

THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES

LE JOURNAL CANADIEN DES SCIENCES NEUROLOGIQUES

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REFERENCES:

1. Bertrand, R.A.: Acta Oto-Laryng. Supp. 305:48, 1972. 2. Guay, R.M.: Applied Thera. 12:25 (Aug.) 1970. 3. Frew, I.J.C. et al: Postgrad. Med. J. 52:501-503, 1976. 4. Wilmot, T.J. et al: J. Laryng. Otol. 9:833-840, 1976. 5. Snow, J.B. Jr. & Suga, F.: A.M.A. Arch. Otolaryng. 97:365, 1973. 6. Martinez, D.M.: Acta Oto-Laryng. Supp. 305:29, 1970.

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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.

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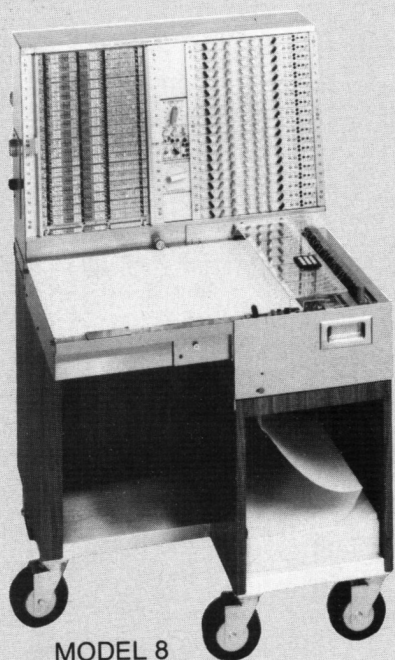
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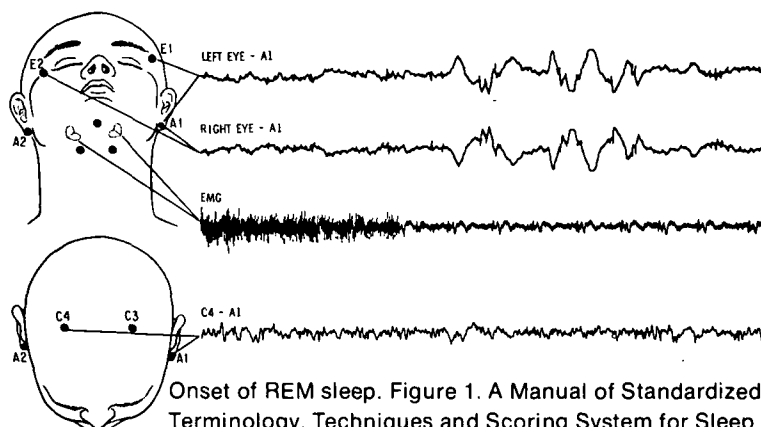
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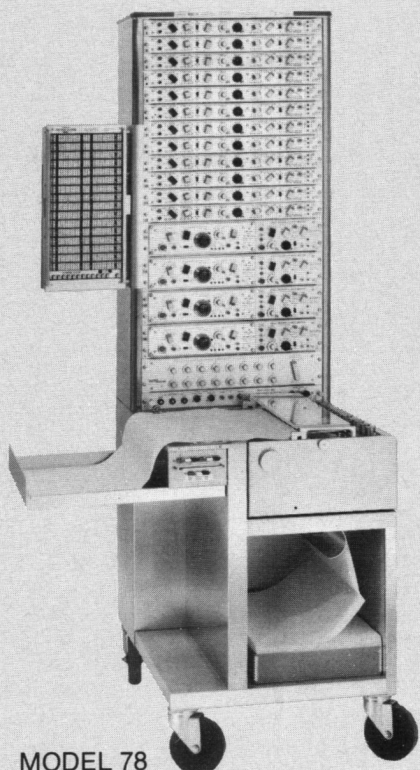
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- No reports of serious side effects, such as hepatotoxicity.
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- Proven safety record in long-term administration.
- Drowsiness, which may occur, is generally dose-related and may be well controlled with proper dosage adjustment.^{2,3}



For Rx Summary, see page xii

Rivotril[®] for the victims of minor motor seizures

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The precise mechanisms of action of **Lioresal** (baclofen) are not fully known. It inhibits both monosynaptic and polysynaptic reflexes at the spinal level, probably by hyperpolarization of afferent terminals, although actions at supra-spinal sites may also occur and contribute to its clinical effect. Although **Lioresal** is an analog of the putative inhibitory neurotransmitter gamma-aminobutyric acid (GABA), there is no conclusive evidence that actions on GABA systems are involved in the production of its clinical effects. Peak plasma concentrations of **Lioresal** are achieved within 2 hours and the plasma half-life is 2-4 hours.

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).

Symptoms and Treatment of Overdosage

Signs and Symptoms: Vomiting, muscular hypotonia, hypotension, drowsiness, accommodation disorders, coma, respiratory depression, and seizures. The signs and symptoms may be further aggravated by co-administration of a variety of other agents including alcohol, diazepam, and tricyclic antidepressants. **Treatment:** The treatment is symptomatic. In the alert patient, empty the stomach promptly by induced 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. A high urinary output should be maintained since **Lioresal** (baclofen) is excreted mainly by the kidneys. Dialysis is indicated in severe poisoning associated with renal failure.

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. R.F. Jones, J.W. Lance, Medical Journal of Australia, 1976, May:654-657.
2. R.G. Feldman: Symposia Reporter, Vol. 3, No. 2 June 1979.
3. **Lioresal** Product Monograph.

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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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