

PERMAX[®] pergolide mesylate A Renewed Opportunity In Parkinson's Disease

Pergolide Mesylate tablets

THERAPEUTIC CLASSIFICATION: Dopamine Agonist

PRESENTATION: Tablets containing .05 mg or .25 mg or 1 mg of pergolide base. INDICATIONS AND CLINICAL USE: As an adjunctive treatment to levodopa in the management of the signs and symptoms of Parkinson's disease

CONTRAINDICATIONS: Hypersensitivity to this drug or other ergot derivatives

WARNINGS: Patients should be warned to begin therapy with low doses and to increase dosage in carefully adjusted increments over a period of 3 to 4 weeks, to minimize the risk of syncope, symptomatic postural and/or sustained hypotension. In controlled trials, pergolide mesylate with L-dopa caused hallucinosis in about 14 percent of patients, as opposed to 3 percent taking placebo with L-dopa. Caution should be exercised when administering to patients prone to cardiac dysrhythmias or with significant underlying cardiac disease. In a placebo-controlled study, patients taking pergolide mesylate had significantly more episodes of atrial premature contractions (APC's) and sinus tachycardia Care should be exercised with regard to engaging in activities requiring rapid and precise responses, such as driving an automobile or operating machinery.

PRECAUTIONS: Abrupt discontinuation of pergolide mesylate, in patients receiving it chronically as an adjunct to L-dopa, may precipitate the onset of hal-lucinations and confusion. Administration to patients receiving L-dopa, may cause and/or exacerbate pre-existing dyskinesias. Patients and their families should be informed of the common adverse consequences of the use of pergolide mesylate and the risk of hypotension. Patients should be advised to tell their doctors if they become pregnant, intend to become pregnant, or if they are breast feeding. Drug interactions: Dopamine antagonists, such as the neuroleptics (phenothiazines, butyphenones, thioxanthines) or metoclopramide, ordinarily should not be administered concurrently with pergolide mesylate (a donamine agonist); these agents may diminish the effectiveness of perceptide mesylate. Caution should be exercised if pergolide mesylate is co-administered with anti-hypertensive agents. Pregnancy: In animal studies there was no evidence of harm to the fetus due to pergolide mesulate. There are, however, no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the benefits outweigh the potential risk to the fetus Nursing mothers: It is not known whether pergolide mesylate is excreted in human milk. The pharmacological action of pergolide mesylate suggests it may interfere with lactation. A decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother

ADVERSE REACTIONS: Body as a whole: Pain, abdominal pain, injury, accident, headache, asthenia, chest pain, back pain, flu syndrome, neck pain. Gastrointestinal: Nausea, constipation, diarrhea, dyspepsia, anorexia, dry mouth, dysphagia. Special senses: Diplopia, abnormal vision, taste perversion, eve disorder. Other events that have been reported include hypotension, atrial premature contractions and sinus tachycardia. Nervous system: Hallucinations psychosis, paranoid reaction, personality disorder, akinesia, dyskinesia, choreoathetosis, dystonia, tremor, abnormal gait, incoordination, speech disorders, dizziness, confusion, depression, anxiety, somnolence, insomnia, abnormal dreams, amnesia. Respiratory system: Rhinitis, dyspnea, pneumonia, pharyngitis, cough increased. Metabolic and nutritional findings: Peripheral edema, weight loss, weight gain. Musculoskeletal system: Twitching myalgia, arthralgia. Skin and appendages system: Sweating rash. Urogenital system Urinary tract infection, urinary frequency, urinary incontinence, prostatic dis-order, dysmenorrhea, hematuria, Hemic and lymphatic system; Anemia,

OVERDOSAGE: There is no clinical experience with massive overdosage. Symptoms and signs have included vomiting, hypotension, agitation, severe hallucinations, severe involuntary movements, tingling sensations, palpitations and ventricular extrasystoles. Treatment: Symptomatic supportive therapy is recommended to maintain blood pressure. Cardiac function should be monitored: an antiarrhythmic agent may be necessary. If signs of CNS stimulation are presen a phenothiazine, or other butyrophenone neuroleptic agent, may be indicated.

References

DRAXIS

- 1. Jankovic J. Pergolide: Short-term and long-term experience in Parkinson's disease. Recent Developments in Parkinson's Disease, ed by S Fahn et al. Raven Press, New York 1986
- 2. Jenner P. The rationale for the use of dopamine agonists in Parkinson's disease. Neurology 1995:45(suppl 3):S6-S12. 3. Olanow CW Fahn S Muenter M Klawans H Hurtig H Stern M
- Shoulson I. Kurlan R Grimes JD Jankovic J et al. A multicenter double-blind placebo-controlled trial of pergolide as an adjunct to

Draxis Health Inc.

Mississauga, Ontario

Sinemet in Parkinson's disease. Moy Disord (1994 Jan) 9(1):40-7. 4. Goetz CG et al. Chronic agonist therapy for Parkinson's disease. A 5-year study of bromocriptine and pergolide. Neurology (1985

DOSAGE AND ADMINISTRATION: Pergolide is administered orally.

Administration should be initiated with a daily dosage of 0.05 gm for the first

two days. The dosage should then be gradually increased by 0.1 or 0.15 mg/day

every third day over the next 12 days of therapy. The dosage may then be

increased by 0.15 mg/day every third day until an optimal therapeutic dosage

is achieved. Percolide mesylate is usually administered in divided doses 3 times

per day. During dosage litration, the dosage of current L-dopa may be cautiously

decreased. SUPPLIED: 0.05 mg: Each ivory coloured, modified rectangle

shaped tablet, scored and engraved with the compnay logo and identi-code 4131, contains: pergolide mesylate 0.05 mg. Also contains lactose. Gluten- and

tartrazine free. Amber HDPE bottles of 30. 0.25 mg: Each green coloured, mod-

ified rectangle-shaped tablet, scored and engraved with the compnay logo and identi-code 4133, contains: pergolide mesylate 0.25 mg. Also contains lactose.

Gluten- and tartrazine free. Amber HDPE bottles of 100. 1 mg: Each pink-

coloured, modified rectangle-shaped tablet, scored and engraved with the compnay logo and identi-code 4135, contains: pergolide mesylate 1 mg. Also

contains lactose. Gluten- and tartrazine free. Amber HDPE bottles of 100.

Store at room temperature

Permax is a schedule F drug

The product monograph is available upon request

- May) 35(5):749-51. Mizuno, Y et al. Pergolide in the treatment of Parkinson's disease Neurology 1995:45(suppl 3):S13-S21. 5.
- 6. Goetz CG et al. Agonist substitution in advanced Parkinson's disease. Neurology 1989;39:1121-1122.

PAAB

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Pediatric Neurologist

The Department of Pediatrics at McMaster University and the Children's Hospital in the Hamilton Health Sciences Corporation are seeking an additional pediatric neurologist with a strong interest and skills in patient care and teaching. The new faculty member will share responsibility for comprehensive clinical services and will participate fully in the educational programs of the University and the Hospital.

Applicants must be eligible to practice in the Province of Ontario and hold certification in Neurology or Pediatrics from the Royal College of Physicians and Surgeons. They should have completed accredited training in Pediatric Neurology. Academic rank will be commensurate with training and experience.

Please submit inquiry, a curriculum vitae, and the names/addresses of three references by November 20th, 1997 to: Dr. Gabriel Ronen, McMaster University, Faculty of Health Sciences, Department of Pediatrics, Health Sciences Centre Room 3N11, 1200 Main Street West, Hamilton, Ontario L8N 3Z5

In accordance with Canadian immigration requirements, this advertisement is directed to Canadian citizens and permanent residents of Canada.

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Scientific Chair T. Jock Murray, M.D. Dalhousie University; Halifax, Nova Scotia

The overall objective of this meeting is to provide an overview of the most recent advances in the diagnosis and treatment of cognitive dysfunction in multiple sclerosis patients. Issues to be addressed include: an historical perspective on cognitive dysfunction; characteristics of the disease, including memory impairment, effects on information processing, and neurobehavioral consequences; diagnostic and assessment methodologies; and current and future therapeutic options. Use of a roundtable format during the latter portion of the meeting will allow the speakers to further address these issues.

For more information on **Cognitive Dysfunction in Multiple Sclerosis Patients** please contact David A. Pherson, Ph.D., Serono Symposia USA, Inc., 100 Longwater Circle, Norwell, MA 02061 Telephone 800-283-8088 or 617-982-9000 FAX 617-982-9481