

THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES

LE JOURNAL CANADIEN DES SCIENCES NEUROLOGIQUES

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Official Journal of the Canadian Neurological Society, the Canadian Neurosurgical Society and the Canadian Society of Electroencephalographers, Electromyographers and Clinical Neurophysiologists.

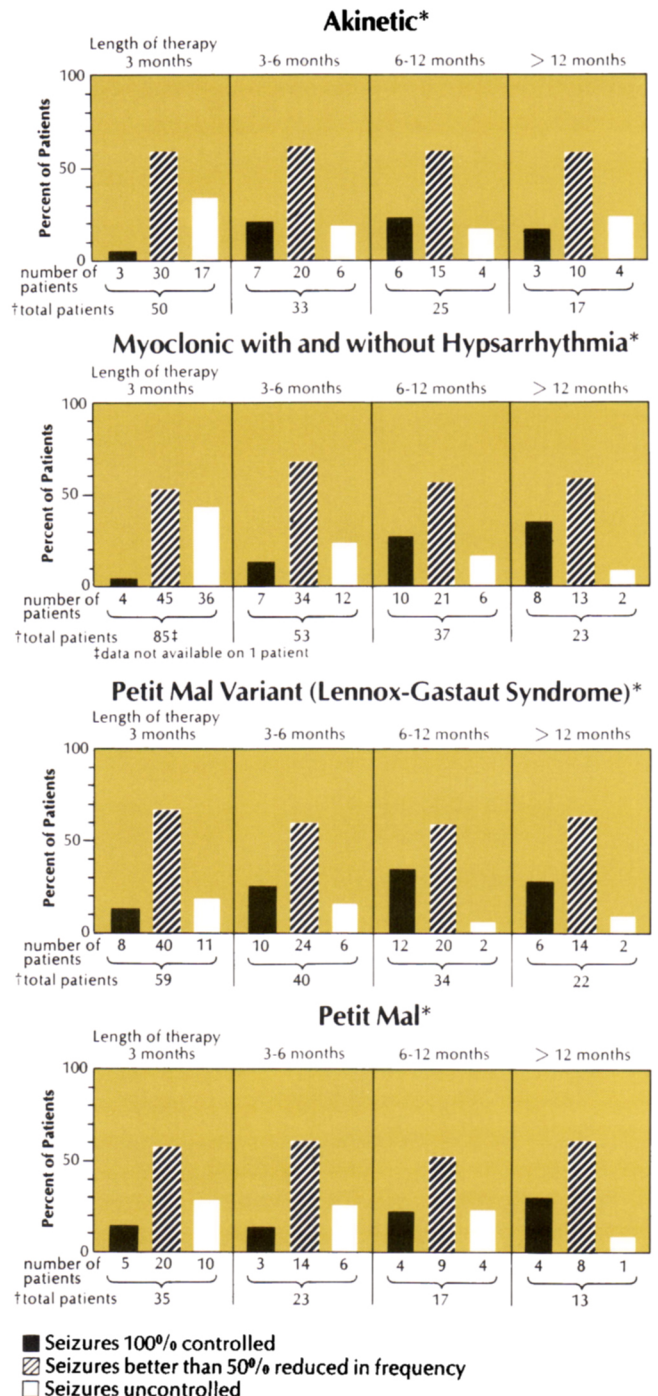
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- it may be of value as principal medication in petit mal where succinimide therapy has failed.
- the most frequently noted side effects, drowsiness and ataxia, generally are dose related and can often be controlled by dosage adjustments.

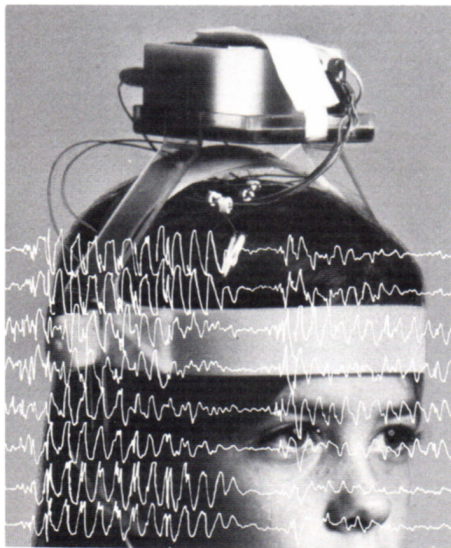
Effect of RIVOTRIL on seizure frequency



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†Patients dropped from the study for a variety of reasons as well as those treated for less than 12 months account for the decrease in total patient population.

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Brief Prescribing Information

Action

RIVOTRIL is a benzodiazepine and has sedative, hypnotic, and anticonvulsant properties characteristic of this class of drugs. As an anticonvulsant, it decreases the frequency, amplitude, duration, and spread of discharges in minor motor seizures and suppresses the spike-and-wave discharge in absence seizures.

The maximum blood level of clonazepam after a single oral dose is reached within 1 to 2 hours. The half-life of clonazepam is approximately 18 to 50 hours, and the main route of excretion is in the urine.

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RIVOTRIL has been found useful when used alone or as an adjunct in the management of myoclonic and akinetic seizures and petit mal variant (Lennox-Gastaut syndrome).

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If a loss of anticonvulsant effect occurs, dosage adjustment may re-establish efficacy in some cases.

Contraindications

In patients with:

- known hypersensitivity to benzodiazepines
- significant liver disease
- narrow-angle glaucoma

Warnings

RIVOTRIL should be used by women of child-bearing potential only when the expected benefits to the patient warrant the possible risks to the fetus. Women who become pregnant should consult their physician promptly with regard to continuing antiepileptic medication.

Mothers receiving RIVOTRIL should not breast feed their infants.

Because adverse effects may possibly become apparent only after years of administration, a risk/benefit consideration of long-term use of RIVOTRIL is important in pediatric patients.

Precautions

The use of multiple anticonvulsants may increase CNS-depressant effects and the dosage of each drug may need adjustment to obtain the optimum effect.

To avoid precipitation of status epilepticus, abrupt withdrawal of RIVOTRIL must be avoided. Substitution of another anticonvulsant may be indicated during RIVOTRIL withdrawal.

In a very few patients, RIVOTRIL may cause a paradoxical increase in seizure activity or new types of seizures. RIVOTRIL may precipitate the onset of grand mal or increase its incidence. The addition of appropriate anticonvulsants or an increase in their dosage may be necessary.

Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness, and should also be warned against the concomitant use of alcohol or other CNS-depressant drugs.

Patients who may be prone to increase drug dosage on their own should be monitored carefully when receiving RIVOTRIL, as benzodiazepines have produced habituation, dependence, and withdrawal symptoms. RIVOTRIL should be administered with caution to patients with impaired renal function.

Periodic liver function tests and blood counts are recommended during long-term therapy with RIVOTRIL.

Treatment with RIVOTRIL should be instituted with caution in patients with chronic respiratory disease, because of the possibility of hypersecretion in the upper respiratory passages.

Adverse reactions

Drowsiness has occurred in 50% and ataxia in 30% of the patients treated with RIVOTRIL. In some cases these effects have diminished with time. Behaviour problems have been noted in approximately 25% and increased salivation in 7% of the patients.

Please see product monograph for a complete list of other possible adverse reactions.

Dosage and administration

Dosage of RIVOTRIL must be determined for each patient according to clinical response and tolerance. Dosage depends, above all, on the age of the patient.

The daily requirement should be given in 2 or 3 divided doses. If the doses are not equal, the larger dose should be given before retiring.

Children up to 10 years or 30 kg: In order to minimize drowsiness, the initial dosage should usually be between 0.01 and 0.03 mg/kg/day and must not exceed 0.05 mg/kg/day.

The dosage should be increased by 0.25 to 0.5 mg/day every third day, unless seizures are controlled or side effects intervene, until a maintenance dosage of 0.1 to 0.2 mg/kg/day has been reached.

Adults: The initial dosage should not exceed 1.5 mg/day.

The dosage should be increased by 0.5 to 1 mg every third day, until seizures are controlled or side effects intervene. The recommended maintenance dosage for adults is 8 to 10 mg/day in 3 divided doses. Dosages in excess of 20 mg/day should be administered with caution.

Whenever RIVOTRIL is added to an anticonvulsant regimen, it should be borne in mind that the use of multiple anticonvulsants may result in increased depressant adverse effects.

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Textbook references should include name of text, author's name, page number, publisher and city.

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carbamazepine

To help control
refractory generalized
tonic-clonic seizures
without excessive sedation



Brief Prescribing Information
Tegretol® 200 mg carbamazepine

Indications and Clinical Use

A. Trigeminal Neuralgia:

Tegretol is indicated for the symptomatic relief of pain of trigeminal neuralgia only during periods of exacerbation of true or primary trigeminal neuralgia (tic douleureux). It should not be used preventively during periods of remission. In some patients, Tegretol has relieved glossopharyngeal neuralgia. For patients who fail to respond to Tegretol, or who are sensitive to the drug, recourse to other accepted measures must be considered.

Tegretol is not a simple analgesic and should not be used to relieve trivial facial pains or headaches.

B. Tegretol has been found useful:

- 1) in the management of psychomotor (temporal lobe) epilepsy and,
- 2) as an adjunct, in some patients with secondary or partial epilepsy with complex symptomatology or secondarily generalized seizures, when administered in combination with other antiepileptic medication.
- 3) as an alternative medication in patients with generalized tonic-clonic seizures who are experiencing marked side effects or fail to respond to other anticonvulsant drugs.

Tegretol is essentially ineffective in controlling petit mal, minor motor, myoclonic and predominantly unilateral seizures, and does not prevent the generalization of epileptic discharge.

Contraindications

Tegretol should not be administered to patients with a history of hepatic disease or serious blood disorder. Tegretol should not be administered immediately before, in conjunction with, or immediately after a monoamine oxidase inhibitor. When it seems desirable to administer Tegretol to a patient who has been receiving a MAO inhibitor, there should be as long a drug-free interval as the clinical condition allows, but in no case should this be less than 14 days. Then the dosage of Tegretol should be low initially, and increased very gradually.

Tegretol should not be administered to patients presenting atrioventricular heart block.

Safe use in pregnancy has not been established. Therefore, Tegretol should not be administered during the first three months of pregnancy. Tegretol should not be given to women of childbearing potential unless, in the opinion of the physician, the expected benefits to the patient outweigh the possible risk to the foetus (See Reproductive Studies). Because of demonstrated toxicity in nursing animals, Tegretol should not be administered to nursing mothers.

Because of the similarity of chemical structure,

Tegretol should not be administered to patients with known hypersensitivity to any of the tricyclic compounds, such as amitriptyline, trimipramine, imipramine, or their analogues or metabolites.

Warnings

Although reported infrequently, serious adverse effects have been observed during the use of Tegretol. Agranulocytosis and aplastic anemia have occurred in a few instances with a fatal outcome. Leucopenia, thrombocytopenia and hepatocellular and cholestatic jaundice have also been reported. It is, therefore, important that Tegretol should be used carefully and close clinical and frequent laboratory supervision should be maintained throughout treatment in order to detect as early as possible signs and symptoms of a possible blood dyscrasia.

Long-term toxicity studies in rats indicated a potential carcinogenic risk. Therefore, the possible risk of drug use must be weighed against the potential benefits before prescribing carbamazepine to individual patients.

Precautions

Monitoring of Haematological and Other Adverse Reactions:

Complete blood studies, including platelet counts, and evaluation of hepatic and renal function and urinalysis should be carried out before treatment is instituted. Careful clinical and laboratory supervision should be maintained throughout treatment, including frequent performance of complete blood counts, in order to detect any early signs or symptoms of blood dyscrasia. Should any signs or symptoms or abnormal laboratory findings suggestive of blood dyscrasia or liver disorder occur, Tegretol should be immediately discontinued until the case is carefully reassessed.

Urinary Retention and Increased Intraocular Pressure:

Because of its anticholinergic action, Tegretol should be given cautiously, if at all, to patients with increased intraocular pressure or urinary retention. Such patients should be followed closely while taking the drug.

Occurrence of Behavioural Disorders: Because it is closely related to the other tricyclic drugs, there is some possibility that Tegretol might activate a latent psychosis, or, in elderly patients, produce agitation or confusion, especially when combined with other drugs. Caution should also be exercised in alcoholics.

Use in Patients with Cardiovascular Disorders: Tegretol should be used cautiously in patients with a history of coronary artery disease, organic heart disease, or congestive failure. If a defective conductive system is suspected, an E.K.G. should be performed before administering Tegretol, in order to exclude patients with atrioventricular block.

Use in Patients taking Oral Contraceptives: In women under treatment with Tegretol, the reliability of oral contraceptives may be adversely affected; such patients should accordingly be advised to use some alternative, non-hormonal method of contraception.

Driving and operating Hazardous Machinery: Because dizziness and drowsiness are possible side effects of Tegretol, patients should be warned about the possible hazards of operating machinery or driving automobiles.

Adverse Reactions

The reactions which have been most frequently reported with Tegretol are drowsiness, unsteadiness on the feet, vertigo, dizziness, gastrointestinal disturbances, and nausea. These reactions usually occur only

during the initial phase of therapy. They have rarely necessitated discontinuing Tegretol therapy, and can be minimized by initiating treatment at a low dosage. The more serious adverse reactions observed are the haematologic, hepatic, cardiovascular and dermatologic reactions, which require discontinuation of therapy.

The following adverse reactions have been reported:

Haematological reactions: Transitory leucopenia, eosinophilia, leucocytosis, thrombocytopenic purpura, agranulocytosis, macrocytic anemia and aplastic anemia. In a few instances, deaths have occurred.

Hepatic disturbances: During the long-term administration of Tegretol, abnormalities in liver function tests and cholestatic or hepatocellular jaundice have been observed.

Dermatological reactions: The following reactions occurred during treatment with Tegretol: skin sensitivity reactions and rashes, erythematous rashes, pruritic eruptions, urticaria, photosensitivity, pigmentary changes, neurodermatitis and in rare cases Stevens-Johnson syndrome, exfoliative dermatitis, alopecia, diaphoresis, erythema multiforme, erythema nodosum, and aggravation of disseminated lupus erythematosus.

Neurological reactions: The reactions reported as occurring during treatment with Tegretol include vertigo, somnolence, disturbances of coordination, confusion, headache, fatigue, blurred vision, transient diplopia and oculomotor disturbances, speech disturbances, abnormal involuntary movements and increase in motor seizures. In addition, peripheral neuritis and paresthesia, depression with agitation, talkativeness, nystagmus, and tinnitus have been reported but only very rarely. There have been some reports of paralysis and other symptoms of cerebral arterial insufficiency but no conclusive relationship to the administration of Tegretol could be established.

Cardiovascular systems: Recurrence of thrombophlebitis in patients with a prior history of thrombophlebitis, congestive heart failure, aggravation of hypertension, Stokes-Adams in patients with AV block, hypotension, syncope and collapse, edema, aggravation of coronary artery disease. Some of these complications (including myocardial infarction and arrhythmia) have been associated with other tricyclic compounds.

Genitourinary reactions: Urinary frequency, acute urinary retention, oliguria with elevated blood pressure, and impotence. Elevation of BUN, albuminuria and glycosuria also have been observed.

Digestive tract: Disturbances associated with Tegretol therapy have included nausea, vomiting, gastric or abdominal discomfort, diarrhoea, anorexia and dryness of the mouth and throat, glossitis and stomatitis.

Eyes: There is no conclusive evidence that Tegretol produces pathological changes in the cornea, lens or retina. However, it should be recognized that many phenothiazines and related drugs have been shown to cause eye changes. By analogy, periodic eye examinations, including slitlamp funduscopy and tonometry, are recommended.

Other reactions reported during treatment with Tegretol include fever and chills, lymphadenopathy, aching joints and muscles, leg cramps and conjunctivitis.

Dosage and Administration

Use in Epilepsy (see Indications): A low initial daily dosage with a gradual increase in dosage is advised. Dosage should be adjusted to the needs of the individual patient.

Adults and Children over 12 years of age: Initially, 100 to 200 mg once or twice a day depending on the severity of the case and previous therapeutic history. The initial dosage is progressively increased, until the best response is obtained, up to 600 mg daily. The usual optimal dosage is 600 mg daily, but occasionally dosages up to 800 to 1000 mg have been used for short periods. As soon as disappearance of seizures has been obtained and maintained, dosage should be reduced very gradually until a minimum effective dose is reached.

Use in trigeminal neuralgia: The initial daily dosage should be small; 200 mg, taken in two doses of 100 mg each is recommended. The total daily dosage can be increased by 200 mg per day until relief of pain is obtained. This is usually achieved at a dosage between 200 and 800 mg daily, but occasionally up to 1200 mg per day may be necessary. As soon as relief of pain has been obtained and maintained, progressive reduction in dosage should be attempted until a minimum effective dosage is reached. Because trigeminal neuralgia is characterized by periods of remission, attempts should be made to reduce or discontinue the use of Tegretol at intervals of not more than 3 months, depending upon the individual clinical course.

Prophylactic use of the drug in trigeminal neuralgia is not recommended.

Tegretol should be taken in two or three divided doses daily, with meals whenever possible.

Dosage Forms

Tegretol is available as a 200 mg white, round, flat, bevelled-edged, double-scored tablet, imprinted with the GEIGY monogram.

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See outside back cover.



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*Reynolds, F.H. et al: Lancet, 923-926, May 1, 1976
**Goodman and Gilman, 5th Edition
***Sherwin, (1973) Arch. Neurol. (28), 178.

(vi)

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BRIEF PRESCRIBING INFORMATION

INDICATIONS (DILANTIN):

DILANTIN is indicated for the control of grand mal epilepsy, psychomotor seizures, and certain other convulsive disorders. Parenteral DILANTIN is indicated for the treatment of status epilepticus and the prophylactic control of seizures in neurosurgery.

PRECAUTIONS AND CONTRAINDICATIONS (DILANTIN):

Periodic examination of the blood is advisable since hematologic disorders in association with DILANTIN administration have been reported. Nystagmus in combination with diplopia and ataxia indicates dosage should be reduced. When DILANTIN with PHENOBARBITAL or PHELANTIN are used, it should be borne in mind that phenobarbital may cause drowsiness, and may be habit-forming. PHELANTIN, because of the methamphetamine content, should be given cautiously to patients with hypertension.

PHELANTIN is contraindicated in patients hypersensitive to ephedrine-like compounds; in those showing anxiety or undue excitability; and in patients with cardiac or coronary disease not likely to tolerate vasoconstrictors. The possibility of toxic effects of DILANTIN during pregnancy has not been explored.

ADVERSE REACTIONS (DILANTIN):

Once proper dosage has been determined, toxic effects of DILANTIN are infrequent. Minor side effects which may occur during the initial stages of therapy include gastric distress, nausea, weight loss, transient nervousness, sleeplessness, and a feeling of unsteadiness, all of which usually subside with continued use. Allergic phenomena such as polyarthropathy, fever, and skin eruptions may occur. Acute generalised morbilliform eruptions with or without a temperature elevation, may occur about two weeks after treatment is begun. The dermatitis may in some instances go on to exfoliation and hepatitis may occur, contraindicating further therapy with DILANTIN. Eruptions usually subside when therapy is discontinued.

Gingival hypertrophy, hirsutism, and excessive motor activity are occasionally encountered, especially in children, adolescents, and young adults. Only occasionally is it necessary to discontinue DILANTIN because of these manifestations. Gingival hypertrophy can be greatly minimized by scrupulous daily care of gums and prophylactic dental care.

Megaloblastic anemia and macrocytosis have been reported but have responded to antianemic therapy. Leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, aplastic anemia, and agranulocytosis have also been reported. Usually these patients were simultaneously receiving other drugs. Lupus erythematosus and erythema multiforme have occurred in patients receiving DILANTIN.

DOSAGE AND ADMINISTRATION (DILANTIN):

In all cases, optimal dosage of DILANTIN must be determined by trial. Dosage in excess of the minimum required to prevent convulsions is not recommended. For most patients, DILANTIN CAPSULES, 100 mg or DILANTIN CAPSULES, 30 mg are suitable for administration.

FORMS AVAILABLE:

In order to provide versatile therapy, DILANTIN is supplied in the following convenient product forms: DILANTIN® CAPSULES, 100 mg (Cap 362). Each white capsule with orange cap contains phenytoin sodium 100 mg.

DILANTIN® CAPSULES, 30 mg (Cap 365). Each white capsule with pale pink cap contains phenytoin sodium 30 mg.

DILANTIN® INFATABS, 50 mg. Each triangular shaped, grooved tablet, contains 50 mg phenytoin.

INFATABS are palatably flavoured tablets, intended primarily for pediatric use.

DILANTIN-125 SUSPENSION. Each 5 ml contains 125 mg phenytoin. DILANTIN-30 SUSPENSION. Each 5 ml contains 30 mg phenytoin.

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⊕ DILANTIN® with 15 mg PHENOBARBITAL CAPSULES, (Cap. 375). Each white capsule with garnet cap contains 100 mg phenytoin sodium and 15 mg phenobarbital.

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DILANTIN® AMPOULES, 250 mg (Amp. 1475). Each 5 ml ampoule contains 250 mg (50 mg/ml) of phenytoin sodium ready-mixed.

INDICATIONS (ZARONTIN):

ZARONTIN is indicated for the control of petit mal epilepsy.

PRECAUTIONS (ZARONTIN):

The physician should be alert to any symptoms indicative of the following conditions which have been reported in association with the use of ZARONTIN: aplastic anemia, agranulocytosis, dermatitis, leukopenia. Periodic blood counts should be performed. The drug should be used with caution in patients with known liver or renal disease or dysfunction. Routine urinalyses and frequent liver function tests are advised. Safe use of this drug in pregnancy has not been established.

Because of the possibility of drug-induced drowsiness, operation of motor vehicles or other machinery by patients on ethosuximide therapy is not advised. ZARONTIN when used alone in mixed types of epilepsy may increase the frequency of grand mal attacks in some patients.

ADVERSE REACTIONS (ZARONTIN):

In 727 patients gastrointestinal side effects occurred in 12.5%, central nervous system symptoms in 6.7%, blood changes in 0.4%, and miscellaneous side effects in 1.2%. Side effects are usually mild and transient and usually subside with continued therapy. Anorexia, gastric distress, nausea, emesis, drowsiness, headache, dizziness, euphoria, and singultus have been reported. Psychiatric or psychologic aberrations, including insomnia, night terrors, inability to concentrate, motor unrest, agitation, and aggressiveness thought to be drug-induced or exacerbated by anticonvulsant medication, were noted in a few patients who had previously shown emotional instability. Leukopenia, agranulocytosis, and severe pancytopenia with fatal outcome, have been reported in association with ethosuximide. In most cases of leukopenia, the condition cleared either on reduction of dosage or discontinuation of the drug. Other reactions in which the extent of ethosuximide implication is not yet determined include myopia, rash, vaginal bleeding, swelling of the tongue, and hirsutism. One instance of temporarily elevated (3-plus) cephalin flocculation test has been reported; patient showed normal values as medication continued.

DOSAGE AND ADMINISTRATION (ZARONTIN):

The initial dose for children under six years of age is 250 mg (1 capsule or 5 ml of syrup) per day; for patients six years of age and older, 500 mg (2 capsules or 10 ml of syrup) per day. The dose thereafter must be individualized according to the patient's response.

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XVth Canadian Congress of Neurological Sciences,

Ottawa, Ontario

June 18-21, 1980

McMaster Faculty of Health Sciences International Meeting. M.D. Program 10th Anniversary, May 4-8, 1980, Hamilton, Ontario. Information: Mr. S. Winn, 2E15, Health Sciences Centre, McMaster University, Hamilton, Ontario, Canada, L8S 4J9, (416) 525-9140, Ext. 2111.

12th WORLD CONGRESS OF NEUROLOGY

Dates: Sunday, September 20 - Friday, September 25, 1981

Congress Site: Kyoto International Conference Hall
Takaraike, Sakyo-ku, Kyoto 606, Japan

A. Main Themes:

1. Hemispheric Specialization in Man
2. Cerebral Vascular Diseases
3. Neurotransmitter and Neuropeptide Dysfunction in Relation to Neurological Disease
4. Viral Infections of the Nervous System

B. Free Communications

C. Scientific Exhibition and Technical Exhibition of Medical Equipment, Books and Pharmaceuticals

D. Symposia related to Neurology

Official Languages: English, French, German and Spanish

Provisional Registration: To reach Secretariat by June 30, 1981

Any further information can be obtained from:

Secretariat
12th World Congress of Neurology
c/o Simul International, Inc.
Kowa Bldg. No. 9
1-8-10, Akasaka, Minato-ku
Tokyo 107, Japan
Telephone: (03) 582-4224

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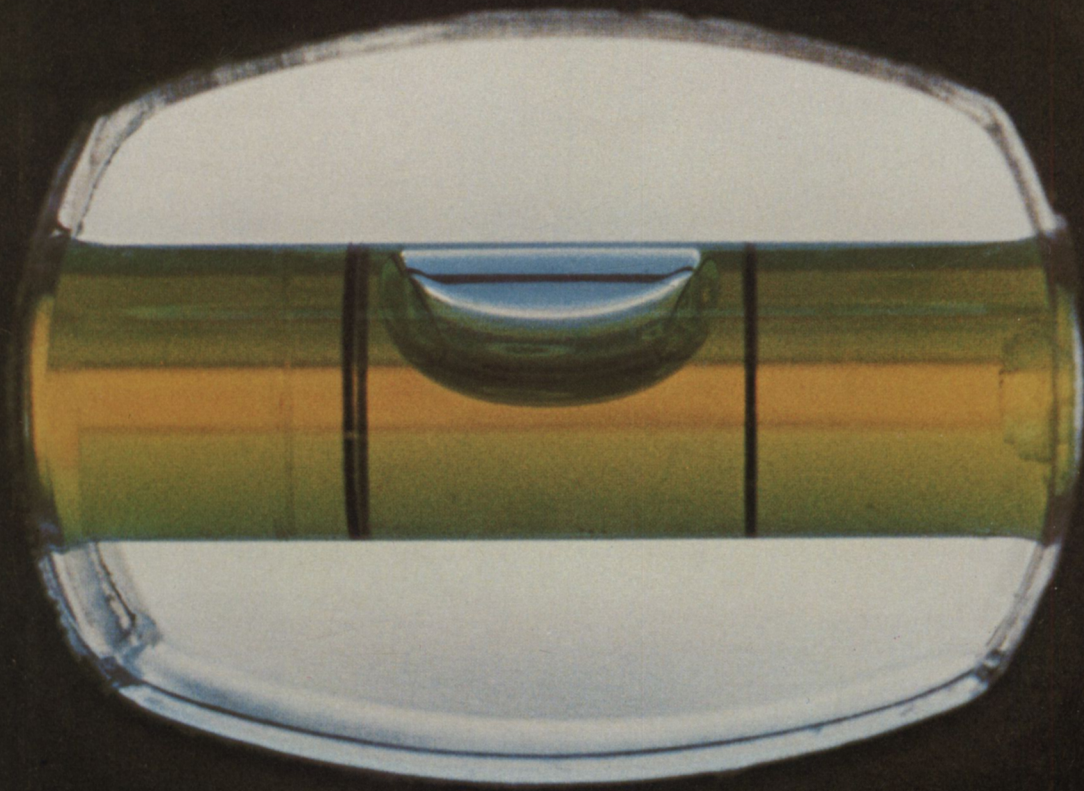
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back into balance**

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INDICATIONS

Treatment of Parkinson's syndrome with exception of drug induced parkinsonism.

CONTRAINDICATIONS

When a sympathomimetic amine is contraindicated; with monoamine oxidase inhibitors, which should be discontinued two weeks prior to starting SINEMET*; in uncompensated cardiovascular, endocrine, hematologic, hepatic, pulmonary or renal disease; in narrow-angle glaucoma; in patients with suspicious, undiagnosed skin lesions or a history of melanoma.

WARNINGS

When given to patients receiving levodopa alone, discontinue levodopa at least 12 hours before initiating SINEMET* at a dosage that provides approximately 20% of previous levodopa.

Not recommended in drug-induced extrapyramidal reactions; contraindicated in management of intention tremor and Huntington's chorea.

Levodopa related central effects such as involuntary movements may occur at lower dosages and sooner, and the 'on and off' phenomenon may appear earlier with combination therapy.

Monitor carefully all patients for the development of mental changes, depression with suicidal tendencies, or other serious antisocial behaviour.

Cardiac function should be monitored continuously during period of initial dosage adjustment in patients with arrhythmias.

Upper gastrointestinal hemorrhage is possible in patients with history of peptic ulcer.

Safety of SINEMET* in patients under 18 years of age not established.

Pregnancy and lactation: In women of child-bearing potential, weigh benefits against risks. Should not be given to nursing mothers. Effects on human pregnancy and lactation unknown.

PRECAUTIONS

General: Periodic evaluations of hepatic, hematopoietic, cardiovascular and renal function recommended in extended therapy. Treat patients with history of convulsions cautiously. **Physical Activity:** Advise patients improved on SINEMET* to increase physical activities gradually, with caution consistent with other medical considerations. **In Glaucoma:** May be given cautiously to patients with wide angle glaucoma, provided intraocular pressure is well controlled and can be carefully monitored during therapy. **With Antihypertensive Therapy:** As symptomatic postural hypotension has been reported occasionally, give cautiously to patients on antihypertensive drugs, checking carefully for changes in pulse rate and blood pressure. Dosage adjustment of antihypertensive drug may be required. **With Psychoactive Drugs:** If concomitant administration is necessary, administer psychoactive drugs with great caution and observe patients for unusual adverse reactions. **With Anesthetics:** Discontinue SINEMET* the night before general anesthesia and reinstitute as soon as patient can take medication orally.

ADVERSE REACTIONS

Most Common: Abnormal Involuntary Movements—usually diminished by dosage reduction—choreiform, dystonic and other involuntary movements. Muscle twitching and blepharospasm may be early signs of excessive dosage.

Other Serious Reactions: Oscillations in performance: diurnal variations, independent oscillations in akinesia with stereotyped dyskinesias, sudden akinetic crises related to dyskinesias, akinesia paradoxa (hypotonic freezing) and 'on and off' phenomenon. **Psychiatric:** paranoid ideation, psychotic episodes, depression with or without development

of suicidal tendencies and dementia. Levodopa may produce hypomania when given regularly to bipolar depressed patients. Rarely convulsions (causal relationship not established). Cardiac irregularities and/or palpitations, orthostatic hypotensive episodes, anorexia, nausea, vomiting and dizziness.

Other adverse reactions that may occur:

Psychiatric: Increased libido with serious antisocial behaviour, euphoria, lethargy, sedation, stimulation, fatigue and malaise, confusion, insomnia, nightmares, hallucinations and delusions, agitation and anxiety. **Neurologic:** ataxia, faintness, impairment of gait, headache, increased hand tremor, akinetic episodes, "akinesia paradoxa", increase in the frequency and duration of the oscillations in performance, torticollis, trismus, tightness of the mouth, lips or tongue, oculogyric crisis, weakness, numbness, bruxism, priapism. **Gastrointestinal:** constipation, diarrhea, epigastric and abdominal distress and pain, flatulence; eructation, hiccups, sialorrhea; difficulty in swallowing, bitter taste, dry mouth; duodenal ulcer; gastrointestinal bleeding; burning sensation of the tongue. **Cardiovascular:** arrhythmias, hypotension, non-specific ECG changes, flushing, phlebitis. **Hematologic:** hemolytic anemia, leukopenia, agranulocytosis. **Dermatologic:** sweating, edema, hair loss, pallor, rash, bad odor, dark sweat. **Musculoskeletal:** low back pain, muscle spasm and twitching, musculoskeletal pain. **Respiratory:** feeling of pressure in the chest, cough, hoarseness, bizarre breathing pattern, postnasal drip. **Urogenital:** urinary frequency, retention, incontinence, hematuria, dark urine, nocturia, and one report of interstitial nephritis. **Special Senses:** blurred vision, diplopia, dilated pupils; activation of latent Horner's syndrome. **Miscellaneous:** hot flashes, weight gain or loss. Abnormalities in laboratory tests reported with levodopa alone, which may occur with SINEMET*: Elevations of blood urea nitrogen, SGOT, SGPT, LDH, bilirubin, alkaline phosphatase or protein bound iodine. Occasional reduction in WBC, hemoglobin and hematocrit. Elevations of uric acid with colorimetric method. Positive Coombs tests reported both with SINEMET* and with levodopa alone, but hemolytic anemia extremely rare.

DOSAGE SUMMARY

In order to reduce the incidence of adverse reactions and achieve maximal benefit, therapy with SINEMET* must be individualized and drug administration continuously matched to the needs and tolerance of the patient. Combined therapy with SINEMET* has a narrower therapeutic range than with levodopa alone because of its greater milligram potency. Therefore, titration and adjustment of dosage should be made in small steps and recommended dosage ranges not be exceeded. Appearance of involuntary movements should be regarded as a sign of levodopa toxicity and an indication of overdosage, requiring dose reduction. Treatment should, therefore, aim at maximal benefit without dyskinesia.

Therapy in Patients not receiving Levodopa:

Initially 1/2 tablet once or twice a day, increase by 1/2 tablet every three days if desirable. An optimum dose of 3 to 5 tablets a day divided into 4 to 6 doses.

Therapy in Patients receiving Levodopa:

Discontinue levodopa for at least 12 hours, then give approximately 20% of the previous levodopa dose in 4 to 6 divided doses.

FOR COMPLETE PRESCRIBING INFORMATION, PARTICULARLY DETAILS OF DOSAGE AND ADMINISTRATION, PLEASE CONSULT PRODUCT MONOGRAPH WHICH IS AVAILABLE ON REQUEST.

HOW SUPPLIED

Ca8804—Tablets SINEMET* 250, dapple-blue, oval, biconvex, scored, compressed tablets coded MSD 654, each containing 25 mg of carbidopa and 250 mg of levodopa. Available in bottles of 100 and 500.

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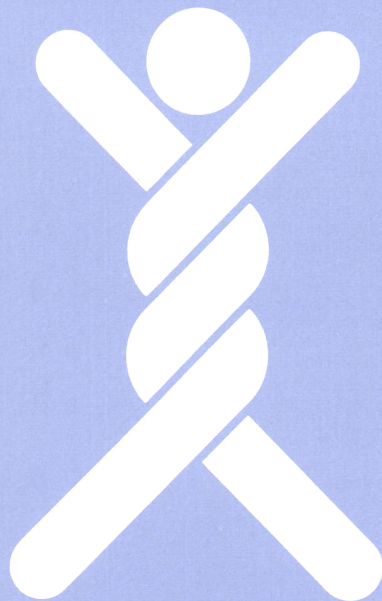
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from multiple sclerosis,
spinal cord injury, and
spinal cord diseases.



Acts primarily at the spinal level

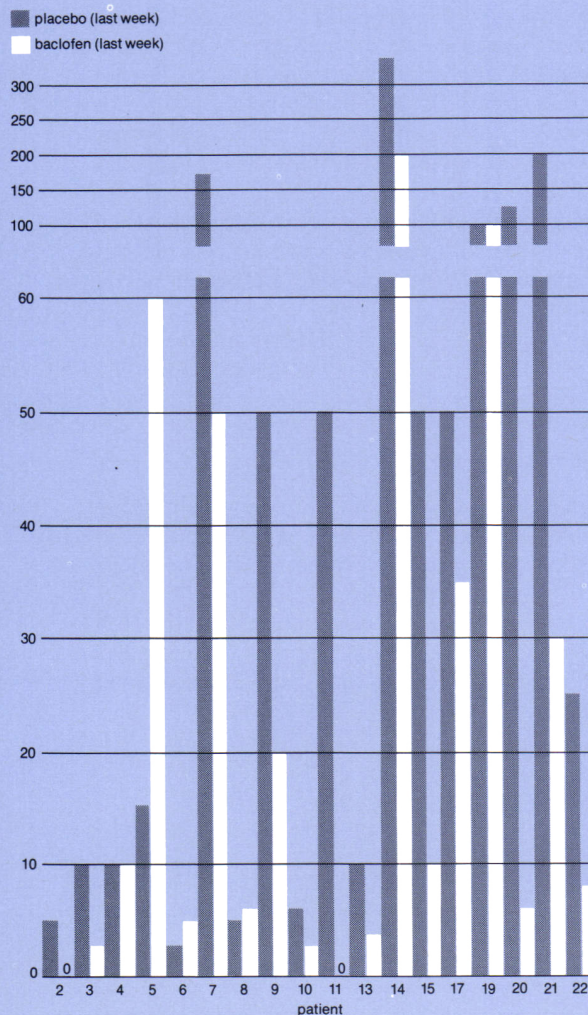
Lioresal is capable of inhibiting both monosynaptic and polysynaptic reflexes at the spinal level, possibly by hyperpolarization of the afferent terminals. However, the precise mechanism of action is not fully known. Actions at supraspinal sites may also occur and contribute to the clinical effect.

esal[®]

Effective and safe

Results of a four-week, double blind crossover study of 22 patients showed 72 percent of 18 patients with spontaneous daytime spasms had a reduction in the frequency when treated with Lioresal. Furthermore, a reduction in severity amplitude, and duration of remaining spasms was also reported in patients treated with Lioresal.¹

Figure 1. Average daily number of spasms during the last week of baclofen and placebo treatment periods in the 18 patients with spontaneous daytime spasms. (From Duncan et al¹)



When compared with placebo and diazepam in a double-blind study, Lioresal proved to be effective in reducing the number of spasms in 50% of patients who had developed tolerance to diazepam.²

In one study of 14 patients with spasticity, "Baclofen caused less sedation than would have been expected from comparable doses of diazepam but it did nevertheless have a tranquilizing effect..."³

And in one double-blind study, "No serious side effects developed and there were no signs of even transient bone marrow, liver, kidney, or gastrointestinal toxicity."¹ A few cases of increased SGOT, elevated alkaline phosphatase and elevated blood sugar have been reported but are not clinically significant. Gastrointestinal and other side effects also have been reported but generally do not persist.

Facilitates physical therapy

By relieving painful spasms Lioresal may allow more active physical therapy and daily function.

The advantages of improvement in resistance to passive movement noted in patients treated with Lioresal included more comfortable positioning and easier transfers and nursing.¹

Effect of treatment on resistance to passive movement (Adapted from Duncan et al¹)

Stage	Baclofen	Placebo
Improved	11 (55%)	1 (5%)
Worsened	0 (0%)	0 (0%)
Unchanged	9 (45%)	19 (95%)
Total	20	20

Geigy

For Brief Prescribing Information, see over

G-9038

Lioresal® baclofen

Brief Prescribing Information

Indications and clinical uses

Lioresal (baclofen) is useful for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis.

Lioresal may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Contraindications

Hypersensitivity to **Lioresal** (baclofen).

Warnings

Abrupt Drug Withdrawal: Following abrupt withdrawal of **Lioresal** (baclofen), visual and auditory hallucinations, confusion, anxiety with tachycardia and sweating, insomnia, and worsening of spasticity have occurred. Therefore, except for serious adverse reactions, the dose should be reduced slowly when the drug is discontinued.

Impaired Renal Function: Because **Lioresal** is primarily excreted unchanged through the kidneys, it should be given with caution, and it may be necessary to reduce the dosage.

Stroke: **Lioresal** has not significantly benefited patients with stroke. These patients have also shown poor tolerability to the drug. **Pregnancy:** Safe use of **Lioresal** during pregnancy or lactation has not been established. High doses are associated with an increased incidence of abdominal hernias in the fetuses of rats and of ossification defects in those of rats and rabbits. Therefore, the drug should be administered to pregnant patients, or women of child-bearing potential only when, in the judgment of the physician, the potential benefits outweigh the possible hazards.

Precautions

Safe use of **Lioresal** (baclofen) in children under age 12 has not been established and it is, therefore, not recommended for use in children.

Because of the possibility of sedation, patients should be cautioned regarding the operation of automobiles or dangerous machinery, and activities made hazardous by decreased alertness. Patients should also be cautioned that the central nervous system effects of **Lioresal** may be additive to those of alcohol and other CNS depressants.

Lioresal should be used with caution where spasticity is utilized to sustain upright posture and balance in locomotion, or whenever spasticity is utilized to obtain increased function.

Extreme caution should be exercised in patients with epilepsy or a history of convulsive disorders. In such patients, the clinical state and electroencephalogram should be monitored at regular intervals during therapy, as deterioration in seizure control and EEG has been reported occasionally in patients taking **Lioresal**.

Caution should be used in treating patients with peptic ulceration, severe psychiatric disorders, elderly patients with cerebrovascular disorders, and in patients receiving antihypertensive therapy.

It is not known whether **Lioresal** is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Adverse Reactions

The most common adverse reactions associated with **Lioresal** (baclofen) are transient drowsiness, dizziness, weakness and fatigue. Others reported: **Neuropsychiatric:** Headache (<10%), insomnia (<10%), and, rarely, 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 (<10%), rare instances of dyspnea, palpitation, chest pain, syncope. **Gastrointestinal:** Nausea, (approx. 10%), constipation (<10%), and, rarely, dry mouth, anorexia, taste disorder, abdominal pain, vomiting, diarrhea, and positive test for occult blood in stool. **Genitourinary:** Urinary frequency (<10%), and, rarely, enuresis, urinary retention, dysuria, impotence, inability to ejaculate, nocturia, hematuria. **Other:** Instances of 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).

Dosage and Administration

The determination of optimal dosage of **Lioresal** (baclofen) requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40-80 mg daily).

The following dosage titration schedule is suggested:

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

Thereafter additional increases may be necessary but the total daily dose should not exceed a maximum of 80 mg daily (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).

Availability: **Lioresal** (baclofen) 10 mg tablets.

Description: White to off-white flat-faced, oval tablets with Geigy monogram on one side and the identification code 23 below the monogram. Fully bisected on the reverse side. Available in bottles of 100 tablets.

References

1. Duncan, G. N., Shahani, B. T., and Young, R. R.: An evaluation of baclofen treatment for certain symptoms in patients with spinal cord lesions. *Neurology*, (May) 1976, pp. 441-446.
2. Jones, R. F.: *Lioresal in the control of spasticity. Spasticity... A topical survey*, Hans Huber Publishers, Bern, 1972, P. 113.
3. McLellan, D. L.: Effects of baclofen upon monosynaptic and tonic vibration reflexes in patients with spasticity. *J. Neurol. Neurosurg. Psychiatry*, 36(4): 555-560, (Aug.) 1973.

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Epilepsy International Congress — 1981

XIV Congress of International League Against Epilepsy
XIII Symposium of International Bureau for Epilepsy

Organized by:

EPILEPSY INTERNATIONAL

International League Against Epilepsy (ILAE)
International Bureau for Epilepsy (IBE)

JAPAN EPILEPSY SOCIETY

JAPAN EPILEPSY ASSOCIATION

1. INVITATION

It is my great pleasure to extend a cordial invitation to all members of affiliated organizations of Epilepsy International as well as individuals interested in any aspect of epilepsy to attend the Epilepsy International Congress-1981.

This is the first world epilepsy congress to be held in Asia. The Congress is to meet in conjunction with the 10th International Congress of Electroencephalography and Clinical Neurophysiology (ICECN) and the 12th World Congress of Neurology (WCN), so that this Congress will serve as a bridge between the two congresses. We hope to organize a truly world-wide congress with participants from many disciplines and interests.

We sincerely hope that the Congress will be a milestone in helping people with epilepsy and that this old but new ailment will eventually be eradicated from throughout the world.

Haruo Akimoto
Congress President

2. PLACE AND DATE

The Congress will be held from Thursday, September 17 to Monday, September 21, 1981 at the Kyoto International Conference Hall located in the northern outskirts of Kyoto City.

This Congress will therefore be a link between the 10th ICECN (Sept. 13 - 18) and the 12th WCN (Sept. 20 - 26), both to be also held at the Kyoto International Conference Hall.



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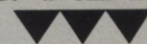
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The Canadian Journal of Neurological Sciences is the official publication of the Canadian Neurological Society, the Canadian Neurosurgical Society and the Canadian Society of Electroencephalographers, and Electromyographers and Clinical Neurophysiologists.

These three Societies meet together as the Canadian Congress of Neurological Sciences once a year. The meetings are usually held in the third week in June. A different city is chosen for the meeting each year.

Details regarding membership in each of the Societies, the date and place of the meeting and the scientific program can be obtained from the Secretaries.

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