The Canadian Journal of Neurological Sciences

Le Journal Canadien des Sciences Neurologiques

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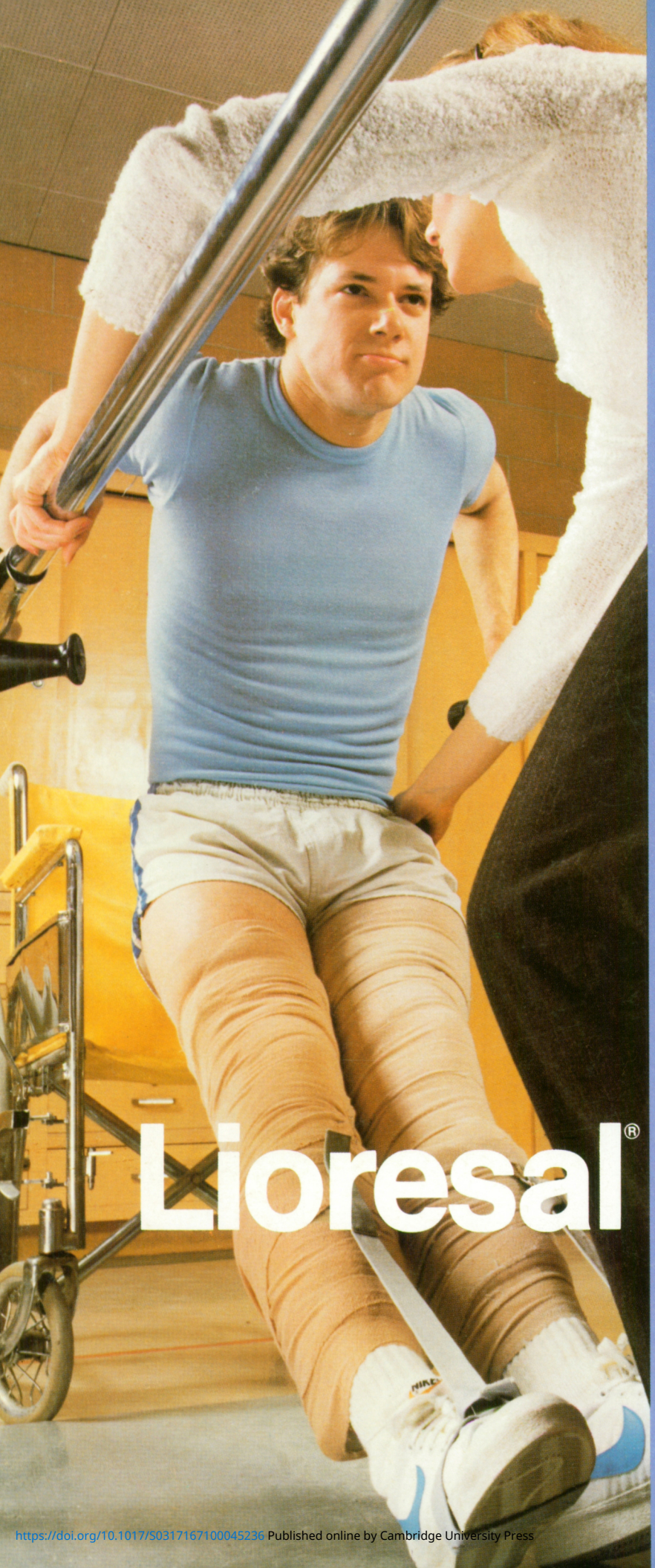

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THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES
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Papers should be identified only by the full name of the author, or authors, and the name of the place in which the work was done.

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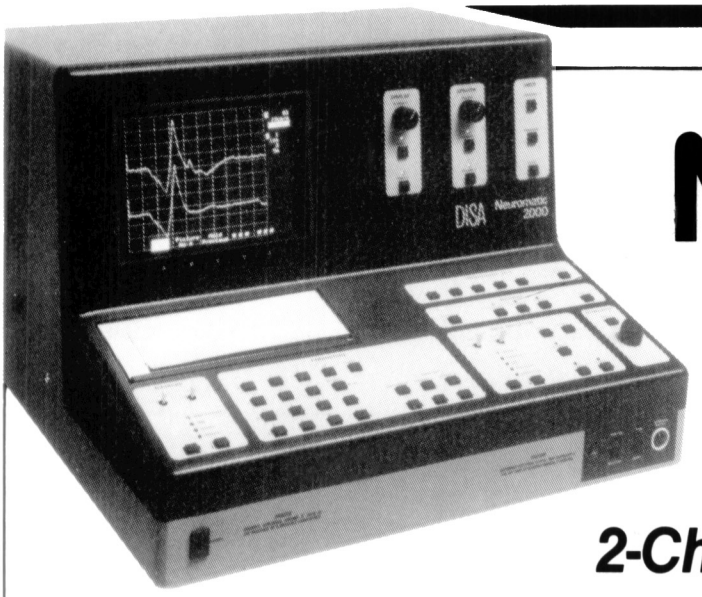

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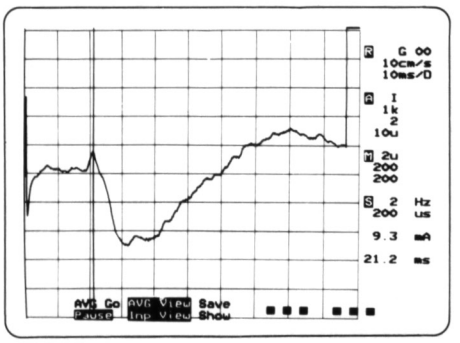

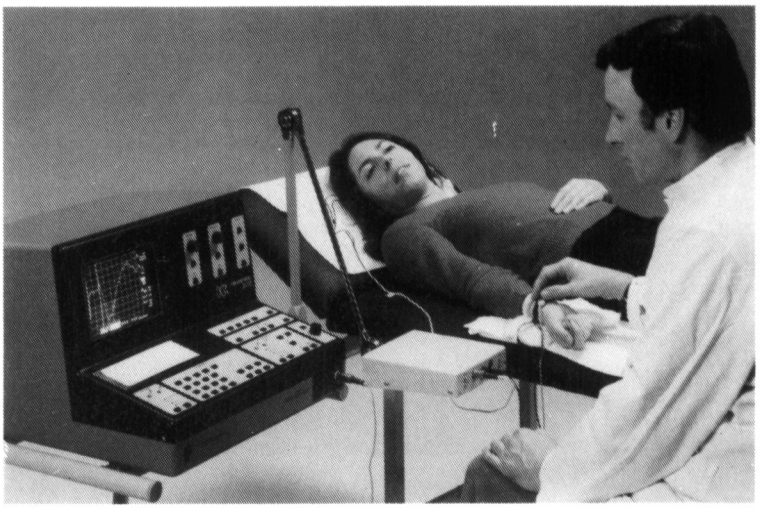

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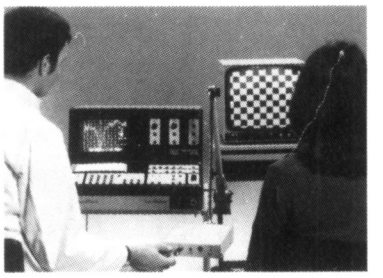

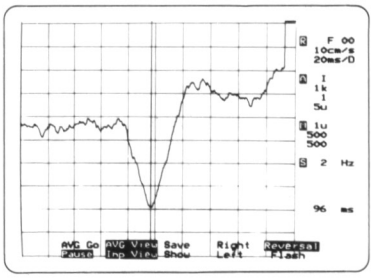

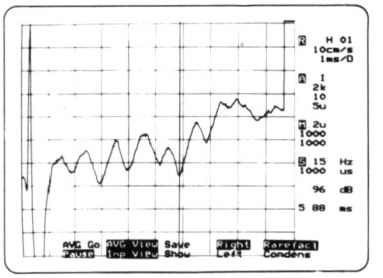

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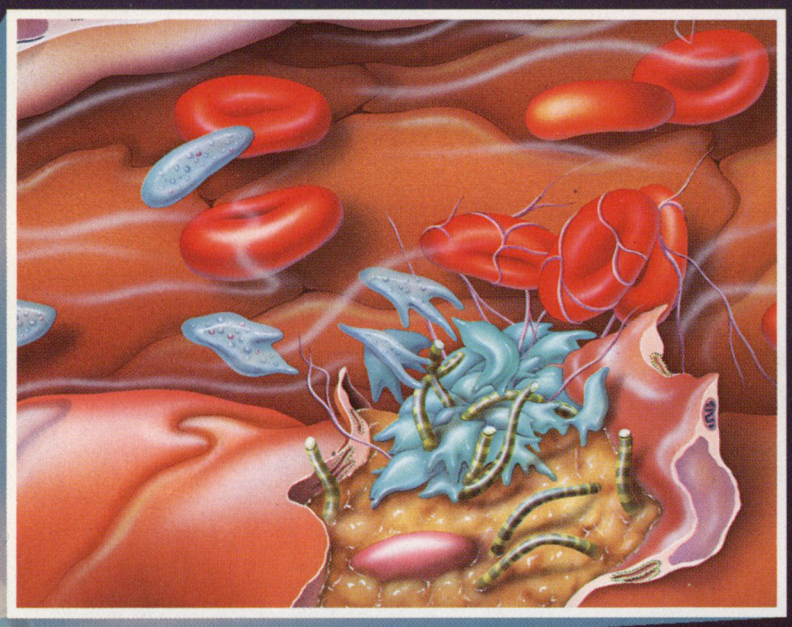

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BRIEF PRESCRIBING INFORMATION

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 depress 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 aminosalicylic acid (PAS) or aminobenzoic acid (PABA) in normal doses may lead to increased toxicity and salicylism.

Salicylates reportedly displace sulfonylureas, 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:

[1] 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.

[2] Mehta, J. Platelets and Prostaglandins in Coronary Artery Disease–Rationale for use of platelet suppressive drugs. Jama 1983; 249: 2818–2823.

[3] *Pumphrey, C. W., Chesebro, J. H. et al.* In Vivo Quantitation of Platelet Deposition on Human Peripheral Arterial Bypass Grafts Using Indium — 111-labelled Platelets — Effect of Dipyridamole and Aspirin. The American Journal of Cardiology, 1983; 51: 796-801.

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Adverse Reactions: In rare instances, drowsiness, dizziness, nausea, vomiting, constipation, skin rash and miosis are possible adverse effects.

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References: 1. Kibbe MH. Dis Nerv Syst 1955; 16:3.* 2. Weisman SJ. Am Pract Digest Treat 1955; 6(7): 1019-21.* 3. Glassman JM, Soyka JP. Curr Ther Res 1980; 28(6): 904-15. 4. Data on file. Sandoz (Canada) Ltd.

*The composition of Fiorinal used in the reference studies was: Sandoptal (butalbital) 50 mg; caffeine - 40 mg; ASA - 200 mg; and phenacetin - 130 mg.

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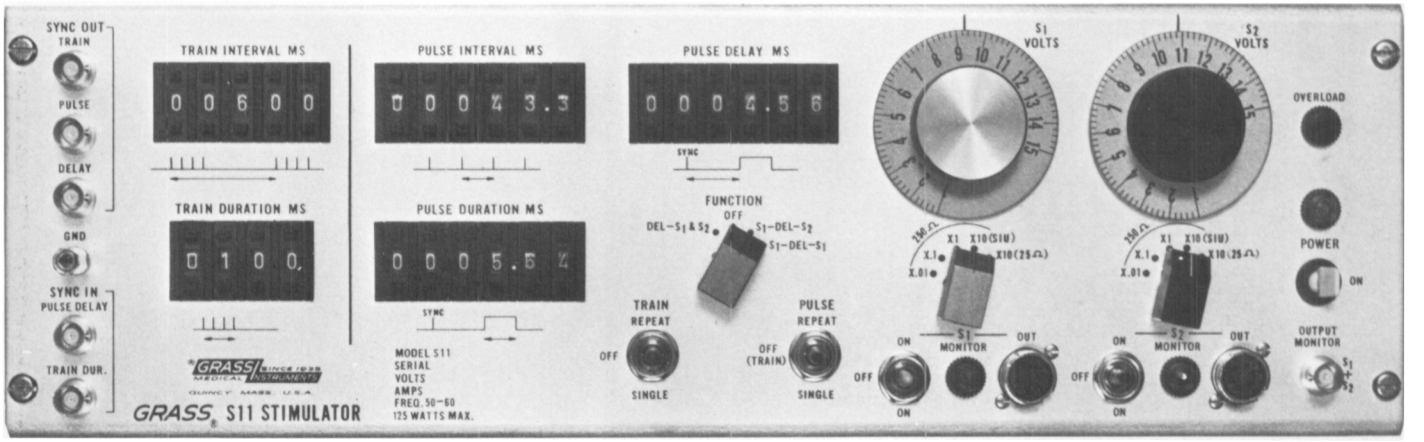

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