Bromodel®

Bromocriptine

Composition: Bromodel® 2.5 mg Tablet: Each tablet contains Bromocriptine Mesilate BP 2.87 mg equivalent to Bromocriptine 2.5 mg.

Mode of action: Acting as a dopamine receptor agonist in the hypothalamus and pituitary gland. It reduces increased prolactin secretion thus reinitiates normal menstrual cycle and manages fertility dysfunctions associated with hyperprolactinemia. It prevents and suppresses milk secretion. In acromegalic patients bromocriptine produces a reduction of increased levels of growth hormone hereby favourably affecting their clinical symptoms and glucose tolerance.

Indications with dosage & administration: Bromocriptine should always be taken during meal.
Menstrual cycle disorders and female infertility: 2.5-3.75 mg (half a tablet 2 or 3 times) daily. If necessary the dose can be increased to 1 tablet 2 or 3 times daily. Treatment is continued until the menstrual cycle returns to normal and/or ovulation is restored. If required, treatment may be continued over several cycles to prevent relapse.
Prolactinomas: 2.5-3.75 mg (half a tablet 2 or 3 times) daily gradually increasing to several tablets daily as required to keep plasma prolactin adequately suppressed.
Acromegaly: Initially 2.5-3.75 mg (half a tablets 2 or 3 times) daily, gradually increasing to 10-20 mg (4 to 8 tablets) daily depending on clinical response and side effects.
Inhibition of lactation: 5 mg (1 tablet twice) daily with morning and evening meals for 14 days. To prevent the onset of lactation treatment should be instituted as early as possible, but not earlier than 4 hours after parturition or abortion. Slight milk secretion occasionally occurs 2 or 3 days after treatment has been withdrawn. This can be stopped by resuming treatment with the same dosage for a further week.
Puerperal breast engorgement: Single dose of 2.5 mg (1 tablet). It may be repeated after 6 to 12 hours, if required, without inappropriate suppression of lactation.
Incipient puerperal mastitis: Same dosage as for inhibition of lactation. An antibiotic should be added to the regimen as required.
Benign breast disease: 2.5-3.75 mg (half a tablet 2 or 3 times) daily, gradually increasing to 2 to 3 tablets per day.
Parkinson's disease: Both in monotherapy or combination therapy treatment should be started with a low dose of 1.25 mg (half a tablet) per day, given preferably in the evening, for one week. In case of combined therapy dosage should be started concurrently with the occurrence of side effects of substitution therapy, e.g. dyskinesia, "end of dose" phenomenon. The adjustment of dosage should be started with the minimal effective dose. The increase of daily dosage should be gradual by increments of 1.25 mg (half a tablet) per day every week. The daily dosage is divided into two or three single doses. An adequate therapeutic response may be reached within 6 to 8 weeks. The common therapeutic dose for monotherapy or combined therapy is 10-40 mg of bromocriptine per day. In latter cases in some patients higher doses may be required, this should be considered individually. For safety reasons the maximum daily dose cannot be higher than 100 mg.

Contraindications: No absolute contraindication is known in endocrinology. In neurology: essential and familial tremor, Huntington's chorea, severe cardiovascular disorders, various forms of endogenous psychoses, untreated hypertension, pregnancy induced toxaemia, hypersensitivity to other ergot alkaloids.

Side effects: During the first few days of treatment some patients may experience nausea, vomiting, headache, dizziness or fatigue, which are not, however, sufficiently serious to require treatment to be discontinued. Initial nausea and/or dizziness may be inhibited by the temporary intake of a suitable antiemetic (e.g. dimenhydrinate, thiethylperazine or metoclopramide), 1 hour prior to the administration of bromocriptine. In rare instances bromocriptine may induce orthostatic hypotension, it is therefore advisable to check blood pressure in ambulant patients in standing position. During high dose treatment hallucinations, confusion, visual disturbance, dyskinesia, dryness of the mouth, constipation and leg cramps may occur. All these side effects are dose dependent and can usually be controlled by a reduction in dosage. Episodes of reversible pallor of the fingers and toes induced by cold may occur occasionally during prolonged treatment, particularly in patients previously exhibiting Raynaud's phenomenon.

Drug interactions: It can be given carefully with the drugs: erythromycin (bromocriptine serum concentration may elevate); dopamine antagonists, e.g. butyrophenones and phenothiazines (bromocriptine effect may decrease). Concurrent use should be avoided with other ergot-alkaloid derivatives.

Warning: In patients wishing to conceive bromocriptine should be discontinued when pregnancy is confirmed. If pregnancy occurs in the presence of a pituitary adenoma and bromocriptine treatment has been stopped close supervision throughout pregnancy and regular check of visual field is essential.
In patients showing a pronounced enlargement of a prolactinoma bromocriptine treatment should be reinstituted. In patients to be treated for mastalgia and nodular and/or cystic breast alterations malignancy must be excluded.
When the drug is used for puerperal inhibition of lactation, particularly in the first week of therapy occasional checking of blood pressure is recommended. Caution is required when high doses are being given to patients with a history of psychotic disorders or severe cardiovascular disease.
In the lack of required experience, the drug should not be prescribed for children less than 15 years of age.
After acute overdosage metoclopramide can be given, preferably parenterally. Since visual disturbance may occur particular care should be exercised when driving vehicles or operating machinery. Tolerability to bromocriptine may be reduced by alcohol.

Storage: Store in a cool and dry place, protected from light.

Packaging: Bromodel® 2.5 mg Tablet: Each carton contains 10X3 tablets in blister pack.

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