

## THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES

VOL. 11, NO. 1 FEB. 1984

<b>SPECIAL FEATURES</b>	
Myoglobinuria 1984 .....	Lewis P. Rowland 1
Anatomy of the Opioid-Systems of the Brain ....	Karl M. Knigge and Shirley A. Joseph 14
Etiology of Parkinson's Disease: A Research Strategy .....	André Barbeau 24
<b>Hypothesis: Phylogenetic Diseases of the Nervous System</b> .....	
Harvey B. Sarnat and Martin G. Netsky	29
<b>ORIGINAL ARTICLES</b>	
Spinal Injuries Due to Hockey .....	Charles H. Tator, Chris E.U. Ekong, David W. Rowed, Michael L. Schwartz, Virginia E. Edmonds and Perry W. Cooper 34
Reversal of Acute Experimental Cerebral Vasospasm by Calcium Antagonism with Verapamil .....	Richard Leblanc, William Feindel, Lucas Yamamoto, John C. Milton and Mory M. Frojmovic 42
An Atypical Case of Progressive Supranuclear Palsy .....	Andrew J. Gomori and Anders A.F. Sima 48
Serial Pattern Shift Visual Evoked Potentials in Multiple Sclerosis .....	Werner J. Becker and Irene M. Richards 53
Electrophysiological Studies in Five Cases of Abetalipoproteinemia .....	N.J. Lowry, M.J. Taylor, W. Belknap, W.J. Logan 60
Rupture of an Experimentally Induced Aneurysm in a Primate .....	F. Espinosa, B. Weir and T. Noseworthy 64
<b>Hydrocephalus and Headaches in Paget's Disease of the Skull: Complete Relief by Ventriculo-Atrial Shunt</b> .....	
Chantal Hausser, Georges Elie Ouaknine and Jacques Sylvestre	69
<b>Friedreich's Ataxia with Dysautonomia and Labile Hypertension</b> .....	
D. Margalith, H.G. Dunn, J.E. Carter and J.M. Wright	73
Fulminating Haemophilus Influenzae b Meningitis .....	N.E. MacDonald, D.L. Keene, A.M.R. Mackenzie, P. Humphreys, A.L. Jefferies and L.P. Ivan 78
<b>RESEARCH NEWS</b>	
Current MRC Funding and Neuroscience Research Training in Canada ....	Pierre Bois 82
<b>BOOK REVIEWS</b> .....	84
<b>NOTES AND ANNOUNCEMENTS</b> .....	86

## CURRENT CONCEPTS AND CONTROVERSIES IN PARKINSON'S DISEASE Vol. 11, No. 1 (Suppl.) Feb. 1984 pages 90-238

## THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES

VOL. 11, NO. 2 MAY 1984

<b>SPECIAL FEATURES</b>	
Calcium Antagonists, Cerebral Ischemia and Vasospasm .....	Bryce Weir 239
Pharmacokinetic Interactions of Antiepileptic Drugs .....	Penny S. Albright and J. Bruni 247
<b>ORIGINAL ARTICLES</b>	
Lateral Asymmetries and Thalamic Components in Far-Field Somatosensory Evoked Potentials .....	M.J. Taylor and S.E. Black 252
The Andermann Syndrome: Agenesis of the Corpus Callosum Associated with Mental Retardation and Progressive Sensorimotor Neuronopathy .....	Albert Larbrisseau, Michel Vanasse, Pierre Brochu and Gaétan Jasmin 257
Ocular and Cerebral Ischemic Mechanisms in Disease of the Internal Carotid Artery .....	R.T. Ross and Ian M. Morrow 262
Sensory Nerve Conduction in Chronic Uremic Patients During the First Six Months of Hemodialysis .....	M.L. D'Amour, L.R. Dufresne, C. Morin and D. Slaughter 269
Dependence of EMG Responses Evoked by Imposed Wrist Displacements on Pre-existing Activity in the Stretched Muscles .....	W. Bedingham and W.G. Tatton 272
Characteristic Alterations in Responses to Imposed Wrist Displacements in Parkinsonian Rigidity and Dystonia Musculorum Deformans .....	W.G. Tatton, W. Bedingham, W.C. Verrier and R.D.G. Blair 281
<b>Characteristics of EMG Responses to Imposed Limb Displacement in Patients with Vascular Hemiplegia</b> .....	
M.C. Verrier, W.G. Tatton and R.D.G. Blair	288
Retrograde Amnesia in Parkinson's Disease .....	Morris Freedman, Peter Rivoira, Nelson Butters, Daniel S. Sax, Robert G. Feldman 297
Occlusive Cerebrovascular Disease in Young Adults .....	Gary M. Klein and T. Peter Seland 302
Fatal Nematine Myopathy in Infancy .....	Joseph B. McMenamin, Laurence E. Becker and E. Gordon Murphy 305
<b>University of Calgary Combined Neuroscience Rounds — Clinicopathological Conference Carcinoma of the Pituitary Gland with Metastases to Bone</b> .....	
S.T. Myles, R.D. Johns and B. Curry	310
<b>XIX Canadian Congress of Neurological Sciences — Program and Abstracts</b> .....	
	318
<b>BOOK REVIEWS</b> .....	351
<b>CALENDAR OF EVENTS</b> .....	353

## THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES

VOL. 11, NO. 3 AUG. 1984

<b>SPECIAL FEATURES</b>	
Editorial Review: Therapeutic Trials in Multiple Sclerosis .....	J.H. Noseworthy, T.P. Seland and G.C. Ebers 355
Editorial Review: Migraine: New Views on an Old Theory .....	John Edmeads 363
<b>ORIGINAL ARTICLES</b>	
Posterior Column Dysfunction in Cervical Spondylotic Myelopathy .....	D.J. MacFadyen 365
Management of Acute Subdural Hematomas from Aneurysmal Rupture .....	Bryce Weir, Terence Myles, Moe Kahn, Falah Maroun, David Malloy, Brien Benoit, Michael McDermott, Douglas Cochrane, Gerard Mohr, Gary Ferguson, Felix Durity 371
Intermittent Treatment of Febrile Convulsions with Nitrazepam .....	Michel Vanasse, Pierre Masson, Guy Geoffroy, Albert Larbrisseau and Pierre C. David 377
A Method for Measurement of Arterial Concentration of Cerebral Blood Flow Tracer for Autoradiographic Experiments .....	Devidas Menon, Mirko Diksic, Ernst Meyer, Kazuhiro Sako and Y. Lucas Yamamoto 380
Spinal Epidural Lipomatosis: A Complication of Glucocorticoid Therapy .....	N.A. Russell, G. Belanger, B.C. Benoit, D.N. Latter, D.L. Finestone and G.W. Armstrong 383
Recurrent Aseptic Meningitis Secondary to Intracranial Epidermoids .....	Werner J. Becker, Gordon V. Watters, Jean-Pierre de Chadrevian and Michel Vanasse 387
Oculoskeletal Myopathy with Abnormal Mitochondria .....	V. Brill, N.B. Rewcastle, J. Humphrey 390
Brain Abscess Due to Petriellidium boydii .....	François Dubeau, Louis E. Roy, Johanne Allard, Michel Laverdiere, Suzanne Rousseau, Fernand Duplantis, Jean Boileau and Jacques Lachapelle 395
Inflammatory Myelopathy Presenting as a Cystic Intramedullary Spinal Cord Lesion .....	B.I. Tranter, T.A. Gray, W.J. Horsey, C.G. Consalves 399
Relapsing Polychondritis with Multifocal Neurological Abnormalities .....	J. Willis, E.A. Atack, G. Kraag 402
<b>Les Abrégés du Congrès Québécois de la Recherche Clinique en Sciences Neurologiques</b> .....	
	405
<b>BOOK REVIEWS</b> .....	412
<b>CALENDAR OF EVENTS</b> .....	415

## THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES

VOL. 11, NO. 4 NOV. 1984

<b>SPECIAL FEATURES</b>	
Presidential Address: The Impact of Head Trauma on Society .....	Leslie Ivan 417
Special Feature: Genetic Linkage of the Huntington's Disease Gene to a DNA Marker .....	James F. Gusella 421
Review Article: Saccadic Intrusions and Oscillations .....	James A. Sharpe and William A. Fletcher 426
<b>ORIGINAL ARTICLES</b>	
The University of Toronto Head Injury Treatment Study: A Prospective, Randomized Comparison of Pentobarbital and Mannitol .....	Michael L. Schwartz, Charles H. Tator, David W. Rowed, S. Ross Reid, Kotoo Meguro and David F. Andrews 434
Partially Reversible Cerebral Atrophy and Functional Improvement in Recently Abstinent Alcoholics .....	P.L. Carlen, D.A. Wilkinson, C. Wortzman and R. Holgate 441
Pharmacological Modification of Blood-Brain Barrier Permeability Following a Cold Lesion .....	Jennifer J. Raymond, David M. Robertson, Henry B. Dinsdale and Sukriti Nag 447
Bromocriptine in the Management of End of Dose Deterioration in Parkinson's Disease .....	J.D. Grimes, D.B. King, O.S. Kofman, P. Molina-Negro, A.F. Wilson and S. Bouchard 452
Free Valproic Acid: Steady-State Pharmacokinetics in Patients with Intractable Epilepsy .....	N. Otten, K. Hall, J. Irvine-Meek, M. Leroux, D. Budnik and S. Seshia 457
Third Ventricle Choroid Plexus Carcinoma .....	R.W. Broad and P.B.R. Allan 461
Aneurysmal Bone Cyst of the Skull .....	N.O. Ameli, K. Abbassioun, A. Azod and H. Saleh 466
Visual Loss Secondary to a Giant Aneurysm in a Patient with Tuberculous Sclerosis .....	Mark Guttman, S. Mark Tanen and Colin D. Lambert 472
Astrocytoma Following Scalp Radiotherapy in Infancy .....	Douglas C.F. Zochodne, J. Gregory Cairncross, Felix P. Arce, John C.F. MacDonald, Warren T. Blume, John P. Girvin and John C.E. Kaufman 475
New Intraventricular Catheter for Volume Pressure Response Measurement .....	John Gorecki and Fraser Saunders 479
<b>CONFERENCE REPORT:</b>	
The Torsion Dystonias .....	Edward G. Harris 481
IN MEMORIAM: James Bert Ryall Cosgrove, M.D., F.R.C.P. (C) .....	483
<b>BOOK REVIEWS</b> .....	485
<b>CORRESPONDENCE</b> .....	489
<b>CALENDAR OF EVENTS</b> .....	491
<b>XX Canadian Congress of Neurological Sciences — Call for Abstracts</b> .....	493
<b>Index to Volume 11 — 1984</b> .....	497

## QUEBEC COOPERATIVE STUDY OF FRIEDREICH'S ATAXIA Vol. 11, No. 4 (Suppl.) Nov. 1984 pages 501-660

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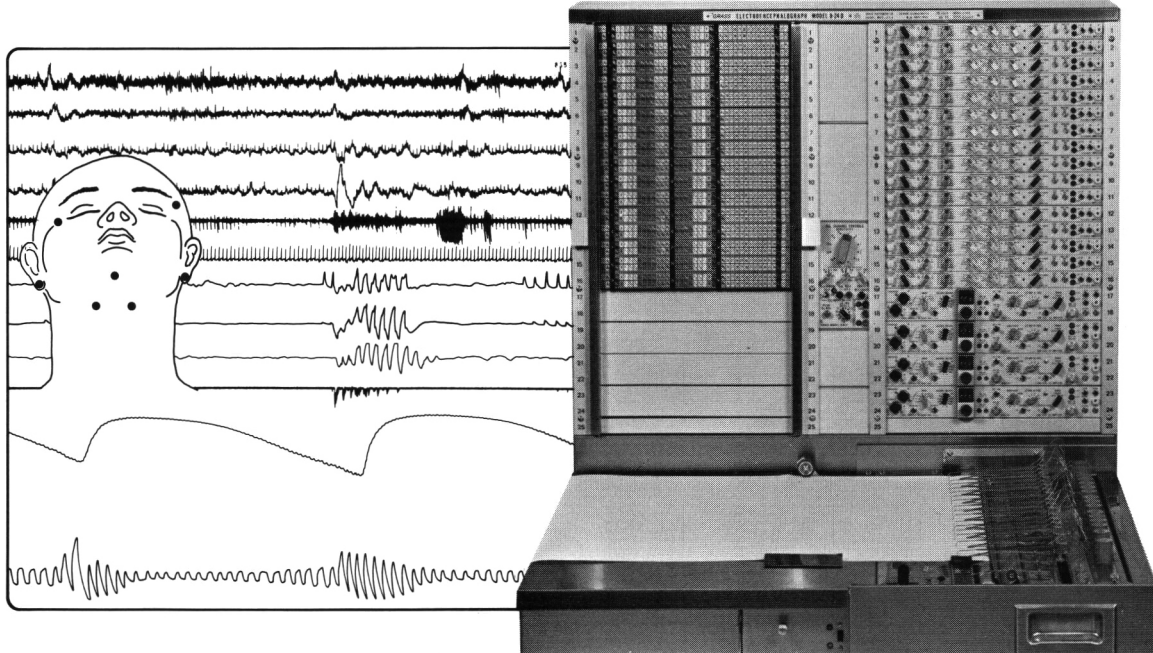
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## BRIEF PRESCRIBING INFORMATION

### THERAPEUTIC OR PHARMACOLOGICAL CLASSIFICATION

Inhibitor of platelet adhesion and aggregation

### INDICATIONS AND CLINICAL USE

Combined therapy with dipyridamole and ASA (Asasantine) is indicated in patients who are recovering from a myocardial infarction. The rate of re-infarction is significantly reduced by such therapy.

### CONTRAINDICATIONS

Salicylate sensitivity, active peptic ulcer.

### WARNING

Patients should be cautioned about the possibility of additional toxic effects of ASA if they are taking "over-the-counter" ASA containing remedies, including cough and cold medications.

### PRECAUTIONS

Since excessive doses of dipyridamole can produce peripheral vasodilation, it should be used with caution in patients with hypotension.

ASA should be administered cautiously to patients with asthma and other allergic conditions, a history of gastrointestinal ulcerations, bleeding tendencies, significant anemia or hypo-prothrombinemia.

Patients taking 2 to 3 g of ASA daily are at an increased risk of developing severe gastrointestinal bleeding following the ingestion of alcohol.

Since salicylates interfere with maternal and infant blood clotting and lengthen the duration of pregnancy and parturition time, they should not be administered during the last trimester of pregnancy unless the need outweighs the potential risks.

Caution is necessary when salicylates and anticoagulants are prescribed concurrently, as salicylates can decrease the concentration of prothrombin in the plasma.

Patients receiving concurrent salicylates and hypoglycemic therapy should be monitored closely, since reduction of the hypoglycemic drug dosage may be necessary.

Although salicylates in large doses are uricosuric agents, smaller amounts may depress uric acid clearance and thus decrease the uricosuric effects of probenecid, sulfinpyrazone, oxyphenbutazone and phenylbutazone. Caution should be exercised when corticosteroids and salicylates are used concurrently.

Acute hepatitis has been reported rarely in patients with systemic lupus erythematosus and juvenile rheumatoid arthritis with plasma salicylate concentrations above 25 mg/100 mL. Patients have recovered upon cessation of therapy.

Salicylate ingestion should be restricted in patients receiving indomethacin (and perhaps other non-narcotic analgesics) for conditions such as rheumatoid arthritis. Salicylates can produce changes in thyroid function tests.

Sodium excretion produced by spironolactone may be decreased by salicylate administration.

Concomitant ingestion of salicylates and aminosalicic acid (PAS) or aminobenzoic acid (PABA) in normal doses may lead to increased toxicity and salicylism.

Salicylates reportedly displace sulfonyleureas, penicillins and methotrexate from their binding sites on plasma proteins.

Salicylates also retard the renal elimination of methotrexate.

### ADVERSE REACTIONS

In a trial of 2026 patients in recurrent myocardial infarction, the most common patient complaints, except for headaches, were those associated with ASA administration. In order of frequency of occurrence, these were stomach pain, headaches, heartburn, dizziness, constipation, hematemesis, bloody stools and/or black, tarry stools, nausea and vomiting. An increased frequency of elevations of serum urea nitrogen, uric acid and creatinine were noted in the active treatment groups but increases for individual patients were small and not associated with clinical problems. There was also a slightly greater frequency of elevated systolic blood pressure readings in the active treatment groups.

When dipyridamole has been used alone, headache, dizziness, nausea, flushing, syncope or weakness and skin rash have occurred during initiation of therapy. In most cases, these tend to be minimal and transient. Gastric irritation, emesis and abdominal cramping may occur at high dosage levels. Rare cases of what appears to be an aggravation of angina pectoris have been reported, usually at the initiation of therapy. On those uncommon occasions when adverse reactions have been persistent or intolerable to the patient, withdrawal of medication has been followed promptly by cessation of the undesirable symptoms.

For ASA alone the following side effects have been reported: gastrointestinal — nausea, vomiting, diarrhea, gastrointestinal bleeding and/or ulceration; ear — tinnitus, vertigo, hearing loss; hematologic — leukopenia, thrombocytopenia, purpura; dermatologic and hypersensitivity — urticaria, angioedema, pruritis, skin eruptions, asthma, anaphylaxis; miscellaneous — acute, reversible hepatotoxicity, mental confusion, drowsiness, sweating, thirst.

### SYMPTOMS AND TREATMENT OF OVERDOSAGE

Hypotension, as a result of high serum levels of dipyridamole, is likely to be of short duration if it occurs but vasopressor substances may be used if necessary.

Salicylate overdosage SYMPTOMS may include rapid and deep breathing, nausea, vomiting, vertigo, tinnitus, flushing, sweating, thirst and tachycardia. In more severe cases, acid-base disturbances including respiratory alkalosis and metabolic acidosis can occur. Severe cases may show fever, hemorrhage, excitement, confusion, convulsions or coma and respiratory failure.

TREATMENT of salicylate overdosage consists of prevention and management of acid-base and fluid and electrolyte disturbances. Renal clearance is increased by increasing urine flow and by alkaline diuresis but care must be taken in this approach to not further aggravate metabolic acidosis and hypokalemia. Acidemia should be prevented by administration of adequate sodium containing fluids and sodium bicarbonate.

Hypoglycemia is an occasional accompaniment of salicylate overdosage and can be managed by glucose solutions. If a hemorrhagic diathesis is evident, give Vitamin K. Hemodialysis may be useful in complex acid-base disturbances particularly in the presence of abnormal renal function.

### DOSAGE AND ADMINISTRATION

The recommended oral dose is 1 capsule of Asasantine, 3 times a day, in patients who have suffered a previous myocardial infarction.

### AVAILABILITY

Asasantine is available as an opaque orange and yellow hard gelatin capsule. Each capsule contains 75 mg Persantine and 330 mg ASA.

Supplied in packages of 100 capsules.

Product Monograph available on request.

### REFERENCES:

- Myocardial ischemia in man: abnormal platelet aggregation and prostaglandin generation. Mehta, J. and Mehta, P. In: Platelets and Prostaglandins in Cardiovascular Disease. Editors: Mehta, J. and Mehta, P. Futura Publishing Co., New York, 345-358, 1981
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### Indications and Clinical Uses

Alleviation of signs and symptoms of spasticity resulting from multiple sclerosis. Spinal cord injuries and other spinal cord diseases.

### Contraindications

Hypersensitivity to LIORESAL.

### Warnings

**Abrupt Drug Withdrawal:** Except for serious adverse reactions, the dose should be reduced slowly when the drug is discontinued to prevent visual and auditory hallucinations, confusion, anxiety with tachycardia and sweating, insomnia, and worsening of spasticity.

**Impaired Renal Function:** Caution is advised in these patients and reduction in dosage may be necessary.

**Stroke:** Has not been of benefit and patients have shown poor tolerability to the drug.

**Pregnancy and Lactation:** Not recommended as safety has not been established. High doses in rats and rabbits are associated with an increase of abdominal hernias and ossification defects in the fetuses.

### Precautions

Not recommended in children under 12 as safety has not been established.

Because sedation may occur, caution patients regarding the operation of automobiles or dangerous machinery, activities made hazardous by decreased alertness, and use of alcohol and other CNS depressants.

Use with caution in spasticity that is utilized to sustain upright posture and balance in locomotion, or whenever spasticity is utilized to obtain increased function, epilepsy or history of convulsive disorders (clinical state and EEG should be monitored), peptic ulceration, severe psychiatric disorders, elderly patients with cerebrovascular disorders, and patients receiving antihypertensive therapy.

### Adverse Reactions

Most common adverse reactions are transient drowsiness, dizziness, weakness and fatigue. Others reported:

**Neuropsychiatric:** Headache, insomnia, euphoria, excitement, depression, confusion, hallucinations, paresthesia, muscle pain, tinnitus, slurred speech, coordination disorder, tremor, rigidity, dystonia, ataxia, blurred vision, nystagmus, strabismus, miosis, mydriasis, diplopia, dysarthria, epileptic seizures.

**Cardiovascular:** Hypotension, dyspnea, palpitation, chest pain, syncope.

**Gastrointestinal:** Nausea, constipation, dry mouth, anorexia, taste disorder, abdominal pain, vomiting, diarrhea, and positive test for occult blood in stool.

**Genitourinary:** Urinary frequency, enuresis, urinary retention, dysuria, impotence, inability to ejaculate, nocturia, hematuria.

**Other:** Rash, pruritus, ankle edema, excessive perspiration, weight gain, nasal congestion. Some of the CNS and genitourinary symptoms reported may be related to the underlying disease rather than to drug therapy.

The following laboratory tests have been found to be abnormal in a few patients receiving LIORESAL: SGOT, alkaline phosphatase and blood sugar (all elevated).

### Symptoms and Treatment of Overdosage

**Signs and Symptoms:** Vomiting, muscular hypotonia, hypotension, drowsiness, accommodation disorders, coma, respiratory depression, and seizures.

**Co-administration of alcohol, diazepam, incyclic anti-depressants, etc., may aggravate the symptoms.**

**Treatment:** Treatment is symptomatic. In the alert patient, empty the stomach (induce emesis followed by lavage). In the obtunded patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis).

Maintain adequate respiratory exchange; do not use respiratory stimulants. Muscular hypotonia may involve the respiratory muscles and require assisted respiration. Maintain high urinary output. Dialysis is indicated in severe poisoning associated with renal failure.

### Dosage and Administration

Optimal dosage of LIORESAL requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually 40-80 mg daily).

The following dosage titration schedule is suggested:

5 mg t.i.d. for 3 days	15 mg t.i.d. for 3 days
10 mg t.i.d. for 3 days	20 mg t.i.d. for 3 days

Total daily dose should not exceed a maximum of 20 mg q.i.d.

The lowest dose compatible with an optimal response is recommended. If benefits are not evident after a reasonable trial period, patients should be slowly withdrawn from the drug (see Warnings).

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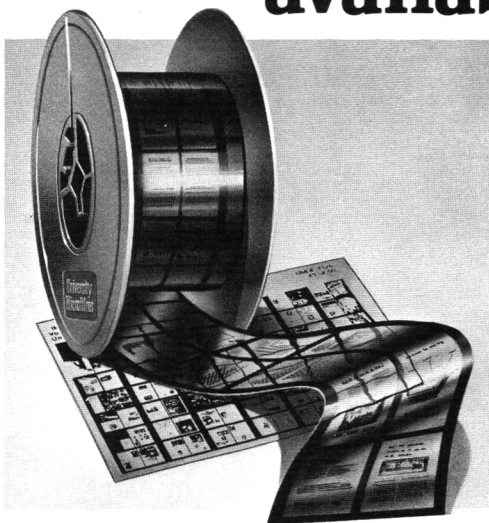
- Feldman et al. *Neurology*, Vol. 28, No. 11 pp 1094-1098, 1978.
- Symposia Reporter*, Vol. 3, No. 2.

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#### REFERENCES:

- 1 Frew, I.J.C. et al. *Postgrad. Med. J.*; 52:501-503, 1976.
- 2 Wilmot, 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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means a  
fuller life later.**

For brief prescribing information see page xvi

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