PRODUCT MONOGRAPH

PrHYDERGINE®

(ergoloid mesylates)

1 mg Tablets

Adjunctive Management of Idiopathic Dementia

SteriMax Inc. 2770 Portland Drive, Oakville, ON L6H 6R4 Control #:

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THERAPEUTIC CLASSIFICATION

Adjunctive Management of Idiopathic Dementia

ACTIONS AND CLINICAL PHARMACOLOGY

The possible mechanism of action of Hydergine (ergoloid mesylates) has not been determined. There is no evidence that ergoloid mesylates affect cerebrovascular insufficiency or cerebral arteriosclerosis.

Ergoloid mesylates do not have the vasoconstrictor effects of the natural ergot alkaloids.

INDICATIONS

Hydergine (ergoloid mesylates) may be of some value in the adjunctive management of selective symptoms of elderly patients with cognitive decline and a moderate impairment of self care, when used as part of a comprehensive therapeutic program, including medical and psychosocial support.

Clinical trials with Hydergine have described a modest improvement in symptoms that reflect on the level of self care in some of these patients.

CONTRAINDICATIONS

Hydergine (ergoloid mesylates) is contraindicated in individuals who have been shown to be hypersensitive to the drug; in severe bradycardia and in severe hypotension. It is also contraindicated in patients who have acute or chronic psychosis regardless of its etiology.

WARNINGS

Before using HYDERGINE (ergoloid mesylates), a careful diagnosis should be made to exclude treatable causes of dementia, including affective disorders, which may respond to specific therapy. Particular care should be taken to exclude delirium and dementiform illness secondary to systemic disease, primary neurological disease, or primary disturbance of mood.

Hydergine (ergoloid mesylates) is not indicated in aged individuals with normal cognitive function.

PRECAUTIONS

Hydergine should be kept out of the reach of children.

ADVERSE REACTIONS

Nausea and vomiting, headaches, dizziness, flushing, blurring of vision, rash, anorexia, nasal stuffiness, abdominal cramps, bradycardia and tachycardia, have been noted.

SYMPTOMS AND TREATMENT OF OVERDOSE

SYMPTOMS

The symptoms of overdosage with Hydergine (ergoloid mesylates) are nasal stuffiness, flushing of the face, headache, nausea and vomiting, tremulousness, spasticity, hypotension, circulatory collapse and coma.

TREATMENT

Treatment is symptomatic and supportive. Empty the stomach by emesis or lavage depending on the level of consciousness of the patient, ensuring maintenance of an adequate airway. Intravenous fluids should be administered with careful supervision of intake and output, but there is no evidence that forced diuresis accelerates the elimination of the drug. Circulatory collapse should be prevented by appropriate positioning of the patient, fluids and, if necessary, vasopressor agents.

DOSAGE AND ADMINISTRATION

One (1) tablet three (3) to four (4) times daily with food.

Since alleviation of symptoms is usually gradual, improvement may not be observed before several weeks. If no clinical improvement is seen at three (3) to four (4) weeks it is advisable to discontinue the drug. Full expression of the beneficial effects of Hydergine (ergoloid mesylates) may take several weeks. In patients who have responded with clinical improvement, it is advisable to discontinue the drug from time to time, in order to assess the need for its continued administration.

AVAILABILITY

Each tablet contains 1 mg ergoloid mesylates. The tablets are round, white, compressed, 8 mm in diameter, flat, with bevelled edges, scored with õVJö on one side and õHYDERGINEö insignia on the other. Available in bottles of 100.

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