

The Canadian Journal of Neurological Sciences

Le Journal Canadien des Sciences Neurologiques



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**XXI Canadian Congress of
Neurological Sciences
London, Ontario**

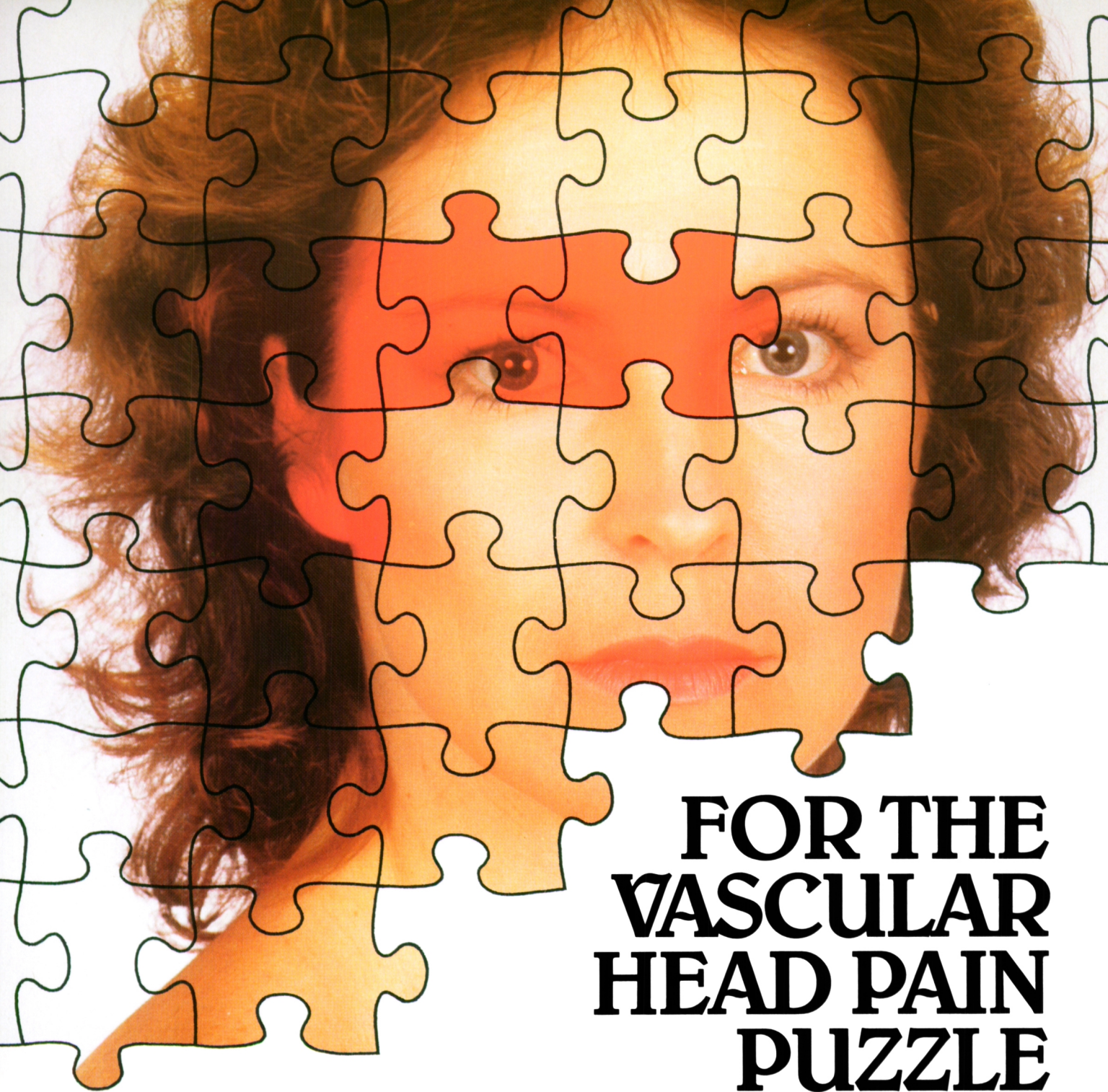
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Volume 13, No. 2

May 1986



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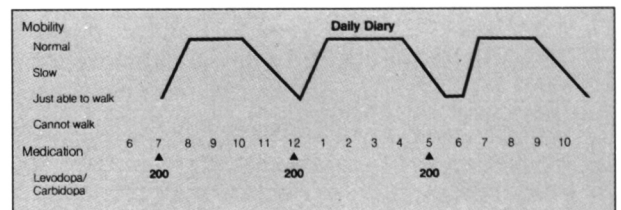
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CONFRONT THE REALITIES OF PARKINSON'S DISEASE

Problems of long-term therapy with levodopa compounds

- Performance fluctuations
- End-of-dose deterioration
- Early morning stiffness
- On-off phenomenon

During the course of a day⁽¹⁾



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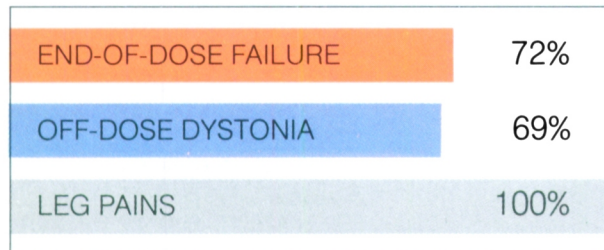
A case of study: Wearing-off of levodopa



After an average of seven years of therapy with levodopa compounds, adding Parlodel resulted in...⁽²⁾

A reduced severity of levodopa complications

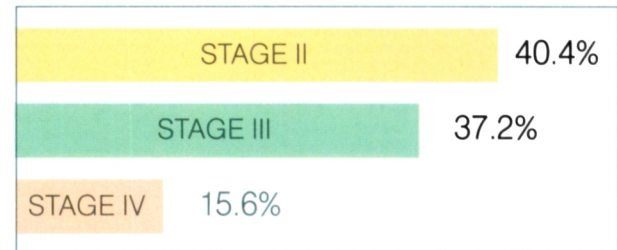
% patients improved



Adapted from the Hoehn Study⁽²⁾.
Parlodel dose range: 12.4-20 mg/day

An improvement in mean neurological scores

% improvement



Adapted from the Hoehn Study⁽²⁾.
Maximum Parlodel dosage: 20 mg/day

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ACTIONS Parlodel (bromocriptine mesylate) is a dopaminomimetic ergot derivative with D₂ type dopamine receptor agonist activity, and has also D₁ dopamine receptor antagonist properties. The dopaminomimetic activity of bromocriptine in the striatum is considered responsible for the clinical benefits seen in selected patients with Parkinson's Disease, when low doses of the drug are gradually added to levodopa therapy in patients on long-term treatment who develop late side effects of levodopa or no longer respond to the medication. Excessive dopaminomimetic drive may, however, provoke psychotic and other adverse reactions.

The extreme variability in G.I. tract absorption, and the extensive and individually variable first-pass metabolism is responsible for the broad variability in plasma concentrations of bromocriptine and, in part, for the variability in dose response.

INDICATIONS* **Parkinson's Disease:** Parlodel (bromocriptine mesylate) has been found to be clinically useful as an adjunct to levodopa (usually with a decarboxylase inhibitor), in the symptomatic management of selected patients with Parkinson's Disease who experience prominent dyskinesia or wearing off reactions on long-term levodopa therapy.

Patients on long-term treatment who are beginning to deteriorate on levodopa therapy may be controlled by reducing the dose of levodopa and adjusting the frequency and schedule of drug administration. Patients maintained on optimal dosages of levodopa who still experience prominent dyskinesia and/or end-of-dose failure, may benefit from the concomitant use of Parlodel, by decreasing the occurrence and/or severity of these manifestations. Since rapid escalation of bromocriptine doses causes severe adverse reactions, it is recommended to combine a slow increase of Parlodel, usually with a concomitant, gradual and limited reduction of levodopa dosage. Continued efficacy of bromocriptine for more than two years has not been established and there is some evidence that its efficacy tends to wane. Evidence available indicates that there is no consistent benefit from bromocriptine in patients who have not responded previously to levodopa, and studies have shown significantly more adverse reactions in bromocriptine treated patients than in patients treated with levodopa. Parlodel is not recommended in the treatment of newly diagnosed patients or as the sole medication in Parkinson's Disease.

CONTRAINDICATIONS Other than sensitivity to ergot alkaloids, no absolute contraindications to treatment with Parlodel (bromocriptine mesylate) are known. For procedure during pregnancy see "Use in Pregnancy" under Precautions.

WARNINGS Long-term treatment (6-36 months) with Parlodel in doses of 20 to 100 mg/day has been associated with pulmonary infiltrates, pleural effusion and thickening of the pleura in a few patients. Where Parlodel was discontinued, these changes slowly reverted to normal.

PRECAUTIONS Parlodel (bromocriptine mesylate) may cause hypotension, primarily postural; periodic monitoring of the blood pressure, particularly during the first days of therapy, is advisable. In some patients dizziness (vertigo) may occur with Parlodel; patients should therefore be cautioned against activities requiring rapid and precise responses such as driving an automobile or operating dangerous machinery until their response has been determined.

Care should be exercised when administering Parlodel concomitantly with phenothiazines or antihypertensive agents. Due to drug interaction at the receptor site, dosage should be adjusted accordingly.

Alcohol should be avoided during treatment with Parlodel. In some patients, the concomitant use of Parlodel and alcohol has given rise to alcohol intolerance and an increase in the severity and incidence of Parlodel's possible adverse reactions.

Parlodel should always be taken with food. In cases where severe adverse effects, such as nausea, vomiting, vertigo or headaches are severe or persisting, the therapeutic dosage of Parlodel should be reduced to one-half tablet daily (1.25 mg) and increased gradually to that recommended.

As with all medication, Parlodel should be kept safely out of the reach of children.

Use in Pregnancy If the patient wishes to become pregnant, Parlodel (bromocriptine mesylate) should be stopped as soon as possible after conception is suspected. In this event immunological confirmation should be done immediately. When pregnancy is confirmed, Parlodel, like all other drugs, should be discontinued unless, in the opinion of the treating physician, the possible benefit to the patient outweighs the potential risk to the fetus.

In human studies with Parlodel (reviewed by Turkali, I.), there were 1410 reported pregnancies, which yielded 1236 live and 5 stillborn infants from women who took Parlodel (bromocriptine mesylate) during early pregnancy. Among the 1241 infants, 43 cases (31 minor and 12 major) of congenital anomalies were reported. The incidence (3.46%) and type of congenital malformations and the incidence of spontaneous abortions (11.13%) in this group of pregnancies does not exceed that generally reported for such occurrences in the population at large.

Gynecological Supervision All women patients receiving Parlodel continuously for six months or more should have a gynecological examination before therapy, yearly if still menstruating, and six-monthly if menopausal. The examination should include cervical and, if possible, endometrial cytology. Post-menopausal women on estrogen therapy should be excluded from Parlodel therapy at the discretion of the physician because estrogen induced uterine bleeding may mask the presence of pathological lesions.

A lifetime rat study revealed that some animals developed uterine tumors and endometrial carcinoma thought to be due to a state of induced estrogen dominance. However, clinical experience in women with a variety of hyperproliferative and other conditions, treated with Parlodel for months or years, failed to demonstrate abnormal trends in hormonal levels or in endometrial cytology.

Normoprolactinemic women treated with Parlodel should be given the lowest effective dose necessary to relieve their symptoms, in order to avoid the possibility of suppression of prolactin below normal levels, with a consequent impairment of luteal function.

Use in Parkinson's Disease: Use of Parlodel (bromocriptine mesylate), particularly in high doses, may be associated with mental confusion and mental disturbances. Since patients with Parkinson's Disease may manifest varying degrees of dementia, caution should be exercised when treating such patients with Parlodel.

Parlodel administered alone or concomitantly with levodopa may cause visual or auditory hallucinations. These usually resolve with dosage reduction, but discontinuation of Parlodel may be required in some cases. Rarely, after high doses, have hallucinations persisted for several weeks following discontinuation of Parlodel. Caution should be exercised when administering Parlodel to patients with a history of myocardial infarction, particularly if they have a residual atrial, nodal or ventricular arrhythmia.

Symptomatic hypotension can occur and, therefore, caution should be exercised when administering Parlodel, particularly in patients receiving antihypertensive medication. Periodic evaluation of hepatic, hematopoietic, cardiovascular and renal function is recommended.

Drug Interactions: The concomitant use of erythromycin may increase bromocriptine plasma levels.

ADVERSE REACTIONS The most frequently observed adverse reactions are nausea, vomiting, headache and gastrointestinal side effects such as abdominal pain, diarrhea and constipation. All these effects may be minimized or even prevented by giving small initial doses of bromocriptine and by taking it with food.

Postural hypotension which can, on rare occasions, lead to fainting and "shock-like" syndromes have been reported in sensitive patients. This is most likely to occur during the first few days of Parlodel treatment.

When bromocriptine is added to levodopa therapy, the incidence of adverse reactions may increase. The most common newly appearing adverse reactions in combination therapy were: nausea, abnormal involuntary movements, hallucinations, confusion, "on-off" phenomenon, dizziness, drowsiness, faintness, fainting, vomiting, asthenia, abdominal discomfort, visual disturbance, ataxia, insomnia, depression, hypotension, shortness of breath, constipation and vertigo.

Less common adverse reactions include, anorexia, anxiety, blepharospasm, dry mouth, dysphagia, edema of the feet and ankles, erythromelalgia, epileptiform seizures, fatigue, headache, lethargia, mottling of skin, nasal stuffiness, nervousness, nightmares, paresthesia, skin rash, urinary frequency, urinary incontinence, urinary retention and rarely signs of 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 elevation of blood urea nitrogen, SGOT, SGPT, GGPT, CPK, alkaline phosphatase and uric acid, which are usually transient and not of clinical significance.

The occurrence of adverse reactions may be lessened by temporarily reducing dosage to one-half tablet two or three times daily.

SYMPTOMS AND TREATMENT OF OVERDOSE

There have been several reports of acute overdosage with Parlodel (bromocriptine mesylate) in children and adults. No life threatening reactions have occurred. Symptoms reported included nausea, vomiting, dizziness, drowsiness, hypotension, sweating and hallucinations. Management is largely symptomatic; the cardiovascular system should be monitored. Metoclopramide can be used to antagonize the emesis and hallucinations in patients who have taken high doses.

DOSAGE AND ADMINISTRATION Parlodel (bromocriptine mesylate) should always be taken with food.

Although Parlodel (bromocriptine mesylate) has been found clinically useful in decreasing the severity and frequency of "on-off" fluctuations of late levodopa therapy, the decision to use bromocriptine as adjunctive treatment and the selection of dosage must be individualized in each case. A low dose is recommended. The initial dose of Parlodel is one half of a 2.5 mg tablet (1.25 mg) at bedtime with food to establish initial tolerance. Thereafter, the recommended dosage is 2.5 mg daily in two divided doses, with meals, (half a 2.5 mg tablet twice daily). The dosage may be increased very gradually, if necessary, by adding an additional 2.5 mg per day, once every 2 to 4 weeks, to be taken always in divided doses with meals. Increments should usually never exceed 2.5 mg. Clinical assessments are recommended at two week intervals or less during dosage titration, to ensure that the lowest effective dosage is not exceeded. The usual dosage range is from a few milligrams to 40 mg daily in two or three divided doses with meals. The median dose varies with the experience of individual investigators, but can be around 10 mg daily or higher. During initial titration it is recommended that the dosage of levodopa should be maintained, if possible. Subsequently, it might be desirable to combine a slow increase of bromocriptine with a concomitant, limited and gradual reduction of levodopa.

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REFERENCES:

1. Grimes J.D. Medical Review Series (Handbook No. 4) 1984;14
2. Hoehn M, Eiton RL. Low dosages of bromocriptine added to levodopa in Parkinson's disease. Neurology 1985;35:199-206



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*For information on other approved indications, please consult the Parlodel product monograph, available to physicians and pharmacists on request.

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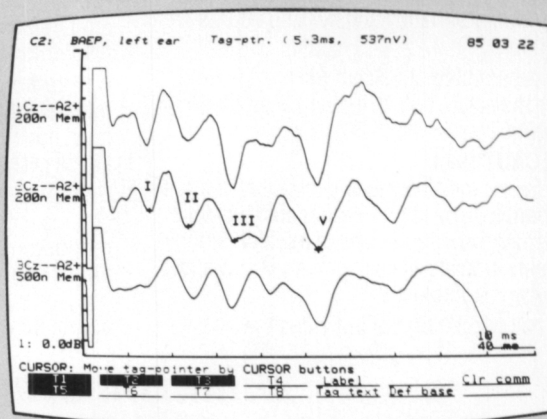
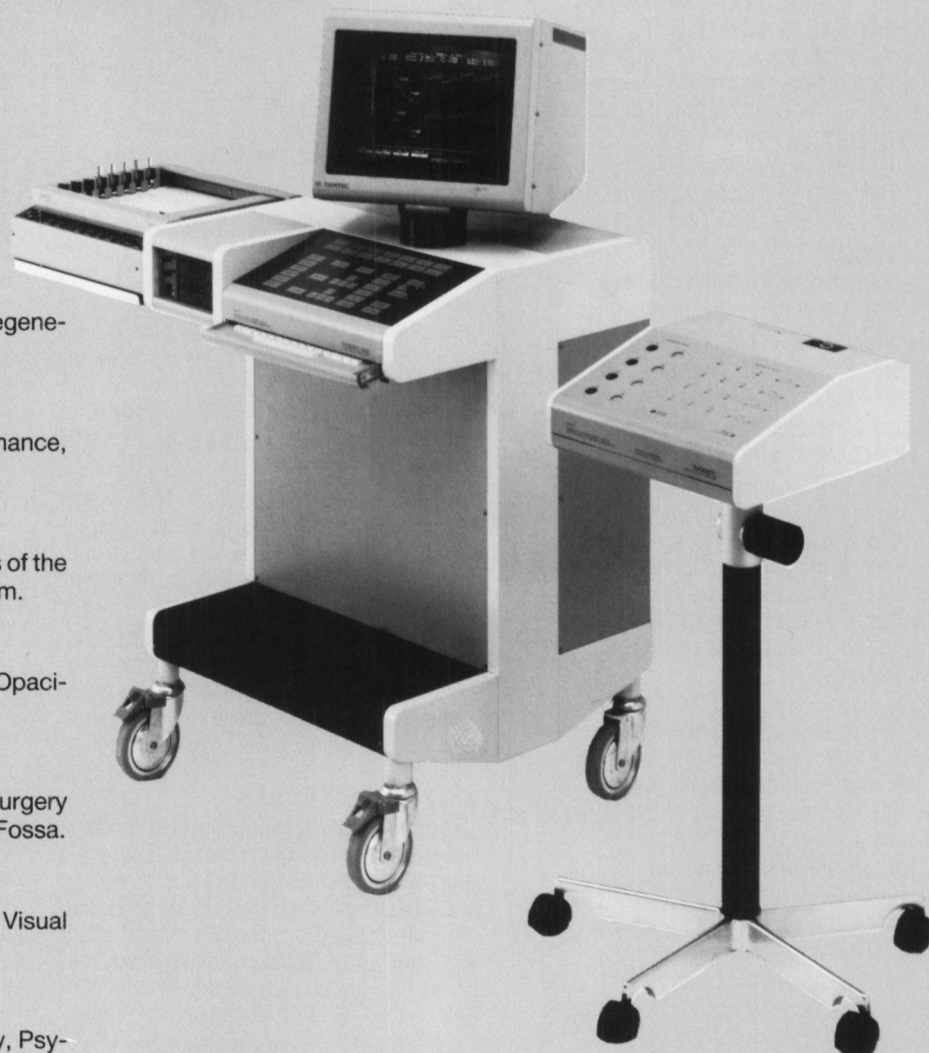
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REFERENCES:

- ¹Frew, I.J.C. et al: Postgrad. Med. J.; 52:501-503, 1976.
²Wilmot, T.J. et al: J. Laryng. Otol; 9:833-840, 1976.

PRESCRIBING INFORMATION

INDICATIONS: SERC may be of value in reducing the episodes of vertigo in Meniere's disease. No claim is made for the effectiveness of SERC in the symptomatic treatment of any form of vertigo other than that associated with Meniere's disease.

DOSAGE AND ADMINISTRATION: The usual adult dosage has been one to two tablets (4 mg. each) administered orally three times a day.

Recommended starting dose is two tablets three times daily. Therapy is then adjusted as needed to maintain patient response. The dosage has ranged from two tablets per day to eight tablets per day. No more than eight tablets are recommended to be taken in any one day.

SERC (betahistine hydrochloride) is not recommended for use in children. As with all drugs, SERC should be kept out of reach of children.

CONTRAINDICATIONS: Several patients with a history of peptic ulcer have experienced an exacerbation of symptoms while using SERC. Although no causal relation has been established SERC is contraindicated in the presence of peptic ulcer and in patients with a history of this condition. SERC is also contraindicated in patients with pheochromocytoma.

PRECAUTIONS: Although clinical intolerance to SERC by patients with bronchial asthma has not been demonstrated, caution should be exercised if the drug is used in these patients.

USE IN PREGNANCY: The safety of SERC in pregnancy has not been established. Therefore, its use in pregnancy or lactation, or in women of childbearing age requires that its potential benefits be weighed against the possible risks.

ADVERSE REACTIONS: Occasional patients have experienced gastric upset, nausea and headache.

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INDICATIONS

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CONTRAINDICATIONS

Dilantin is contraindicated in those patients with a history of hypersensitivity to hydantoin products.

WARNINGS

Abrupt withdrawal of phenytoin in epileptic patients may precipitate status epilepticus.

Phenytoin is not indicated in seizures due to hypoglycemia or other causes which may be immediately identified and corrected.

Phenytoin metabolism may be significantly altered by the concomitant use of other drugs such as:

A. Barbiturates may enhance the rate of metabolism of phenytoin. This effect, however, is variable and unpredictable. It has been reported that in some patients the concomitant administration of carbamazepine resulted in an increased rate of phenytoin metabolism.

B. Coumarin anticoagulants, disulfiram, phenylbutazone, and sulfaphenazole may inhibit the metabolism of phenytoin, resulting in increased serum levels of the drug. This may lead to an increased incidence of nystagmus, ataxia, or other toxic signs.

C. Isoniazid inhibits the metabolism of phenytoin so that with combined therapy, patients who are slow acetylators may suffer from phenytoin intoxication.

D. Tricyclic antidepressants in high doses may precipitate seizures, and the dosage of phenytoin may have to be adjusted accordingly.

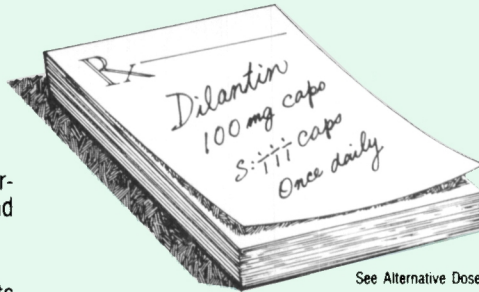
Usage in Pregnancy: The effects of Dilantin in human pregnancy and nursing infants are unknown.

The prescribing physician will have to determine the risk/benefit in treating or counselling epileptic women of childbearing potential.

PRECAUTIONS

The liver is the chief site of biotransformation of phenytoin, patients with impaired liver function may show early signs of toxicity. Elderly patients or those who are gravely ill may show early signs of toxicity.

A small percentage of individuals who have



See Alternative Dose

been treated with phenytoin have been shown to metabolize the drug slowly. Slow metabolism may be due to limited enzyme availability and lack of induction; it appears to be genetically determined.

Phenytoin has been associated with reversible lymph node hyperplasia. If lymph node enlargement occurs in patients on phenytoin, every effort should be made to substitute another anticonvulsant drug or drug combination.

Drugs that control generalized tonic-clonic (grand mal) seizures are not effective for absence (petit mal) seizures. Therefore, if both conditions are present, combined drug therapy is needed.

Hyperglycemia, resulting from the drug's inhibitory effect on insulin release, has been reported. Phenytoin may also raise the blood sugar level in persons already suffering from hyperglycemia.

ADVERSE REACTIONS

Central Nervous System: The most common manifestations encountered with phenytoin therapy include nystagmus, ataxia, slurred speech, and mental confusion. Dizziness, insomnia, transient nervousness, motor twitchings, and headache have also been observed. These side effects may disappear with continuing therapy at a reduced dosage level.

Gastrointestinal System: Phenytoin may cause nausea, vomiting, and constipation. Administration of the drug with or immediately after meals may help prevent gastrointestinal discomfort.

Integumentary System: Dermatological manifestations sometimes accompanied by fever have included scarlatiniform or morbiliform rashes.

Hemopoietic System: Hemopoietic complications, some fatal, have occasionally been reported in association with administration of phenytoin. These have included thrombocytopenia, leukopenia, granulocytopenia, agranulocytosis, and pancytopenia.

Other: Gingival hyperplasia occurs frequently; this incidence may be reduced by good oral hygiene including gum massage, frequent brushing and appropriate dental care. Polyarthropathy and hirsutism occur occasionally. Hyperglycemia has been reported. Toxic hepatitis, liver damage, and periarteritis nodosa may occur and can be fatal.

MANAGEMENT OF OVERDOSE

The mean lethal dose in adults is estimated to be 2 to 5 grams. The cardinal initial symptoms are nystagmus, ataxia and dysarthria. The patient then becomes comatose, the pupils are unresponsive and hypotension occurs. Death is due to respiratory depression and apnea. Treatment is nonspecific since there is no known antidote. First, the stomach should be emptied. If the gag reflex is absent, the airway should be supported. Oxygen, vasopressors and assisted ventilation may be necessary for central nervous system, respiratory and cardiovascular depression. Finally, hemodialysis can be considered since phenytoin is not completely bound to plasma proteins.

DOSAGE AND ADMINISTRATION

Dosage should be individualized to provide maximum benefit. In some cases, serum blood level determinations may be necessary for optimal dosage adjustments — the clinically effective serum level is usually 10-20 mcg/mL.

Adult Dose: Patients who have received no previous treatment may be started on one 100 mg Dilantin Capsule three times daily and the dose then adjusted to suit individual requirements.

Pediatric Dose: Initially, 5 mg/kg/day in two or three equally divided doses, with subsequent dosage individualized to a maximum of 300 mg daily. A recommended daily maintenance dosage is usually 4 to 8 mg/kg. Children over 6 years old may require the minimum adult dose (300 mg/day). Pediatric dosage forms available include a 30 mg Capsule, a 50 mg palatably flavoured Infatab, or an oral suspension form containing 30 or 125 mg of Dilantin in each 5 mL.

Alternative Dose: Once-a-day dosage for adults with 300 mg of Dilantin may be considered if seizure control is established with divided doses of three 100 mg Capsules daily.

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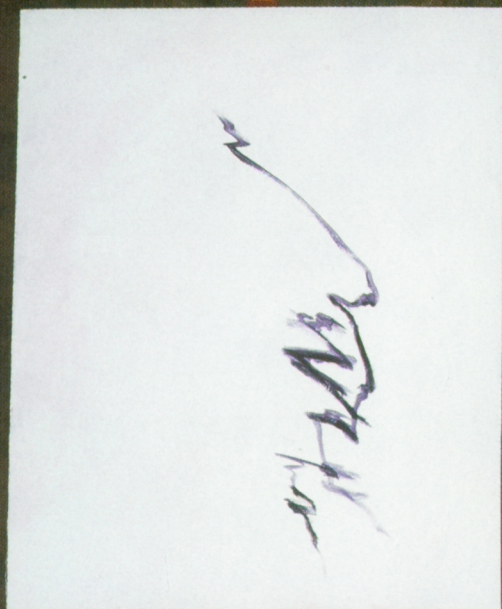
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The Canadian Journal of Neurological Sciences publishes original articles in the clinical and basic neurosciences. Manuscripts are considered for publication with the understanding that, except for identified review articles, they have not been published elsewhere except in abstract form and are not under simultaneous consideration by another publication. Manuscripts should be submitted to:

The Editor
Canadian Journal of Neurological Sciences
Faculty of Medicine,
University of Calgary
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Manuscripts and all illustrations should be submitted in triplicate. Papers will be accepted in English or French. All papers should be accompanied by an abstract or a résumé of approximately 150 words on a separate page, preferably in both languages, although the Journal will provide the translation if requested. All manuscripts should be double spaced throughout, including references and legends for illustrations. Margins of at least 25 mm should be left on all sides.

For detailed instructions regarding style and layout, authors should refer to "Uniform requirements for manuscripts submitted to biomedical journals". Copies of this document may be obtained by writing to the Journal office, but the main points will be summarized here. Articles should be subdivided under conventional headings of "introduction", "methods and materials", "results" and "discussion" but other headings and subheadings will be considered if more suitable for a particular manuscript. A title page should identify the title of the article, authors, name of institution(s) from which the work originated, and the address and telephone number of the author to whom communications should be addressed. Pages of text should be numbered consecutively. Acknowledgements, including recognition of financial support, should be typed on a separate page at the end of the text.

References are to be numbered in the order of citation in the text. Those cited only in tables or in legends for illustrations are numbered in accordance with a sequence established by the first identification in the text of a particular table or illustration. Titles of journals should be abbreviated according to the style used in Index Medicus. References should be complete including the names of the first three authors followed by "et al"

if there are more than three authors, full title, year of publication, volume number, and inclusive pagination for journal articles. Book or chapter references should also include the place of publication and name of the publisher. Examples of correct forms of references follow:

Journals

Poirier LJ, Filion M, Larochelle L, et al. Physiopathology of experimental parkinsonism in the monkey. *Can J Neurol Sci* 1975; 2: 255-263

Chapter in a book

McGeer PL, McGeer EG. Amino acid neurotransmitters. In: Siegel GJ, Albers RW, Agranoff BW, Katzman R, eds. *Basic Neurochemistry*. Boston: Little, Brown & Co, 1981: 233-254

Illustrations should be high quality glossy black-and-white photographic prints, preferably 127 x 173 mm (5 x 7"). Original artwork and radiographs should not be submitted. The additional cost of colour illustration must be borne by the author; quotations are available upon request from the Journal office. All figures should be identified on the back with the author's name and figure number. Letters and arrows applied to the figures to identify particular findings should be professional appliques suitable for publication. Photomicrographs should include a calibration bar with the scale indicated on the figure or in the legend. Legends for illustrations should be typed on a separate page from the illustrations themselves.

Tables should each be on a separate page and be identified with the title or heading. Particular care should be taken in the preparation of tables to ensure that the data are presented in the most clear and precise format. Each column should have a short or abbreviated heading. Place explanatory matter in footnotes, not in the heading. Do not submit tables as photographs.

The SI system (système international d'unités) should be used in reporting all laboratory data, even if originally reported in another system. Temperatures are reported in degrees Celsius. Other measurements should be reported in the metric system. English language text may use either British or American spelling, but should be consistent throughout.

Review articles on selected topics also are published by the Journal. These are usually invited, but unsolicited reviews will be considered. It is suggested that authors intending to submit reviews contact the Editor in advance.

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Le Journal Canadien des Sciences Neurologiques publie des articles originaux dans les sciences neurologiques, cliniques et fondamentales. Les manuscrits ne sont considérés pour publication qu'à la condition expresse, à l'exception des articles de revue clairement identifiés comme tel, qu'ils n'aient pas été publiés ailleurs, sauf sous forme de résumé et qu'ils ne soient pas sous considération simultanée par un autre journal. Les manuscrits doivent être soumis à:

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Les manuscrits et toutes les illustrations doivent être soumis en triplicata. Les articles seront acceptés en français ou en anglais. Tous les articles doivent être accompagnés d'un résumé d'environ 150 mots, sur page séparée, préférablement dans les deux langues, quoique le Journal puisse fournir cette traduction sur requête. Les manuscrits doivent être dactylographiés complètement à double interligne y compris les références et les légendes pour illustrations. Des marges d'au moins 25 mm doivent être laissées de tous les côtés.

Pour les conseils plus détaillés sur le style et la présentation du texte, les auteurs doivent se référer au texte intitulé "Règlements uniformes pour les manuscrits soumis aux journaux biomédicaux". On peut obtenir une copie de ce document en écrivant au bureau du Journal, mais en voici les principaux points: Les articles doivent être présentés selon le plan habituel: "Introduction", "Matériel et méthodes", "Résultats" et "Discussion", mais il est possible d'employer d'autres titres ou sous-titres si nécessaire pour un manuscrit en particulier. Sur une page titre séparée on doit identifier le titre de l'article, les auteurs, les institutions d'où origine le travail, ainsi que l'adresse et le numéro de téléphone de l'auteur à qui devront être adressées les communications. Les remerciements, incluant ceux pour l'appui financier, doivent être dactylographiés sur page séparée à la fin du texte. Les références doivent être numérotées dans l'ordre où elles sont citées dans le texte. Celles qui sont citées seulement dans les tableaux ou légendes d'illustrations sont numérotées selon la séquence établie par la première identification dans le texte de ces tableaux ou illustrations particulières. Les titres des Journaux doivent être abrégés selon le style utilisé dans Index Medicus. Les références doivent être complètes, incluant le nom des trois premiers auteurs suivis de "et al", s'il y a plus de trois auteurs, le titre complet, l'année de publication, le

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Poirier LJ, Filion M, Larochelle L, et al. Physiopathology of experimental parkinsonism in the monkey. *Can J Neurol Sci* 1975; 2: 255-263

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McGeer PL, McGeer EG, Amino acid neurotransmitters. In: Siegel GJ, Albers RW, Agranoff BW, Katzman R, eds. *Basic Neurochemistry*. Boston: Little, Brown & Co, 1981: 233-254

Les illustrations doivent être sur papier brillant de haute qualité et imprimés en blanc et noir, préférablement 127 x 173 mm (5 x 7"). Les illustrations et photographies originales ne doivent pas être soumises. Le coût supplémentaire des illustrations en couleur revient entièrement à l'auteur; les coûts détaillés peuvent être obtenus directement au bureau du Journal. Il faut identifier toutes illustrations en inscrivant au dos le nom de l'auteur et le numéro. Toutes lettres ou flèches appliquées aux illustrations pour identifier un aspect particulier doivent être de qualité professionnelle. Les photomicrographies doivent inclure une barre de calibration dont l'échelle est mentionnée dans la légende. Les légendes des illustrations doivent être dactylographiées sur une page séparée de celles-ci.

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Nous accueillons les lettres à l'Editeur. Celles-ci doivent se limiter à deux pages, double interligne et peuvent contenir une seule illustration et ne citer qu'un maximum de quatre références.



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