstituted 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become pregnant, a decision should be made as to whether the therapy continues to be medically necessary or can be withdrawn. If it is continued, the drug should be withdrawn in those who may experience hypertensive disorders of pregnancy (including eclampsia, preeclampsia, or pregnancy-induced hypertension) unless withdrawal of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%).
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.
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 reinstituted 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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>Not Found</td>
</tr>
<tr>
<td>Auto-Ignition Temperature</td>
<td>Not Found</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Water Spray, dry chemical, carbon dioxide</td>
</tr>
<tr>
<td>Fire Fighting Procedure</td>
<td>As with all fires, evacuate personnel to a</td>
</tr>
</tbody>
</table>

### Upper Flammable Limit: Not Found

### Lower Flammable Limit: Not Found

### 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.
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
BROMOCRYPTINE MESYLATE TABLETS, USP

Strength: 2.5 mg.  Pack Size: 30/100 Tablets per bottle   Revision No.: 02

Section 9. Physical and chemical properties

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

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
Reactivity in water  No Data Available  Evaporation rate  No Data Available
% Volatile by volume  No Data Available  Specific gravity  No Data Available
Vapour pressure  No Data Available

Other information  No Data Available

Section 10. Stability and Reactivity

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 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

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.

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

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