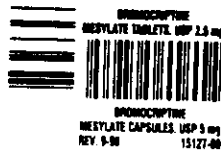


CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-100

FINAL PRINTED LABELING

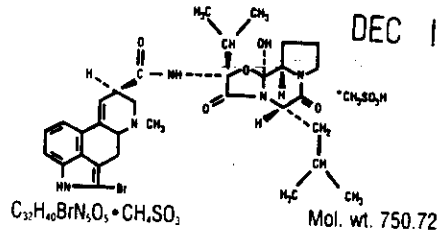


DEC 10 1998

DESCRIPTION

Bromocriptine mesylate is an ergot derivative with potent dopamine receptor agonist activity. Bromocriptine mesylate is chemically designated as 2-bromocryptopyrrolidine monomethanesulfonate (salt). Bromocriptine mesylate is a white or slightly colored, fine crystalline powder odorless or having a weak characteristic odor.

Structural Formula



2.5 mg Tablets

Each tablet for oral administration contains bromocriptine mesylate equivalent to 2.5 mg bromocriptine. In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, lactose monohydrate, magnesium stearate, polydioxane, corn starch, maleic acid and disodium edetate.

5 mg Capsules

Each capsule for oral administration contains bromocriptine mesylate equivalent to 5 mg bromocriptine. In addition, each capsule contains the following inactive ingredients: colloidal silicon dioxide, corn starch, disodium edetate, gelatin, lactose monohydrate, magnesium stearate, maleic acid, polydioxane, titanium dioxide, and red ferric oxide.

CLINICAL PHARMACOLOGY

Bromocriptine mesylate is a dopamine receptor agonist, which activates post-synaptic dopamine receptors. The dopaminergic neurons in the tuberomammillary 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, bromocriptine mesylate significantly reduces plasma levels of prolactin in patients with physiologically elevated prolactin as well as in states is obtained at dose levels that do not affect secretion of other tropic hormones from the anterior pituitary. Experiments have demonstrated that bromocriptine induces long lasting stereotyped behavior in rodents and turning behavior in rats having unilateral lesions in the substantia nigra. These actions, characteristic of those produced by dopamine, are inhibited by dopamine antagonists and suggest a direct action of bromocriptine on striatal dopamine receptors.

Bromocriptine mesylate 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 in the majority of patients.

In about 75% of cases of amenorrhea and galactorrhea, bromocriptine mesylate therapy suppresses the galactorrhea completely, or almost completely, and reinitiates normal ovulatory menstrual cycles.

Menses are usually reinitiated prior to complete suppression of galactorrhea; the time for this on average is 6 to 8 weeks. However, some patients respond within a few days, and others may take up to 8 months.

Galactorrhea may take longer to control depending on the degree of stimulation of the mammary tissue prior to therapy. At least a 75% reduction in secretion is usually observed after 8 to 12 weeks. Some patients may fail to respond even after 12 months of therapy. In many acromegalic patients, bromocriptine mesylate produces a prompt and sustained reduction in circulating levels of serum growth hormone.

Bromocriptine mesylate produces its therapeutic effect in the treatment of Parkinson's disease, a clinical condition characterized by a progressive deficiency in dopamine synthesis in the substantia nigra, by directly stimulating the dopamine receptors in the corpus striatum. In contrast, levodopa exerts its therapeutic effect only after conversion to dopamine by the neurons of the substantia nigra, which are known to be numerically diminished in this patient population.

Pharmacokinetics

The pharmacokinetics and metabolism of bromocriptine in human subjects were studied with the help of radioactively labeled drug. Twenty-eight percent of an oral dose was absorbed from the gastrointestinal tract. The blood levels following a 2.5 mg dose were in the range of 2 to 3 ng equivalents/mL. Plasma levels were in the range of 4 to 6 ng equivalents/mL, indicating that the red blood cells did not contain appreciable amounts of drug and/or metabolites. *In-vitro* experiments showed that the drug was 90% to 96% bound to serum albumin.

Bromocriptine was completely metabolized prior to excretion. The major route of excretion of absorbed drug was via the bile. Only 2.5% to 5.5% of the dose was excreted in the urine. Almost all (84.6%) of the administered dose was excreted in the feces in 120 hours.

INDICATIONS AND USAGE

Hyperprolactinemia-Associated Dysfunctions

Bromocriptine mesylate capsules or tablets are indicated for the treatment of dysfunctions associated with hyperprolactinemia including amenorrhea with or without galactorrhea, infertility or hypogonadism. Bromocriptine mesylate 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 therapy may be used to reduce the tumor mass prior to surgery.

Acromegaly

Bromocriptine mesylate capsules or tablets are indicated in the treatment of acromegaly. Bromocriptine mesylate therapy, alone or as adjunctive therapy with pituitary irradiation or surgery, reduces serum growth hormone by 50% or more in approximately one-half of patients treated, although not usually to normal levels. Since the effects of external pituitary radiation may not become maximal for several years, adjunctive therapy with bromocriptine mesylate offers potential benefit before the effects of irradiation are manifested.

Parkinson's Disease

Bromocriptine mesylate capsules or tablets are indicated in the treatment of the signs and symptoms of idiopathic or postencephalic Parkinson's disease. As adjunctive treatment to levodopa (alone or with a peripheral decarboxylase inhibitor), bromocriptine mesylate therapy may provide additional therapeutic benefits in those patients who are currently maintained on doses 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. Bromocriptine mesylate therapy may permit a reduction of the maintenance dose of levodopa and thus may ameliorate the occurrence and/or severity of adverse reactions associated with long-term levodopa therapy such as abnormal involuntary movements (e.g. dyskinesias) and the marked swings in motor function ("on-off" phenomenon). Continued efficacy of bromocriptine mesylate therapy during treatment of more than two years has not been established.

Data are insufficient to evaluate potential benefit from treating newly diagnosed Parkinson's disease with bromocriptine mesylate. Studies have shown, however, significantly more adverse reactions (notably nausea, hallucinations, confusion and hypotension) in bromocriptine mesylate treated patients than in levodopa/carbidopa treated patients. Patients unresponsive to levodopa are poor candidates for bromocriptine mesylate therapy.

CONTRAINDICATIONS

Uncontrolled hypertension and sensitivity to any ergot alkaloids. In patients being treated for hyperprolactinemia bromocriptine mesylate should be withdrawn when pregnancy is diagnosed (see PRECAUTIONS, Hyperprolactinemic States). In the event that bromocriptine mesylate is instituted to control a rapidly expanding macroadenoma (see PRECAUTIONS, Hyperprolactinemic States) and a patient experiences a hypertensive disorder of pregnancy, the benefit of continuing bromocriptine mesylate must be weighed against the possible risk of its use during a hypertensive disorder of pregnancy. When bromocriptine mesylate 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 unless withdrawal of bromocriptine mesylate 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.

WARNINGS

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 mesylate 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 being reported to produce improvement in the visual fields of patients in whom nerve compression has occurred during pregnancy. The safety of bromocriptine mesylate treatment during pregnancy to the mother and fetus has not been established.

Symptomatic hypotension can occur in patients treated with bromocriptine mesylate for any indication. In postpartum studies with bromocriptine mesylate, decreases in supine systolic and diastolic pressures of greater than 20 mm and 10 mm Hg, respectively, have been observed in almost 30% of patients receiving bromocriptine mesylate. On occasion, the drop in supine systolic pressure was as much as 50 to 59 mm Hg. While hypotension during the start of therapy with bromocriptine mesylate occurs in some patients, in postmarketing experience in the U.S. in postpartum patients 89 cases of hypertension have been reported, sometimes at the initiation of therapy, but often developing in the second week of therapy; seizures have been reported in 72 cases (including 4 cases of status epilepticus), both with and without the prior development of hypertension; 30 cases of stroke have been reported mostly in postpartum patients whose prenatal and perinatal records were available.

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Uncontrolled hypertension and sensitivity to any ergot alkaloids. In patients being treated for hyperprolactinemia bromocriptine mesylate should be withdrawn when pregnancy is diagnosed (see **PRECAUTIONS, Hyperprolactinemic States**). In the event that bromocriptine mesylate is reinstituted to control a rapidly expanding macroadenoma (see **PRECAUTIONS, Hyperprolactinemic States**) and a patient experiences a hypertensive disorder of pregnancy, the benefit of continuing bromocriptine mesylate must be weighed against the possible risk of its use during a hypertensive disorder of pregnancy. When bromocriptine mesylate 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 mesylate 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.

WARNINGS

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If pregnancy occurs during bromocriptine mesylate 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. Reinstatement of bromocriptine mesylate 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 mesylate treatment during pregnancy to the mother and fetus has not been established.

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Although a causal relationship between bromocriptine mesylate administration and hypertension, seizures, strokes, and myocardial infarction in postpartum women has not been established, use of the drug for prevention of physiological lactation, or in patients with uncontrolled hypertension is not recommended. In patients being treated for hyperprolactinemia bromocriptine mesylate should be withdrawn when pregnancy is diagnosed (see **PRECAUTIONS, Hyperprolactinemic States**). In the event that bromocriptine mesylate is reinstituted to control a rapidly expanding macroadenoma (see **PRECAUTIONS, Hyperprolactinemic States**) and a patient experiences a hypertensive disorder of pregnancy, the benefit of continuing bromocriptine mesylate must be weighed against the possible risk of its use during a hypertensive disorder of pregnancy. When bromocriptine mesylate is being used to treat acromegaly 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 is considered to be medically contraindicated. Because of the possibility of an interaction between bromocriptine mesylate and other ergot alkaloids, the concomitant use of these medications is not recommended. Particular attention should be paid to patients who have recently received other drugs that can alter the blood pressure. Periodic monitoring of the blood pressure, particularly during the first weeks of therapy is prudent. If hypertension, severe, progressive, or unremitting headache (with or without visual disturbance), or evidence of CNS toxicity develops, drug therapy should be discontinued and the patient should be evaluated promptly.

Long-term treatment (6 to 36 months) with bromocriptine mesylate in doses ranging from 20 to 100 mg/day has been associated with pulmonary infiltrates, pleural effusion and thickening of the pleura in a few patients. In those instances in which bromocriptine mesylate treatment was terminated, the changes slowly reverted towards normal.

PRECAUTIONS

General

Safety and efficacy of bromocriptine mesylate have not been established in patients with renal or hepatic disease. Care should be exercised when administering bromocriptine mesylate 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 mesylate during pregnancy, they should be cautiously observed, particularly during the post-partum period if they have a history of cardiovascular disease.

Hyperprolactinemic States

The relative efficacy of bromocriptine mesylate versus surgery in preserving visual fields is not known. Patients with rapidly progressive visual field loss should be evaluated by a neurosurgeon to help decide on the most appropriate therapy. Since pregnancy is often the therapeutic objective in many hyperprolactinemic patients presenting with amenorrhea/galactorrhea and hypogonadism (infertility), a careful assessment of the pituitary is essential to detect the presence of a prolactin-secreting adenoma. Patients not seeking pregnancy, or those harboring large adenomas, should be advised to use contraceptive measures, other than oral contraceptives, during treatment with bromocriptine mesylate. Since pregnancy may occur prior to resumption of menses, a pregnancy test is recommended at least every four weeks during the amenorrheic period, and, once menses are reinitiated, every time a patient misses a menstrual period. Treatment with bromocriptine mesylate capsules or tablets should be discontinued as soon as pregnancy has been established. Patients must be monitored closely throughout pregnancy for signs and symptoms that may signal the enlargement of a previously undetected or existing prolactin-secreting tumor. Discontinuation of bromocriptine mesylate treatment in patients with known macroadenomas has been associated with rapid regrowth of tumor and increase in serum prolactin in most cases.

Acromegaly

Cold sensitive digital vasospasm has been observed in some acromegalic patients treated with bromocriptine mesylate. The response, should it occur, can be reversed by reducing the dose of bromocriptine mesylate and may be prevented by keeping the fingers warm. Cases of severe gastrointestinal bleeding from peptic ulcers have been reported. Some fatal. Although there is no evidence that bromocriptine mesylate increases the incidence of peptic ulcers in acromegalic patients, symptoms suggestive of peptic ulcer should be investigated thoroughly and treated appropriately. Patients with a history of peptic ulcer or gastrointestinal bleeding should be observed carefully during treatment with bromocriptine mesylate.

Possible tumor expansion while receiving bromocriptine mesylate therapy has been reported in a few patients. Since the natural history of growth hormone secreting tumors is unknown, all patients should be carefully monitored and, if evidence of tumor expansion develops, discontinuation of treatment and alternative procedures considered.

Parkinson's Disease

Safety during long-term use for more than two years at the doses required for parkinsonism has not been established.

As with any chronic therapy, periodic evaluation of hepatic, hematopoietic, cardiovascular and renal function is recommended. Symptomatic hypotension can occur and, therefore, caution should be exercised when treating patients receiving antihypertensive drugs.

High doses of bromocriptine mesylate may be associated with confusion and mental disturbances. Since parkinsonian patients may manifest mild degrees of dementia, caution should be used when treating such patients.

Bromocriptine mesylate administered alone or concomitantly with levodopa may cause hallucinations (visual or auditory). Hallucinations usually resolve with dosage reduction; occasionally, discontinuation of bromocriptine mesylate is required. Rarely, after high doses hallucinations have persisted for several weeks following discontinuation of bromocriptine mesylate.

As with levodopa, caution should be exercised when administering bromocriptine mesylate to patients with a history of myocardial infarction who have a residual atrial, nodal, or ventricular arrhythmia.

isometric depression, hypertension, shortness of breath, constipation, and vertigo.

Less common adverse reactions which may be encountered include: anorexia, anxiety, bipolar disorder, dry mouth, dysphagia, edema of the feet and ankles, erythromelalgia, epileptiform seizure, fatigue, headache, lethargy, mottling of skin, nasal stuffiness, nervousness, nightmares, paresthesia, skin rash, urinary frequency, urinary incontinence, urinary retention, and rarely, signs and symptoms of ergotism such as tingling of fingers, cold feet, numbness, muscle cramps of feet and legs or exacerbation of Raynaud's Syndrome.

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.

Adverse Events Observed in Other Conditions: Postpartum Patients

In postpartum studies with bromocriptine mesylate 23 percent of postpartum patients treated had at least 1 side effect, but they were generally mild to moderate in degree. Therapy was discontinued in approximately 3% of patients. The most frequently occurring adverse reactions were: headache (10%), dizziness (8%), nausea (7%), vomiting (3%), fatigue (1.0%), syncope (0.7%), diarrhea (0.4%) and cramps (0.4%). Decreases in blood pressure (≥ 20 mm Hg systolic and ≥ 10 mm Hg diastolic) occurred in 28% of patients at least once during the first 3 postpartum days; these were usually of a transient nature. Reports of fainting in the postpartum may possibly be related to this effect. In postmarketing experience in the U.S., serious adverse reactions reported include 72 cases of seizures (including 4 cases of status epilepticus), 30 cases of stroke, and 9 cases of myocardial infarction among postpartum patients. Seizure cases were not necessarily accompanied by the development of hypertension. An unrelenting and often progressively severe headache, sometimes accompanied by visual disturbance, often preceded by hours to days many cases of seizure and/or stroke. Most patients had shown no evidence of any of the hypertensive disorders of pregnancy including eclampsia, preeclampsia or pregnancy induced hypertension. One stroke case was associated with sagittal sinus thrombosis, and another was associated with cerebral and cerebellar vasculitis. One case of myocardial infarction was associated with unexplained disseminated intravascular coagulation and a second occurred in conjunction with use of another ergot alkaloid. The relationship of these adverse reactions to bromocriptine mesylate administration has not been established.

OVERDOSAGE

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, delirium, 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.

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 IV fluids. If satisfactory relief of hypotension cannot be achieved by using the above measures to their fullest extent, vasopressors should be considered.

DOSEAGE AND ADMINISTRATION

General

It is recommended that bromocriptine mesylate 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 is 1/2 to one 2.5 mg tablet daily. An additional 2.5 mg tablet may be added to the treatment regimen as tolerated every 3 to 7 days until an optimal therapeutic response is achieved. The therapeutic dosage usually is 5 to 7.5 mg and ranges from 2.5 to 15 mg/day.

In order to reduce the likelihood of prolonged exposure to bromocriptine mesylate should an unsuspected pregnancy occur, a mechanical contraceptive should be used in conjunction with bromocriptine mesylate therapy until normal ovulatory menstrual cycles have been restored. Contraception may then be discontinued in patients desiring pregnancy.

Thereafter, if menstruation does not occur within 3 days of the expected date, bromocriptine mesylate therapy should be discontinued and a pregnancy test performed.

Acromegaly

Virtually all acromegalic patients receiving therapeutic benefit from bromocriptine mesylate also have reductions in circulating levels of growth hormone. Therefore, periodic assessment of circulating levels of growth hormone will, in most cases, serve as a guide in determining the therapeutic potential of bromocriptine mesylate. If, after a brief trial with bromocriptine mesylate therapy, no significant reduction in growth hormone levels has taken place, careful assessment of the clinical features of the disease should be made, and if no change has occurred, dosage adjustment or discontinuation of therapy should be considered.

The initial recommended dosage is 1/2 to one 2.5 mg bromocriptine mesylate tablet on retiring (with food) for 3 days. An additional 1/2 to 1 tablet should be added to the treatment regimen as tolerated every 3 to 7 days until the patient obtains optimal therapeutic benefit. Patients should be reevaluated monthly and the dosage adjusted based on reductions of growth hormone or clinical response. The usual optimal therapeutic dosage range of bromocriptine mesylate varies from 20 to 30 mg per day in most patients. The maximum dosage should not exceed 100 mg per day.

Patients treated with pituitary irradiation should be withdrawn from bromocriptine mesylate therapy on a yearly basis to assess both the clinical effects of radiation on the disease process as well as the effects of bromocriptine mesylate therapy. Usually a 4 to 8 week withdrawal period is adequate for this purpose. Recurrence of the signs/symptoms or increases in growth hormone indicate the disease process is still active and further courses of bromocriptine mesylate should be considered.

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 mesylate is 1/2 of a 2.5 mg tablet twice daily with meals. Assessments are advised at two week intervals during dosage titration to ensure that the lowest dosage producing an optimal therapeutic response is not exceeded. If necessary, the dosage may be increased every 14 to 28 days by 2.5 mg per c.v. with meals. Should it be advisable to reduce the dosage of levodopa because of adverse reactions, the daily dosage of bromocriptine mesylate, if increased, should be accomplished gradually in small (2.5 mg) increments.

The safety of bromocriptine mesylate has not been demonstrated in dosages exceeding 100 mg per day.

HOW SUPPLIED

Bromocriptine mesylate tablets, USP 2.5 mg are white round tablets, scored on one side with debossed code BCT 2 1/2 on reverse side, and are available in bottles of 30 and 100.

Bromocriptine mesylate capsules, USP 5 mg are opaque pink capsules, imprinted BCT 5 on both the cap and the body, in bottles of 30 and 100.

Store below 25°C (77°F). Dispense in a light, child-resistant container as defined in the USP.

Keep this and all drugs out of the reach of children.

Rx Only

REV 9-98

Manufactured by Lek d d
Ljubljana, Slovenia
Packaged by Rosemont Pharmaceutical Corporation
Denver, CO 80223

U69



Lot No. 90-00112-00-00
Exp. Date: Rev. 10-87

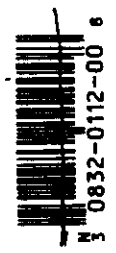
NDC 0832-0112-00
Bromocriptine Mesylate Capsules, USP
5 mg*
Caution: Federal law prohibits dispensing without prescription.
100 Capsules



*Each capsule contains bromocriptine mesylate equivalent to 5 mg bromocriptine.
Usual Dosage: See accompanying literature for complete information.
Dispense in a light, light-resistant container as defined in the USP.
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Lot No.:
Exp.:

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Mfg. by: **Lot 001, Lisle, Ill., Rosemont
Pharmaceutical Corp.
Denver, Colorado 80222**
N 50-0112-03-00 Rev. 10-87



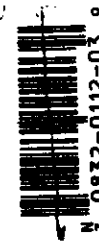
**NDC 0832-0112-03
Bromocriptine
Mesylate
Capsules, USP
5 mg*
30
Capsules**

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N 0832-0110-03 9

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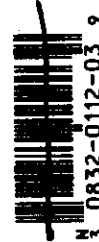
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