Bromotine®

Generic Name: Bromocriptine Mesylate 2.5 mg
Dosage Form: Tablet
TG Name: Antiparkinson drugs, Motility stimulants/Dopamine antagonist

1. What Bromotine® is and what it is used for?

Bromocriptine mesilate is a nonhormonal, nonestrogenic agent that inhibits the secretion of prolactin in humans, with little or no effect on other pituitary hormones, except in patients with acromegaly, where it lowers elevated blood levels of growth hormone. Bromocriptine mesilate is a dopamine receptor agonist, which activates post-synaptic dopamine receptors.The dopaminergic neurons in the tuberoinfundibular process modulate the secretion of prolactin from the anterior pituitary by secreting a prolactin inhibitory factor (thought to be dopamine); in the corpus striatum the dopaminergic neurons are involved in the control of motor function. Clinically, it significantly reduces plasma levels of prolactin in patients with physiologically elevated prolactin as well as in patients with hyperprolactinemia.

Hyperprolactinemia-Associated Dysfunctions: Dysfunctions associated with hyperprolactinemia including amenorrhea with or without galactorrhea, infertility or hypogonadism.

Prolactin secreting adenomas: ln cases where adenectomy is elected, a course of bromocriptine mesilate therapy may be used to reduce the tumor mass prior to surgery.

Acromegaly: Parkinson's Disease: Idiopathic or postencephalitic Parkinson's disease- As adjunctive treatment to levodopa (alone or with a peripheral decarboxylase inhibitor).

2. Before you take Bromotine®

Bromotine® is contraindicated in patient with known hypersensitivity to Bromocriptine Mesylate or any of its excipients.

Take special care with Bromotine®
Interaction

Bromocriptine may interact with dopamine antagonists, butyrophenones, and certain other agents. Compounds in these categories result in a decreased efficacy of Bromocriptine: phenothi-azines, haloperidol, metodopramide, pimozide. Concomitant use of Bromocriptine with other ergot alkaloids is not recommended.

Pregnancy & Lactation

Pregnancy category B. Bromocriptine should not be used during lactation in postpartum women.

Precautions & Warnings

Safety and efficacy of bromocriptine mesilate have not been established in patients with renal or hepatic disease. Care should be exercised when administering Bromocriptine therapy concomitantly with other medications known to lower blood pressure.The drug should be used with caution in patients with a history of psychosis or cardiovascular disease. If acromegalic patients or patients with

prolactinoma or Parkinson's disease are being treated with Bromocriptine during pregnancy, they should be cautiously observed.

3. How to take Bromotine®

General: It is recommended that Bromocriptine mesilate be taken with food. Patients should be evaluated frequently during dose escalation to determine the lowest dosage that produces a therapeutic response.

Hyperprolactinemic lndications: The initial dosage is 0.5 mg to 2.5 mg tablet daily. An additional 2.5 mg tablet may be added to the treatment regimen as tolerated as tolerated every 2-7 days until an optimal therapeutic response is achieved.Based on limited data in children of age 11 to 15 the initial dose is 0.5 to 2.5 mg tablet daily. Dosing may need to be increased as tolerated until a therapeutic response is achieved. The therapeutic dosage ranged from 2.5-10 mg daily in children with prolactin-secreting pituitary adenomas.

Acromegaly: The initial recommended dosage is 0.5 to 2.5 mg on retiring (with food) for 3 days. An additional 0.5 to 2.5 mg should be added to the treatment regimen as tolerated every 3-7 days until patient obtains optimal therapeutic benefit. The maximal dosage should not exceed 100 mg/day.

Parkinson's disease: The basic principle of bromocriptine mesilate therapy is to initiate treatment at a low dosage. The initial dose of Bromocriptine mesilate is 0.5 of a 2.5 mg tablet twice daily with meals. If necessary,the dosage may be increased every 14-28 days by 2.5 mg/day with meals.The safety of bromocriptine mesilate has not been demonstrated in dosages exceeding 100 mg/day.

4. Possible side effects

Contraindications

Uncontrolled hypertension and sensitivity to any ergot alkaloids. In patients being treated for hyperprolactinemia Bromocriptine mesilate should be withdrawn when pregnancy is diagnosed.

Post-partum period in women with a history of coronary artery disease & other severe cardiovascular conditions.

Side Effects

Side effects in decreasing order of frequency are: nausea, headache, dizziness, fatigue, lightheadedness, vomiting, abdominal cramps, nasal congestion constipation, diarrhea and drowsiness. A slight hypotensive effect may accompany treatment. The occurrence of adverse reactions may be lessened by temporarily reducing dosage to 0.5 mg. Abnormalities in laboratory tests may include elevations in blood urea nitrogen, SGOT, SGPT, GGPT, CPK, alkaline phosphatase and uric acid, which are usually transient and not of clinical significance

Tell your doctor if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

5. How to store Bromotine®?

Keep below 30°C temperature, away from light & moisture. Keep out of the reach of children.